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S.C. SUPREME COURT

THE STATE OF SOUTH CAROLINA
In the Supreme Court

APPEAL FROM RICHLAND COUNTY
Kristi F. Curtis, Circuit Court Judge

Appellate Case No. 2024-001321
Civil Action No. 2016-CP-40-06276

OPTERNATIVE, INC.,
Appellant,

v.

SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS AND SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING, AND REGULATION,
Respondents,

and

SOUTH CAROLINA OPTOMETRIC PHYSICIANS ASSOCIATION,
Respondent-Intervenor.

RECORD ON APPEAL

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RECORD ON APPEAL

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FORM 4

STATE OF SOUTH CAROLINA
COUNTY OF Richland
IN THE COURT OF COMMON PLEAS

JUDGMENT IN A CIVIL CASE

CASE NO. 2016CP4006276

Opternative Inc
PLAINTIFF(S)

South Carolina Board Of Medical Examiners et al
DEFENDANT(S)

DISPOSITION TYPE (CHECK ONE)

☐ **JURY VERDICT**. This action came before the court for a trial by jury. The issues have been tried and a verdict rendered.

☑ **DECISION BY THE COURT**. This action came to trial or hearing before the court. The issues have been tried or heard and a decision rendered.

☐ **ACTION DISMISSED** (*CHECK REASON*): ☐ Rule 12(b), SCRCP; ☐ Rule 41(a), SCRCP (Vol. Nonsuit); ☐ Rule 43(k), SCRCP (Settled); ☐ Other

☐ **ACTION STRICKEN** (*CHECK REASON*): ☐ Rule 40(j), SCRCP; ☐ Bankruptcy; ☐ Binding arbitration, subject to right to restore to confirm, vacate or modify arbitration award; ☐ Other

☐ **STAYED DUE TO BANKRUPTCY**

☐ **DISPOSITION OF APPEAL TO THE CIRCUIT COURT** (*CHECK APPLICABLE BOX*): ☐ Affirmed; ☐ Reversed; ☐ Remanded; ☐ Other

NOTE: ATTORNEYS ARE RESPONSIBLE FOR NOTIFYING LOWER COURT, TRIBUNAL, OR ADMINISTRATIVE AGENCY OF THE CIRCUIT COURT RULING IN THIS APPEAL.

IT IS ORDERED AND ADJUDGED: ☐ See attached order (formal order to follow) ☑ Statement of Judgment by the Court:

The Court heard the Motion for Summary Judgment filed on behalf of Defendant-Intervenor SC Optometric Physicians Association via WebEx on June 3, 2024 and took the matter under advisement. At the beginning of the hearing, Plaintiff's counsel informed the court that Plaintiff's Motion to Strike SCOPA's motion and accompanying materials was withdrawn, and the court agreed to consider all of the memoranda and exhibits filed by both parties in support of and in opposition to the Motion for Summary Judgment in ruling on the current motion. After reviewing the materials and relevant case law, SCOPA's Motion for Summary Judgment is GRANTED. Counsel for SCOPA is directed to draft a proposed order consistent with SCOPA's Memorandum in Support of Summary Judgment and email it to all attorneys of record for review before e-filing the proposed order for the court's review and signature.

ORDER INFORMATION

This order ☐ ends ☑ does not end the case. ☐ See Page 2 for additional information.

For Clerk of Court Office Use Only

This judgment was electronically entered by the Clerk of Court as reflected on the Electronic Time Stamp, and a copy mailed first class to any party not proceeding in the Electronic Filing System on 06/19/2024 .

NAMES OF TRADITIONAL FILERS SERVED BY MAIL

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Court Reporter:

E-Filing Note: The date of Entry of Judgment is the same date as reflected on the Electronic File Stamp and the clerk's entering of the date of judgment above is not required in those counties. The clerk will mail a copy of the judgment to parties who are not E-Filers or who are appearing pro se. See Rule 77(d), SCRCP.

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Richland Common Pleas

Case Caption:	Opternative Inc vs South Carolina Board Of Medical Examiners , defendant, et al
Case Number:	2016CP4006276
Type:	Order/Electronic Form 4

So Ordered

s/ Kristi F. Curtis, Circuit Court Judge, No. 2762

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STATE OF SOUTH CAROLINA COUNTY OF RICHLAND Opternative Inc., Plaintiff, v. South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation, Defendants, and South Carolina Optometric Physicians Association, Defendant-Intervenor.	IN THE COURT OF COMMON PLEAS FOR THE FIFTH JUDICIAL CIRCUIT Civil Action No. 2016-CP-40-06276 **ORDER GRANTING SUMMARY JUDGMENT TO DEFENDANT-INTERVENOR**

This matter is before the Court on cross-motions for summary judgment filed pursuant to Rule 56 of the South Carolina Rules of Civil Procedure by Plaintiff Opternative Inc. ("Plaintiff") on June 15, 2023, and by Defendant-Intervenor South Carolina Optometric Physicians Association ("SCOPA") on August 7, 2023. Defendants South Carolina Board of Medical Examiners and South Carolina Department of Labor, Licensing and Regulation (collectively, "Defendants") filed a response in opposition to Plaintiff's motion on August 4, 2024. On August 7, 2023, Plaintiff moved to strike SCOPA's motion for summary judgment, and on May 29, 2024, Plaintiff filed a response to SCOPA's motion for summary judgment.

A hearing took place by WebEx on June 3, 2024. At the beginning of the hearing, Plaintiff's counsel informed the Court that Plaintiff's Motion to Strike was withdrawn, and the Court agreed to consider all memoranda and exhibits filed by both parties in support of and in opposition to the motions for summary judgment.

After review of the materials submitted to the Court and consideration of the arguments made

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by counsel at the hearing, and based on applicable law, this Court concludes summary judgment is appropriate against Plaintiff as to all causes of action set forth in the pleadings in this case. Therefore, pursuant to Rule 56, SCRCP, this Court denies Plaintiff's Motion for Summary Judgment and grants summary judgment in favor of Defendants and SCOPA.

BACKGROUND AND PROCEDURAL HISTORY

Plaintiff[1] initiated this action against Defendants on October 20, 2016, seeking a declaratory judgment that portions of the Eye Care Consumer Protection Law, S.C. Code Ann. §§ 40-24-10, *et seq.* ("ECCPL") are unconstitutional because they result in a denial of both equal protection and substantive due process. Specifically, Plaintiff challenges sections 40-24-20(C) and (D) of the ECCPL, alleging these provisions violate Article I, Section 3 of the South Carolina Constitution. It also challenges Section 40-24-10(9) of the ECCPL, which provides that vision assessments:

> may not be based solely on objective refractive data or information generated by an automated testing device, including an auto refractor or other electronic refractive-only testing device, to provide a medical diagnosis or to establish a refractive error for a patient as part of an eye examination.

S.C. Code Ann. 40-24-10(9).

The Court granted SCOPA's motion to intervene on February 22, 2017. Following a brief discovery period, Defendants moved for summary judgment on the basis that (1) Plaintiff lacked standing to challenge the constitutionality of the ECCPL, and (2) even if Plaintiff possessed standing, the ECCPL passes constitutional muster because it bears a reasonable relationship to its legislative purpose that is supported by rational basis. Plaintiff responded with its own Motion for Summary Judgment on September 6, 2017, arguing the ECCPL amounted to "naked economic protectionism" that served no purpose except protecting the financial interests of brick-and-mortar optometrists "all

[1] Plaintiff was called Opternative Inc. at the time the action was commenced but changed its name in 2018 to Visibly, Inc.

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while doing literally nothing to protect the public health or safety." (Pl.'s Mot. Summ. J. 1-2). On October 3, 2017, SCOPA filed a brief in support of Defendants' motion and opposition of Plaintiff's motion.

The circuit court granted Defendants' Motion for Summary Judgment and dismissed Plaintiff's Complaint with prejudice on January 26, 2018, finding Plaintiff failed to demonstrate that it had standing to bring its Complaint. In light of this conclusion, the circuit court expressly declined to address the parties' equal protection and due process arguments regarding the constitutionality of the ECCPL.

On February 23, 2018, Plaintiff filed a Notice of Appeal from the circuit court's order granting summary judgment to the Defendants. On May 5, 2021, the Court of Appeals reversed the circuit court's order, finding Plaintiff had satisfied the requirements for constitutional standing. *Opternative, Inc. v. S.C. Bd. Med. Exam'rs*, 433 S.C. 405, 418, 859 S.E.2d 263, 270 (Ct. App. 2021). The South Carolina Supreme Court affirmed the decision of the Court of Appeals on August 24, 2022. *Opternative, Inc. v. S.C. Bd. Med. Exam'rs*, 437 S.C. 258, 878 S.E.2d 861 (2022). The case was then remitted to this Court for further disposition.

FACTS

I. THE PARTIES

Founded in 2012 by Aaron Dallek and Steven Lee, O.D., Plaintiff is a Chicago-based telehealth company that developed a technology through which individuals can use a computer or smartphone to determine the refractive error of their eyesight without having an ophthalmologist or optometrist in the room ("Technology"). Plaintiff currently offers its Technology in approximately 35 states and, in addition to its remote vision tests, sells contact lenses through its subsidiary, Next Day Contacts, LLC, an online contact lens retailer.

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SCOPA is an association of optometric physicians practicing in South Carolina. Optometrists are independent primary health care professionals for the eye that examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures as well as identify related systemic conditions affecting the eye. Ophthalmologists are medical doctors specializing in eye and vision care, who by study and training are qualified to diagnose and treat ocular diseases, perform eye exams and surgeries and prescribe lenses to correct vision problems. Ophthalmologists who practice in South Carolina are licensed and regulated by the South Carolina Board of Medical Examiners ("BME"), within the Department of Labor, Licensing & Regulation ("LLR").

II. PLAINTIFF'S TECHNOLOGY AND IN-PERSON EYE EXAMINATIONS

Users can access Plaintiff's Technology through Plaintiff's website or, alternatively, they may be routed to Plaintiff's vision test through any one of its dozens of affiliated third-party corrective lenses retailers. Plaintiff's Technology then collects the user's information by soliciting responses to questions and visual stimuli through a computer interface. Plaintiff uses the responses to generate a dataset about the user and his or her ocular refractive error, which—after receiving a fee from the user—it will then send to Optimized Eye Care, Inc. ("Optimized"), a separate corporation that contracts with optometrists and ophthalmologists to review the results and write prescriptions. Once a prescription is generated, Optimized will send it via Plaintiff back to the original user, who can use the prescription to purchase contacts. Plaintiff's Technology does not measure objective data about the user's eyes or eye health, it cannot detect or aid in diagnosing diseases of the eye or systemic diseases, nor does it perform a corneal examination and evaluation.

Conducting comprehensive eye examinations is within the scope of practice of both optometrists and ophthalmologists. Comprehensive eye examinations consist of, but are not limited

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to, the following: a review of the patient's health history; measuring visual acuity, both aided and unaided; performing an examination with a slit lamp of the anterior segments of the eyes and eyelids; performing an internal ophthalmoscopic examination through a dilated pupil, including evaluation of the optic nerve head, macular and peripheral retina; performing a subjective refraction; performing tonometry; evaluating pupils; assessing ocular motility and eye alignment; performing confrontation visual field or similar screening field; performing other tests and procedures as indicated by the patient's chief complaint, case history or objective signs and symptoms discovered during the course of the eye examination; making a diagnosis and formulating a treatment plan; seeking consultation and/or making referrals for assessment/treatment to other health providers as appropriate.

Optometrists and ophthalmologists are under an affirmative obligation to look after the health and safety of their patients, which requires them to use their judgment to determine whether their patients' complaints or symptoms pertaining to their eyesight or eye health are indicators of systemic or body-wide disease processes or pathologies. They are likewise obliged to make such determinations even when the disease processes or pathologies are asymptomatic. It undisputed that optometrists and ophthalmologists are best able to make those necessary determinations through in-person comprehensive eye examinations.

Both optometrists and ophthalmologists are authorized to issue prescriptions for corrective lenses, including spectacles and contact lenses. A contact lens evaluation is a set of diagnostic tests and procedures performed in addition to a comprehensive eye examination. These tests and procedures include a measurement of the corneal curvature (keratometry or corneal topography) and an evaluation of the anterior segment and tear layer of the eye in relation to the contact lens fit. A poorly fit contact lens can cause irritation to the eyes, and the prolonged use of irritating contact lenses can cause pain, scarring, and vision loss even when a patient does not exhibit any symptoms. Such

consequences of a poorly fit contact lens can only be detected by a corneal evaluation. (Shipp Aff., ¶ 14; Robinson Aff., ¶ 12). Typically, a prescriber will not prescribe contact lenses they have not seen on their patient's eyes and will factor in a trial period to evaluate how the lenses are fitting and whether the lenses are causing vision problems. (Shipp Depo. 41:3-12; 53:8 – 54:12).

Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination. There is also a risk that individuals may mistakenly believe that they have received a comprehensive eye examination after receiving a prescription for spectacles or contact lenses from an ophthalmologist who only relies upon Visibly's Technology. (Shipp Aff., ¶ 15; Robinson Aff., ¶ 15).

In addition to assessing eye and vision problems, an eye examination may be the first opportunity to detect diabetes and other health conditions. Examples include high blood pressure, hypercholesterolemia, and certain inflammatory diseases. Diabetes is currently the nation's seventh leading cause of death in the United States. Diabetes is also a risk factor for heart disease and stroke, and a leading cause of kidney disease and blindness in adults. Early detection can allow early treatment and management of both systemic and eye-related diabetic changes. One of the more debilitating eye-related outcomes associated with type 2 diabetes in adults is vision impairment, including blindness. Diabetes-related eye conditions include, but are not limited to, refractive changes, cataracts, diabetic retinopathy, and glaucoma. Diabetic retinopathy is among the leading causes of preventable blindness in the United States. Most symptoms associated with diabetic eye disease progress slowly, and unnoticeably; therefore, comprehensive dilated eye examinations are necessary to diagnose, prevent and manage these conditions. Importantly, diabetic eye disease can be detected and diagnosed during a routine comprehensive dilated eye examination.

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III. THE EYE CARE CONSUMER PROTECTION LAW

The General Assembly passed the ECCPL on April 29, 2016. Governor Nikki Haley vetoed the ECCPL on May 16, 2016, but on May 19, 2016, the General Assembly overrode the Governor's veto by a vote of 98 to 1 in the House of Representatives and by a vote of 39 to 3 in the Senate. The ECCPL is now codified at S.C. Code Ann. §§ 40-24-10 and 40-24-20.

The ECCPL contains two parts: the first part establishes the relevant definitions, while the second part contains the substance of the Act. Part one of the ECCPL defines a "provider" as "an individual licensed by the South Carolina Board of Examiners in Optometry or the South Carolina Board of Medical Examiners," meaning both optometrists and ophthalmologists are governed by the Act. S.C. Code Ann. § 40-24-10(7). Part two of the ECCPL provides as follows:

> **SECTION 40-24-20.** Valid prescription required to dispense spectacles or contact lenses; penalties.
>
> (A) A person in this State may not dispense spectacles or contact lenses to a patient without a valid prescription from a provider.
>
> (B) To be valid, a prescription must contain an expiration date on spectacles or contact lenses of one year from the date of examination by the provider or a statement of the reasons why a shorter time is appropriate based on the medical needs of the patient. The prescription must take into consideration medical findings made and refractive error discovered during the eye examination. If a provider determines a patient is a suitable candidate for a prescription for contact lenses or spectacles, a provider may not thereafter refuse to issue a prescription for spectacles or contact lenses to a patient.
>
> (C) A prescription for spectacles or contact lenses may not be based solely on the refractive eye error of the human eye or be generated by a kiosk.
>
> (D) Violation of this section constitutes misconduct as provided for in Sections 40-37-110 and 40-47-110. A provider who violates this section is subject to the penalties authorized in Chapter 37, Title 40 or Chapter 47, Title 40, as applicable.[2]

S.C. Code Ann. § 40-24-20.

[2] Chapter 37, Title 40 applies to optometrists. Chapter 47, Title 40 applies to ophthalmologists, among other physicians.

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In sum, the ECCPL establishes a baseline in the standard of care for corrective lens prescriptions such that they must be based upon more than refractive error measurements generated by a computer or smart phone.

APPLICABLE LEGAL STANDARD

I. SUMMARY JUDGMENT

Summary judgment shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Rule 56(c), SCRCP. "In determining whether any triable issue of fact exists, the evidence and all inferences which can reasonably be drawn therefrom must be viewed in the light most favorable to the nonmoving party." *Quail Hill, LLC v. Cnty. of Richland*, 387 S.C. 223, 235, 692 S.E.2d 499, 505 (2010) (citation omitted). Even when the evidentiary facts are not disputed, "if the conclusions to be drawn from them are, summary judgment should be denied." *Coker v. Cummings*, 381 S.C. 45, 49, 671 S.E.2d 383, 385 (2008). "Summary judgment is not appropriate when further inquiry into the facts is desirable to clarify the application of law." *Id.*

II. STATUES PRESUMED CONSTITUTIONAL

"Statutes are presumed constitutional, and a law that neither creates a suspect class nor abridges a fundamental right is given only minimal equal protection scrutiny." *Faircloth v. Finesod*, 938 F.2d 513, 516 (4th Cir. 1991) (citing *City of New Orleans v. Dukes*, 427 U.S. 297, 303 (1976)). A statute is presumed constitutional and will not be declared unconstitutional unless its repugnance to the constitution is clear and beyond a reasonable doubt. *Sojourner v. Town of St. George*, 383 S.C. 171, 175, 679 S.E.2d 182, 185 (2009). "Constitutional constructions of statutes are not only judicially preferred, they are mandated[.]" *State v. McGrier*, 378 S.C. 320, 329, 663 S.E.2d 15, 19 (2008)

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(quoting *Henderson v. Evans*, 268 S.C. 127, 132, 232 S.E.2d 331, 333-34 (1977)).

When the constitutionality of a statute is at issue, "every presumption will be made in favor of its validity, and no statute will be considered unconstitutional unless its invalidity leaves no doubt that it conflicts with the constitution." *S.C. Dep't Soc. Servs. v. Sarah W.*, 402 S.C. 324, 334, 741 S.E.2d 739, 745 (2013); *see also Dunes W. Golf Club, LLC v. Town of Mount Pleasant*, 401 S.C. 280, 296, 737 S.E.2d 601, 609 (2013); *McMaster v. Columbia Bd. Zoning Appeals*, 395 S.C. 499, 504, 719 S.E.2d 660, 663 (2011). Accordingly, the burden is on the challenging party to prove the unconstitutionality of the statute. *Home Health Serv., Inc. v. S.C. Tax Comm'n*, 312 S.C. 324, 327, 440 S.E.2d 375, 377 (1994) (emphasis added).

Similarly, "those attacking the rationality of the legislative classification have the burden 'to negative every conceivable basis which might support it.'" *F.C.C. v. Beach Commc'ns, Inc.*, 508 U.S. 307 (1993) (quoting *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 364 (1973)); *accord McLeod v. Starnes*, 396 S.C. 647, 723 S.E.2d 198 (2012) ("[A] classification is presumed reasonable and will remain valid unless and until the party [making an equal protection challenge] proves beyond a reasonable doubt that there 'is no admissible hypothesis upon which it can be justified.'" (quoting *Carolina Amusement Co. v. Martin*, 236 S.C. 558, 576, 115 S.E.2d 273, 282 (1960))).

ANALYSIS

Plaintiff challenges the ECCPL on grounds of equal protection and due process and argues the statute is mere economic protectionist legislation that violates the South Carolina Constitution. In particular, Plaintiff first claims that the ECCPL denies it equal protection of the law because it treats doctors who prescribe contact lenses differently than all other doctors who use telemedicine. Plaintiff further claims that the ECCPL violates South Carolina's due process clause because it does not rationally protect patient health and only serves to insulate brick-and-mortar optometrists from online

competition.

I. SOUTH CAROLINA'S EQUAL PROTECTION CLAUSE

The Court turns first to an analysis of whether the ECCPL violates South Carolina's Equal Protection Clause. "Courts generally analyze equal protection challenges under one of three standards: (1) rational basis; (2) intermediate scrutiny; or (3) strict scrutiny. If the classification does not implicate a suspect class or abridge a fundamental right, the rational basis test is used." *Denene, Inc. v. City of Charleston*, 359 S.C. 85, 91, 596 S.E.2d 917, 920 (2004). The parties do not dispute that the determination of whether the ECCPL violates the Equal Protection Clause turns upon the application of the rational basis test.

"Under the rational basis test, the requirements of equal protection are satisfied when: (1) the classification bears a reasonable relation to the legislative purpose sought to be affected; (2) the members of the class are treated alike under similar circumstances and conditions; and (3) the classification rests on some reasonable basis." *Id.*; *see also Bodman v. State*, 403 S.C. 60, 69, 742 S.E.2d 363, 367 (2013); *Harleysville Mut. Ins. Co. v. State*, 401 S.C. 15, 26, 736 S.E.2d 651, 656-57 (2012); *Sunset Cay, LLC v. City of Folly Beach*, 357 S.C. 414, 428, 593 S.E.2d 462, 469 (2004); *Fraternal Order of Police v. S.C. Dep't Revenue*, 352 S.C. 420, 430, 574 S.E.2d 717, 722 (2002); *Gary Concrete Prods., Inc. v. Riley*, 285 S.C. 498, 504, 331 S.E.2d 335, 339 (1985). South Carolina's equal protection jurisprudence reveals no discernable difference between its application of the rational basis test to questions of equal protection under the South Carolina Constitution and the federal courts' use of the standard to measure equal protection under the United States Constitution.

A. The ECCPL is Reasonably Related to Its Legislative Purpose.

The ECCPL protects the public health and welfare because it upholds the standard of care for eye care professionals in South Carolina and prevents citizens from unwittingly putting their eye

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health at risk by obtaining a prescription for corrective lenses without a comprehensive eye examination. The applicable standard of care for eye care professionals in South Carolina requires them to use their medical judgment to determine whether their patients' complaints or symptoms pertaining to their eyesight or eye health are indicators of systemic or body-wide disease processes or pathologies. As Plaintiff acknowledges, certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination. Corrective lens wearers may therefore incur health risks if they forego regular eye exams that would allow the optometrist or ophthalmologist to spot emerging health problems in their early stages.

Plaintiff argues that the ECCPL does nothing to protect the public health and safety, ignoring the evidence in the record to the contrary. For instance, it fails to acknowledge that one-year prescriptions for corrective lenses are consistent with national optometric standards and with extant South Carolina and federal law concerning contact lenses. *See*, *e.g.*, S.C. Code Ann. § 37-25-10 *et seq.*; 15 U.S.C. § 7601 *et seq.*; 16 C.F.R. § 315.1. It likewise glosses over the fundamental requirement of the ECCPL: that corrective lens prescriptions must be based on more than just a refractive examination. *See* S.C. Code Ann. § 40-24-20 (Supp. 2016).

Instead, Plaintiff argues that the ECCPL does not serve its stated purposes because it does not *require* eye-health exams, nor does it *require* eye doctors to check for emerging health problems. Again, this ignores that optometrists and ophthalmologists are already under an affirmative obligation as part of their standard of care to look after the health and safety of their patients, including using their judgment to determine whether their patients' complaints or symptoms are indicative of a latent disease or other issue. The ECCPL need not spell out what particular steps an optometrist or ophthalmologist needs to take during a comprehensive eye examination for it to survive rational basis

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scrutiny. Both the General Assembly and the common law have long recognized that the standard of care for professionals across a wide range of disciplines is too nuanced and fact-specific to be established by legislative act. *See, e.g.*, S.C. Code Ann. § 15-36-100 (Supp. 2016) (expert witness must attest to standard of care and its breach as a prerequisite to bringing a claim for professional negligence); *Dawkins v. Union Hosp. Dist.*, 408 S.C. 171, 758 S.E.2d 501 (2014) (expert testimony required in medical malpractice action). What the ECCPL does is establish a baseline for corrective lens prescriptions, just as other laws and regulations establish minimum requirements in the healthcare context and otherwise. *See, e.g.*, S.C. Code Ann. § 40-33-32 (outlining minimum standards for licensure as a nurse); S.C. Code Ann. § 40-57-135 (establishing minimum standards for real estate brokers-in-charge management agreements); S.C. Code Ann. § 37-15-30 (setting minimum standards for using a contest as a ruse to promote the sale of goods, property or services).

To that end, Plaintiff acknowledges in its disclaimer to potential consumers that its Technology is not available to individuals over the age of 55, stating: "Because we want to ensure that our patients' health is at its best, we recommend that those over 55 see a doctor in person to ensure that any of these health conditions that we acquire as we get older are not missed." In doing so, Plaintiff has instituted its own minimum baseline for the appropriate standard of care regarding the need for in-person eye exams for those over a certain age.

The South Carolina Constitution grants the General Assembly the authority to legislate for the protection of the public health and welfare, and this Court finds the ECCPL does just that by protecting the public from receiving inadequate eye care. Because there is an identifiable risk that the law addresses, Plaintiff has not met its evidentiary burden to overcome the presumption of the ECCPL's constitutionality

B. The ECCPL Treats All Ophthalmologist and Optometrists Alike Under Similar Circumstances and Conditions.

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The ECCPL creates a bright line rule for all ophthalmologists and optometrists to follow. This is not a case in which some ophthalmologists or optometrists are treated differently than others. *See, e.g.*, *Daniel v. Cruz*, 268 S.C. 11, 14, 231 S.E.2d 293, 294 (1977) (holding legislation that treated fortune tellers in one county differently from those in another violated equal protection). Nor are ophthalmologists and optometrists being treated differently from other health care providers, as the ECCPL only applies to conduct that falls within ophthalmologists and optometrists' scope of practice. *See, e.g.*, *Joseph v. S.C. Dep't Lab., Licensing & Regul.*, 417 S.C. 436, 450-53 790 S.E.2d 763, 770-72 (2016) (holding classification which distinguished physical therapists from other licensed healthcare providers had no rational relationship to the legislative purposes of a statute at issue); *Broome v. Truluck*, 270 S.C. 227, 230-32, 241 S.E.2d 739, 740-41 (1978) (holding different statutes of limitations for different professionals involved in making improvements to real property violated equal protection).

Plaintiff argues the ECCPL singles out ophthalmologists from other types of physicians because "dermatologists, cardiologists, endocrinologists, psychiatrists, family doctors, and all other doctors are allowed to prescribe using telemedicine." This comparison is inapposite. These other types of doctors cannot prescribe contact lenses, while eye doctors can. While eye doctors may still prescribe treatment via telemedicine as permitted under South Carolina law and their standard of care, they cannot base a prescription for corrective lenses based solely upon the refractive error measured by a kiosk or computer. In other words, the standard for prescribing corrective lenses is applied uniformly, just like eye doctors, or any other type of doctor, cannot prescribe "drugs to individuals the licensee has never personally examined based solely on answers to a set of questions." S.C. Code Ann. § 40-47-113.

Furthermore, the ECCPL prohibit reliance upon Plaintiff's Technology in the course of

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treating a patient; it merely proscribes writing prescriptions for patients based solely upon the refractive error that the Technology measures. Plaintiff acknowledges that it is possible for eye doctors to use its Technology in conjunction with an in-person eye exam, although it has not attempted to market it for use in that manner because that is not where the "demand" lies. Regardless, South Carolina is not unique in determining it is necessary to protect consumers in this fashion while acknowledging a place for telemedicine. *See e.g.,* Ga. Code Ann. § 31-12-12(a)(5) and (b)(1)(C) (mandating that "[n]o person in this state shall write a prescription for contact lenses or spectacles unless an eye examination is conducted," and defining "eye examination" as a "real-time examination, which includes the use of telemedicine, in accordance with the applicable standard of care of the prescriber, of the ocular health and visual status of an individual that does not consist solely of objective refractive data or information generated by an automated testing device, including an autorefractor or kiosk, in order to establish a medical diagnosis or refractive diagnosis for the establishment of refractive error, conducted with the patient and prescriber in the same physical location or via telemedicine.").

The ECCPL bears a reasonable relation to the State's legitimate interest in protecting the eye and systemic health of South Carolina citizens. The ECCPL's utility in tackling traditional police power concerns easily survives rational basis scrutiny. The distinction between ophthalmologists who write prescriptions for corrective lenses based solely upon Plaintiff's Technology and the ophthalmologists who write prescriptions based upon a comprehensive eye examination is not arbitrary or capricious, but a rational reflection of the statutory standard for appropriate patient care in the realm of eye health. This Court is not empowered to pass judgment upon that standard, except to acknowledge the legislative prerogative to establish it.

C. The Classification in the ECCPL Has a Reasonable Basis.

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In arguing the ECCPL has no rational basis, Plaintiff relies heavily upon *Joseph v. South Carolina Department of Labor, Licensing & Regulation*, 417 S.C. 436, 790 S.E.2d 763 (2016). In *Joseph*, the Supreme Court held that the statute at issue "deprives physicians of the right to practice medicine in the best interest of their patients" by not being able to hire physical therapists. *Id.* at 452, 790 S.E.2d at 771. Plaintiff draws a parallel with that case, claiming the ECCPL deprives ophthalmologists of their right to practice medicine in the best interest of their patients. The comparison fails because the ECCPL addresses a particular public health risk, whereas it was impossible to find any such risk to the public health and welfare that the statute in *Joseph* was allegedly designed to mitigate.

The text of the ECCPL does not prevent ophthalmologists from exercising their medical judgment to write corrective lens prescriptions. If anything, it prevents Plaintiff, and other similar healthcare technology providers, from fulfilling a market desire for convenience, to the detriment of ophthalmologists' patients. *See Denene, Inc.*, 359 S.C. at 97, 596 S.E.2d at 923 ("No one has an unfettered right to pursue a business detrimental to the public health, safety, and welfare."). Unlike the statute at issue in *Joseph*, the ECCPL does not prevent ophthalmologists and optometrists from practicing medicine in the best interest of their patients. To the contrary, the ECCPL prevents corrective lens prescriptions from being issued without an examination that takes into consideration a patient's overall health. Addressing that risk is well within the General Assembly's constitutional prerogative.

Accordingly, this Court concludes Plaintiff has not proved beyond a reasonable doubt that the ECCPL violates the Equal Protection Clause.

II. SUBSTANTIVE DUE PROCESS

Likewise, this Court concludes Plaintiff has not proved beyond a reasonable doubt that the

ECCPL violates its right to substantive due process. The test for a substantive due process claim is "[w]hether [a statute] bears a reasonable relationship to any legitimate interest of government." *R.L. Jordan Co. v. Boardman Petroleum, Inc.*, 338 S.C. 475, 478, 527 S.E.2d 763, 765 (2000). "In order to prove a denial of substantive due process, a party must show that he was arbitrarily and capriciously deprived of a cognizable property interest rooted in state law." *Harbit v. City of Charleston*, 382 S.C. 383, 394, 675 S.E.2d 776, 782 (Ct. App. 2009) (citing *Sunset Cay, LLC*, 357 S.C. at 430, 593 S.E.2d at 470). "The State's deprivation of the property interest must fall so far beyond the outer boundaries of legitimate governmental authority that no process could remedy the deficiency." *Id.*

Although the analysis of Plaintiff's due process claim largely mirrors its equal protection claim, it is nonetheless clear that the ECCPL bears a reasonable relationship to the State's legitimate interest in protecting the eye and systemic health of South Carolina citizens.

The undisputed facts before the Court reveal that the ECCPL's legislative purpose is to protect the public from receiving inadequate eye care. The ECCPL protects the public health and welfare because it prevents citizens from unwittingly putting their eye health at risk by obtaining a prescription for corrective lenses without a comprehensive eye examination. There is no dispute that that undiagnosed diseases of the eye are a public concern, and that certain diseases of the eye or of the body may go undiagnosed if patients forego an in-person comprehensive eye examination. The provisions of the ECCPL are reasonably related to protecting and upholding the applicable statutory standard of care for medical professionals in South Carolina, which requires them to use their professional judgment to determine whether their patients' symptoms are indicators of systemic diseases.

Accordingly, because the South Carolina Constitution grants the General Assembly the authority to legislate for the protection of the public health and welfare, and because the ECCPL does

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just that, the ECCPL is constitutional. Plaintiff has not met its evidentiary burden to overcome the presumption of constitutionality beyond a reasonable doubt.

CONCLUSION

For the above-stated reasons, this Court concludes Plaintiff has not to carried its evidentiary burden to overcome the presumption of the ECCPL's constitutionality beyond a reasonable doubt. Summary judgment is therefore warranted on Plaintiff's claims against Defendants.

Accordingly, for the reasons stated in this Order, the Court hereby grants the Motion for Summary Judgment filed by SCOPA. Plaintiff's claims against Defendants are hereby dismissed with prejudice.

IT IS SO ORDERED.

(*Judge's E-Signature Page to Follow*)

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Richland Common Pleas

Case Caption:	Opternative Inc vs South Carolina Board Of Medical Examiners , defendant, et al
Case Number:	2016CP4006276
Type:	Order/Summary Judgment

So Ordered

s/ Kristi F. Curtis, Circuit Court Judge, No. 2762

THE STATE OF SOUTH CAROLINA
In The Supreme Court

Opternative, Inc., Respondent,

v.

South Carolina Board of Medical Examiners and the South Carolina Department of Labor, Licensing & Regulation, Defendants,

and South Carolina Optometric Physicians Association, Defendants-Intervenors,

of which South Carolina Optometric Physicians Association is the Petitioner.

Appellate Case No. 2021-000818

ON WRIT OF CERTIORARI TO THE COURT OF APPEALS

Appeal From Richland County
DeAndrea G. Benjamin, Circuit Court Judge

Opinion No. 28106
Submitted August 10, 2022 – Filed August 24, 2022

AFFIRMED

Kirby Darr Shealy, III, and Luke M. Allen, both of Adams and Reese LLP, of Columbia, for Petitioner.

William C. Wood, Jr., of Columbia, and Miles Edward Coleman, of Greenville, both of Nelson Mullins Riley & Scarborough, LLP; and Robert J. McNamara and Joshua A. Windham, of the Institute for Justice, of Arlington, Virginia, admitted pro hac vice, for Respondent.

PER CURIAM: Petitioner, the South Carolina Optometric Physicians Association, seeks a writ of certiorari to review the court of appeals opinion in *Opternative, Inc. v. S.C. Bd. of Med. Examiners*, 433 S.C. 405, 859 S.E.2d 263 (Ct. App. 2021). We grant the petition, dispense with briefing, and affirm, with clarification, the court of appeals' determination that Opternative, Inc. has constitutional standing to challenge the constitutionality of the Eye Care Consumer Protection Law.[1]

Standing is "a fundamental prerequisite to instituting an action." *Youngblood v. S.C. Dep't of Soc. Servs.*, 402 S.C. 311, 317, 741 S.E.2d 515, 518 (2013). Whether a party has standing, however, is a separate question from whether that party will prevail on the merits. *See Pres. Soc'y of Charleston v. S.C. Dep't of Health & Env't Control*, 430 S.C. 200, 215–16, 845 S.E.2d 481, 489 (2020) (stating it is error to confuse standing and the merits such that a party must prove it will prevail on the merits in order to establish standing). In the context of constitutional standing, any discussion of the three elements required for constitutional standing—injury in fact, causal connection, and redressability—is not an analysis of the merits of the underlying action. *See Pres. Soc'y of Charleston*, 430 S.C. at 210, 845 S.E.2d at 486 (summarizing the three elements of constitutional standing). Rather, an analysis of constitutional standing is solely an analysis of the allegations the plaintiff made in the complaint. *See Carnival Corp. v. Historic Ansonborough Neighborhood Ass'n*, 407 S.C. 67, 76–77, 753 S.E.2d 846, 851 (2014) (analyzing only the plaintiffs' allegations before concluding they lacked standing). Accordingly, the decision of the court of appeals as to standing should in no way be construed as a comment on the merits of the action. *See Pres. Soc'y of Charleston*, 430 S.C. at 219, 845 S.E.2d at 491 (emphasizing "that our decision as to standing should in no way be construed as a signal of our view of the merits of the issues").

[1] *See* S.C. Code Ann. §§ 40-24-10 to -20 (Supp. 2021).

AFFIRMED.

BEATTY, C.J., KITTREDGE, HEARN, FEW and JAMES, JJ., concur.

THE STATE OF SOUTH CAROLINA
In The Court of Appeals

Opternative, Inc., Appellant,

v.

South Carolina Board of Medical Examiners and the South Carolina Department of Labor, Licensing & Regulation, Respondents,

And South Carolina Optometric Physicians Association, Respondent.

Appellate Case No. 2018-000326

Appeal From Richland County
DeAndrea G. Benjamin, Circuit Court Judge

Opinion No. 5818
Heard November 2, 2020 – Filed May 5, 2021

REVERSED AND REMANDED

Miles Edward Coleman, of Greenville, and William C. Wood, Jr., of Columbia, both of Nelson Mullins Riley & Scarborough, LLP; and Robert J. McNamara and Joshua A. Windham, of the Institute for Justice, of Arlington, Virginia, admitted pro hac vice, all for Appellant.

Eugene Hamilton Matthews, of Richardson Plowden & Robinson, P.A., of Columbia, for Respondents South Carolina Board of Medical Examiners and South Carolina Department of Labor, Licensing and Regulation.

Kirby Darr Shealy, III, of Adams and Reese, LLP, of Columbia, for Respondent South Carolina Optometric Physicians Association.

WILLIAMS, J.: This appeal arises from Opternative, Inc.'s (Opternative) action challenging the constitutionality of sections 40-24-10 and 40-24-20 of the South Carolina Code (Supp. 2020). The trial court found Opternative lacked standing to challenge the statutes and granted summary judgment to the South Carolina Department of Labor, Licensing and Regulation (the Department), the South Carolina Board of Medical Examiners (the Board), and the South Carolina Optometric Physicians Association (the Association) (collectively, Respondents). We reverse and remand.

FACTS/PROCEDURAL HISTORY

Opternative developed technology (Technology) that would allow an individual to determine the refractive error[1] of his or her eyesight without going to an optometrist or ophthalmologist for an examination. With the Technology, the individual answers a series of questions relating to his or her medical history and uses a computer and a smart phone to complete the examination to determine his or her refractive error. The results are then reviewed by a South Carolina-licensed ophthalmologist, and if the ophthalmologist determines the individual needs a prescription for corrective lenses, the ophthalmologist writes a prescription. According to Opternative, the Technology is available to the public for free and Opternative only charges the patient for the ophthalmologist's review.

In 2016, the General Assembly enacted the Eye Care Consumer Protection Law (the Act). *See* §§ 40-24-10 to -20. Following the Act's implementation, ophthalmologists stopped using the Technology, believing the Act prohibited its use. Opternative filed an action against the Department and the Board, seeking a declaratory judgment finding the Act violated its rights under the South Carolina Constitution and an injunction prohibiting enforcement of the Act. The

[1] The refractive error relates to how light bends within the eye. The patient's refractive error can be determined by different methods, but one method involves asking the patient whether certain lenses placed in front of his or her eye make a projected image better or worse.

Association moved to intervene, and the trial court granted the motion following Opternative's conditional consent.[2]

Opternative submitted two affidavits to the trial court—one by Daniel Bodde, its Chief Marketing Officer, and one by Doctor Edward Chaum, an ophthalmologist. Bodde stated in his affidavit that Opternative was successfully operating in South Carolina to provide prescriptions to state residents through an ophthalmologist. But, Opternative's operations in the state ended once the Act was passed because ophthalmologists stopped using its Technology to provide prescriptions. Bodde stated Opternative was in contact with ophthalmologists who would resume use of the Technology to write corrective-lens prescriptions if the Act was struck down. In his affidavit, Dr. Chaum stated he used the Technology to write prescriptions for South Carolina residents but stopped doing so when the Act went into effect.

The Department and the Board moved for summary judgment, asserting Opternative lacked standing and the Act was constitutional. Opternative opposed the motion and requested summary judgment in its favor. The Association filed a memorandum of law joining the Department and the Board's motion and providing additional arguments regarding the Act's validity. Following a hearing on the motions, the trial court granted summary judgment in favor of Respondents, finding Opternative lacked standing because the Act only prohibited Opternative's chosen business model. The court expressly declined to address the issue of the Act's validity. This appeal followed.

ISSUE ON APPEAL

Did the trial court err in finding that Opternative lacked standing to challenge the validity of the Act?

STANDARD OF REVIEW

This court reviews a grant of summary judgment under the same standard applied by the trial court under Rule 56(c), SCRCP. *Loflin v. BMP Dev., LP*, 427 S.C. 580, 588, 832 S.E.2d 294, 298 (Ct. App. 2019). Pursuant to Rule 56(c), summary judgment is proper if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no

[2] The Association worked with legislators to draft the Act and lobbied for the Act. The Association moved to intervene because optometrists are subject to the Act's provisions.

genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." "In determining whether any triable issues of fact exist, the evidence and all inferences which can be reasonably drawn from the evidence must be viewed in the light most favorable to the nonmoving party." *Hancock v. Mid-S. Mgmt. Co.*, 381 S.C. 326, 329–30, 673 S.E.2d 801, 802 (2009). To withstand a summary judgment motion in cases applying a heightened burden of proof, the nonmoving party must provide "more than a mere scintilla of evidence." *Id.* at 330–31, 673 S.E.2d at 803. "[A] scintilla is a perceptible amount. There still must be a verifiable spark, not something conjured by shadows." *Gibson v. Epting*, 426 S.C. 346, 352, 827 S.E.2d 178, 181 (Ct. App. 2019). Because a statute will not be declared unconstitutional unless it is clearly proven beyond a reasonable doubt, more than a mere scintilla of evidence is required to defeat a summary judgment motion in cases questioning a statute's validity. *See Joytime Distribs. & Amusement Co. v. State*, 338 S.C. 634, 640, 528 S.E.2d 647, 650 (1999) (per curiam) ("A legislative act will not be declared unconstitutional unless its repugnance to the constitution is clear and beyond a reasonable doubt.").

LAW/ANALYSIS

Under South Carolina law, standing can be established in three ways: (1) by statute, (2) by constitutional standing, and (3) under the public importance exception. *Bodman v. State*, 403 S.C. 60, 66–67, 742 S.E.2d 363, 366 (2013). Opternative's arguments at trial and on appeal are limited to constitutional standing. Accordingly, we review standing only under this theory.

Constitutional standing consists of three elements: "(1) the plaintiff must have suffered an 'injury in fact;' (2) there must be a causal connection between the injury and the conduct complained of; and (3) it must be likely, as opposed to merely speculative, that the injury will be 'redressed by a favorable decision.'" *Joseph v. S.C. Dep't of Labor, Licensing & Regulation*, 417 S.C. 436, 449, 790 S.E.2d 763, 770 (2016) (plurality opinion) (quoting *Sea Pines Ass'n for Prot. of Wildlife, Inc. v. S.C. Dep't of Nat. Res.*, 345 S.C. 594, 601, 550 S.E.2d 287, 291 (2001)). "A party seeking to establish standing carries the burden of demonstrating each element." *Id.*

Opternative argues the trial court erred in granting Respondents summary judgment. Specifically, Opternative asserts it satisfied the three elements of standing and therefore requests that this court remand the matter for a determination on its motion for summary judgment as to the Act's constitutionality.

I. Injury in Fact

Opternative argues the trial court erred in finding it had not suffered an injury as a result of the Act's enactment because the Act only prohibited Opternative's chosen business model. We agree.

Opternative asserts it was injured when its operations in South Carolina ended and that the Act was the source of its injury because the Act prohibits ophthalmologists from using its Technology to prescribe corrective lenses. Because this theory of injury depends on an interpretation of the Act, we must first interpret the Act to determine whether it actually causes Opternative an injury in fact. *See Jowers v. S.C. Dep't of Health & Envtl. Control*, 423 S.C. 343, 354, 815 S.E.2d 446, 452 (2018). Statutory interpretation is an issue of law that this court reviews de novo. *S.C. Dep't of Soc. Servs. v. Boulware*, 422 S.C. 1, 6, 809 S.E.2d 223, 226 (2018).

The Act requires that a prescription written by an optometrist or an ophthalmologist to correct refractive error be "based on an eye examination." § 40-24-10(6). "Eye examination" is defined as an assessment of the patient's ocular health and must include an assessment of the patient's "visual status."[3] § 40-24-10(3). The patient's visual status assessment cannot "be based solely on objective refractive data or information generated by an automated testing device . . . to provide a medical diagnosis or to establish a refractive error for a patient as part of an eye examination." § 40-24-10(9). Additionally, the Act states a prescription "may not be based solely on the refractive eye error of the human eye or be generated by a kiosk." § 40-24-20(C). The Act defines "kiosk" as "automated equipment or an automated application, which is designed to be used on a phone, computer, or Internet-based device that can be used in person or remotely to provide refractive data or information." § 40-24-10(4).

We agree with the trial court that the Act prohibits Opternative's current business model. Under its model, ophthalmologists review only the information provided by the Technology and do not interact with the patient or conduct any other type of examination or assessment before writing a prescription. Because a prescription cannot be based solely on the patient's refractive error but also requires medical findings regarding the patient's ocular health and visual status, the Act precludes

[3] Doctor Michael W. Zolman, a South Carolina-licensed optometrist, stated in his deposition that "ocular health" is an anatomical assessment and "visual status" is an assessment of visual accuracy, accommodation of amplitudes, and ocular alignment.

ophthalmologists from relying solely on Opternative's Technology when issuing prescriptions. *See* § 40-24-10(3).

However, we find the trial court erred in ruling the Act's prohibition of Opternative's chosen business model was not an injury in fact. An injury in fact is "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) 'actual or imminent'" rather than conjectural or hypothetical. *ATC S., Inc. v. Charleston County*, 380 S.C. 191, 195, 669 S.E.2d 337, 339 (2008) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)). An economic interest is a legally protected interest. *See Toussaint v. State Bd. of Med. Exam'rs*, 285 S.C. 266, 268, 329 S.E.2d 433, 434–35 ("[The a]ppellant's 'interest in his own reputation and in his economic well-being' clearly give him a personal stake in the outcome of the controversy." (quoting *Jenkins v. McKeithen*, 395 U.S. 411, 423 (1969))).

In *Joseph*, our supreme court held a physical therapist and two doctors suffered an injury and had standing to challenge a particular law. 417 S.C. at 449–50, 790 S.E.2d at 770. The law precluded physical therapists from being employed by a doctor and treating patients referred to them by the doctor. *Id.* at 443–44, 790 S.E.2d at 766–67. However, the law did not prohibit doctors from employing other healthcare professionals and referring patients to them. *Id.* at 442, 790 S.E.2d at 766. The law also did not prohibit a physical therapist from being employed in a physical therapist group practice and treating patients referred by another therapist in the practice. *Id.* at 445, 790 S.E.2d at 767–68. The court held this was sufficient to find the appellants had suffered an injury because the law prohibited the appellants from pursuing their profession under the arrangement they desired. *Id.* at 449–50, 790 S.E.2d at 770.

We find Opternative suffered an injury in fact. Opternative's affidavits provide evidence that Opternative suffered an actual and particularized injury: Opternative previously conducted business in South Carolina, but it no longer does. Similar to the physical therapists and physicians in *Joseph*, Opternative is prohibited from engaging in business under the business model it desires. *See id.* Pursuant to *Joseph*, the fact that the Act would allow Opternative to operate under a different model does not eliminate Opternative's ability to challenge the Act. *See id.* Although the State can regulate businesses and business models in pursuit of protecting the public, those affected by such laws have the right to challenge their validity. *Compare Denene, Inc. v. City of Charleston*, 359 S.C. 85, 97, 596 S.E.2d 917, 923 (2004) (stating the government can regulate and restrict businesses in pursuit of preserving public health, safety, and welfare), *with Joytime*, 338 S.C. at

639–40, 528 S.E.2d at 649–50 (finding the appellant had standing to challenge a statute regulating its business). Therefore, we hold the trial court erred in finding Opternative had not suffered an injury in fact because it could change its business model to comply with the Act.

II. Causation

Opternative argues the trial court erred in finding there was no causal connection between its injury and the Act. We agree.

The second element of standing is establishing a causal connection between the injury and the challenged conduct. *See Joseph*, 417 S.C. at 467, 790 S.E.2d at 779. A causal connection exists if the injury is "fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court." *Sea Pines*, 345 S.C. at 601, 550 S.E.2d at 291 (omissions and alterations in original) (quoting *Lujan*, 504 U.S. at 560). Establishing a "but for" causal connection or showing a substantial likelihood that the challenged action caused the injury is sufficient. *Duke Power Co. v. Carolina Envtl. Study Grp., Inc.*, 438 U.S. 59, 74–78 (1978); *see also Bailey v. S.C. Dep't of Health & Envtl. Control*, 388 S.C. 1, 7, 693 S.E.2d 426, 429 (Ct. App. 2010) (finding no causal connection existed when the conduct causing the appellant's alleged injury existed before the challenged state action).

We find the trial court erred in holding there was no causal connection between Opternative's injury and the Act. The trial court reasoned Opternative's injury was caused by ophthalmologists declining to use the Technology, which was "an act from a third party not before the court." We disagree. The ophthalmologists' decision to stop using the Technology was not an independent action because it is fairly traceable to the Act. *See Sea Pines*, 345 S.C. at 601, 550 S.E.2d at 291 ("[T]he injury has to be 'fairly . . . trace[able] to the challenged action of the defendant . . . .'" (first omission and second alteration in original) (quoting *Lujan*, 504 U.S. at 560)). Opternative's affidavits presented evidence that ophthalmologists stopped using the Technology because the Act prohibited Opternative's business model. *See Joseph*, 417 S.C. at 449–50, 790 S.E.2d at 770 (stating there was a causal connection between the doctors and physical therapist's injury of not being able to work in an employer-employee arrangement and the laws precluding such an employment arrangement). The record does not contain any evidence that ophthalmologists stopped using the Technology for any other reason. Accordingly, the evidence, when viewed in the light most favorable to Opternative, shows a "substantial likelihood" that the Act caused Opternative's

injury. *See Duke Power*, 438 U.S. at 77 (stating a showing of substantial likelihood satisfies the causal connection requirement); *cf. Bailey*, 388 S.C. at 7, 693 S.E.2d at 429 (finding no causal connection existed when the conduct causing the appellant's alleged injury existed before the challenged state action).

The Department and the Board assert Opternative also failed to show a causal connection because (1) they have not had an occasion to enforce the Act, (2) they do not have any authority over Opternative, and (3) Opternative has not complained of any conduct by the Department or the Board. *See Sea Pines*, 345 S.C. at 601, 550 S.E.2d at 291 ("[T]here must be a causal connection between the injury and the conduct complained of—the injury has to be 'fairly . . . trace[able] to the challenged action of the defendant . . . .'" (first omission and second alteration in original) (quoting *Lujan*, 504 U.S. at 560)). We disagree.

The Department and the Board are responsible for enforcing violations of the Act. *See* S.C. Code Ann. § 40-1-40(B) (2011) (stating the Department oversees the Board); S.C. Code Ann. § 40-47-10(I) (2011 & Supp. 2020) (providing the Board with the powers and duties of regulating the practice of medicine); S.C. Code Ann. §40-47-110 (2011 & Supp. 2020) (providing the Board with the authority to take disciplinary action for misconduct by licensed professionals); § 40-24-20(D) (stating violation of the Act constitutes misconduct as provided in section 40-47-110). The Department's and the Board's future enforcement of the Act against ophthalmologists using the Technology affects Opternative. Also, the fact that the Department and the Board have not taken any action against Opternative or to enforce the Act does not affect Opternative's standing. Opternative seeks declaratory judgment of the Act's validity, and a party does not have to first violate a statute to challenge its validity. *See Joseph*, 417 S.C. at 450, 790 S.C. at 770 ("The Declaratory Judgment Act should be liberally construed to accomplish its intended purpose of affording a speedy and inexpensive method of deciding legal disputes and of settling legal rights and relationships, without awaiting a violation of the rights or a disturbance of the relationships." (quoting *Pond Place Partners, Inc. v. Poole*, 351 S.C. 1, 16, 567 S.E.2d 881, 888–89 (Ct. App. 2002))). Finally, because Opternative provides a service to the public and ophthalmologists, the Department's and the Board's lack of regulatory authority over Opternative is irrelevant. *See Quality Towing, Inc. v. City of Myrtle Beach*, 340 S.C. 29, 34, 530 S.E.2d 369, 371 (2000) ("[V]endors and those in like positions have been uniformly permitted to resist efforts at restricting their operations by acting as advocates of the rights of third parties who seek access to their market or function." (alteration in original) (quoting *Craig v. Boren*, 429 U.S. 190, 195, (1976))).

Accordingly, we hold the trial court erred in finding there was no causal connection between Opternative's injury and the Act.

III. Redressability

Opternative argues the trial court erred in finding a lack of redressability. We agree.

To satisfy the third element of standing, "it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" *Hoyler v. State*, 428 S.C. 279, 305, 833 S.E.2d 845, 859 (Ct. App. 2019) (quoting *Sea Pines*, 354 S.C. at 601, 550 S.E.2d at 291). When summary judgment would be appropriate under Rule 56, the nonmoving party cannot solely rely on allegations or denials asserted in his pleadings but must respond, such as through an affidavit, and show there is a genuine issue of fact for trial. Rule 56(e). "Supporting and opposing affidavits shall be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated therein." *Id.*

The trial court erred in finding Opternative failed to show a favorable decision would redress its injury. The trial court referred only to Opternative's complaint when discussing redressability and did not address Bodde's affidavit. In his affidavit, Bodde stated that based on his personal knowledge and experience, Opternative was in contact with ophthalmologists who indicated they would resume use of the Technology if the Act was struck down. *See* Rule 56(e) ("Supporting and opposing affidavits shall be made on personal knowledge . . . ."). When viewed in the light most favorable to Opternative, this is evidence that a favorable decision would redress Opternative's injury. *See Hancock*, 381 S.C. at 329–30, 673 S.E.2d at 802 (stating all the evidence and all inferences therefrom are viewed in the light most favorable to the nonmoving party). Accordingly, we reverse this finding.

CONCLUSION

Based on the foregoing, we hold the trial court erred in finding Opternative lacked standing, and we reverse. Because the trial court ruled only on the issue of standing and did not rule on the merits of Opternative's constitutional challenge to the Act, we decline to address the merits on appeal. Therefore, we remand this case for further consideration.

Accordingly, the trial court's order is

REVERSED AND REMANDED.

HUFF and GEATHERS, JJ., concur.

STATE OF SOUTH CAROLINA

COUNTY OF RICHLAND

IN THE COURT OF COMMON PLEAS
FIFTH JUDICIAL CIRCUIT

Opternative, Inc.,

Plaintiff,

v.

South Carolina Board of Medical Examiners and the South Carolina Department of Labor, Licensing & Regulation,

Defendants.

and

South Carolina Optometric Physicians Association,

Defendant-Intervenor.

C/A No.: 2016-CP-40-06276

ORDER

FILED
2018 JAN 26 AM 11:23
JEANNETTE W. McBRIDE
C.C.P. & G.S.

THIS MATTER came before this Court on October 4, 2017, on cross-Motions for Summary Judgment by Plaintiff Opternative, Inc. ("Plaintiff" or "Opternative") and Defendants South Carolina Board of Medical Examiners (the "Board") and the South Carolina Department of Labor, Licensing & Regulation ("LLR") (collectively the "Defendants"). Defendant-Intervenor South Carolina Optometric Physicians Association ("SCOPA") was also present and participated in oral argument.

In this action, Plaintiff has brought a declaratory judgment action to challenge the constitutionality of South Carolina's Eye Care Consumer Protection Law ("ECCPL"), S.C. Code Ann. § 40-24-10 *et seq.*, arguing that the ECCPL is protectionist legislation and unconstitutional on grounds of (1) due process and (2) equal protection. (Plaintiff's Complaint, ¶¶ 87-97).

For the reasons set forth below, I hereby GRANT the Defendants' Motion for Summary Judgment only as to the issue of standing and DENY the Plaintiffs' Motion for Summary Judgment. The case is, therefore, dismissed with prejudice.

PLAINTIFF'S LAWSUIT

Plaintiff is a private foreign corporation that has developed an online technology designed to conduct eye examinations and produce prescriptions for corrective lens. (Plaintiff's Complaint, ¶¶ 1, 5). In bringing this declaratory judgment action, Plaintiff argues that the ECCPL is protectionist legislation and unconstitutional on grounds of (1) due process and (2) equal protection. (Plaintiff's Complaint, ¶¶ 87-97). Regarding both grounds, Plaintiff alleged that "[u]nless Defendants are enjoined from enforcing the ECCPL, Opternative will suffer continuing and irreparable harm." (Plaintiff's Complaint, ¶¶ 91, 97). In its Complaint, Opternative describes the injury to the Plaintiff in the following manner:

"80. As a direct result of the passage of the ECCPL, the use of Opternative's Technology has been effectively prohibited in South Carolina.

81. Prior to the adoption of the ECCPL, Opternative could (and did) allow a South Carolina-licensed ophthalmologist to write corrective-lens prescriptions for South Carolina residents.

82. As a direct result of the passage of the ECCPL, South Carolina-licensed ophthalmologists are legally prohibited from working with Opternative to provide corrective-lens prescriptions for South Carolina residents.

83. As a direct result of the passage of the ECCPL, South Carolina-licensed ophthalmologists are no longer willing to work with Opternative to provide corrective-lens prescriptions for South Carolina residents.

84. As a direct result of the passage of the ECCPL, Opternative has ceased business operations in South Carolina.

85. But for the ECCPL, Opternative would still be facilitating corrective-lens prescriptions for South Carolina residents.

86. But for the ECCPL, state-licensed ophthalmologists would be willing to work with Opternative to provide corrective-lens prescriptions for South Carolina residents."

THE ECCPL

The ECCPL has two parts. The first part establishes the definitions of terms that it uses, and the second establishes the substance of the act.

Importantly, the first part of the act defines "provider" as "an individual licensed by the South Carolina Board of Examiners in Optometry or the South Carolina Board of Medical Examiners." S.C. Code Ann. § 40-24-10(7). The second part of the ECCPL provides as follows:

> **SECTION 40-24-20.** Valid prescription required to dispense spectacles or contact lenses; penalties.
>
> (A) A person in this State may not dispense spectacles or contact lenses to a patient without a valid prescription from a provider.
>
> (B) To be valid, a prescription must contain an expiration date on spectacles or contact lenses of one year from the date of examination by the provider or a statement of the reasons why a shorter time is appropriate based on the medical needs of the patient. The prescription must take into consideration medical findings made and refractive error discovered during the eye examination. If a provider determines a patient is a suitable candidate for a prescription for contact lenses or spectacles, a provider may not thereafter refuse to issue a prescription for spectacles or contact lenses to a patient.
>
> (C) A prescription for spectacles or contact lenses may not be based solely on the refractive eye error of the human eye or be generated by a kiosk.

THE BOARD AND LLR

The Board is the professional licensing board in South Carolina that regulates physician practice and conduct. S.C. Code Ann. § 40-47-5 *et seq*. The Board does not regulate Opternative, as it is not a physician licensed in the State of South Carolina. S.C. Code Ann. § 40-1-70; S.C. Code Ann. § 40-47-10(I).

The LLR administers the Board. S.C. Code Ann. § 40-1-40(B). Like the Board, LLR does not regulate Opternative, as it is not licensed by a Board that LLR administers. Rather, LLR merely "is responsible for all administrative, fiscal, investigative, inspectional, clerical, secretarial, and license renewal operation and activities" of the Board, and in fact does make such support available to the Board. S.C. Code Ann. § 40-1-50(A).

DECISION

I. THE LAWSUIT MUST BE DISMISSED BECAUSE PLAINTIFF DOES NOT HAVE PROPER STANDING.

Where a private party seeks to have a statue declared unconstitutional, it must first demonstrate that it has standing. *ATC v. Charleston Cty.*, 380 S.C. 191, 195–96, 669 S.E.2d 337, 339 (2008). Standing is defined as "a personal stake in the subject matter of a lawsuit." *Sea Pines Ass'n for the Prot. of Wildlife, Inc. v. S.C. Dep't of Natural Res.*, 345 S.C. 594, 600, 550 S.E.2d 287, 291 (2001) (citing *Charleston Cnty. Sch. Dist. v. Charleston Cnty. Election Comm'n*, 336 S.C. 174, 519 S.E.2d 567 (1999)).

A private person or entity does not have standing unless he has sustained, or is in immediate danger of sustaining, prejudice from an executive or legislative action. *Baird v. Charleston County,* 333 S.C. 519, 511 S.E.2d 69 (1999). Such imminent prejudice must be of a personal nature to the party laying claim to standing, and not merely of general interest common to all members of the public. *Id.* (citing *Citizens for Lee County, Inc. v. Lee County,* 308 S.C. 23, 416 S.E.2d 641 (1992)).

To make the required showing, the challenging party must satisfy the following three-part test:

> First, the plaintiff must have suffered an "injury in fact" – an invasion of a legally protected interest which is (a) concrete and particularized, and (b) "actual or imminent, not 'conjectural' or 'hypothetical,' " Second, there must be a causal connection between the injury and the conduct complained of-the injury has to be "fairly ... trace[able] to the challenged action of the defendant, and not ... th[e] result [of] the independent action of some third party not before the court." Third, it must be "likely," as opposed to merely "speculative," that the injury will be "redressed by a favorable decision."

ATC, 380 S.C. at 195-96, 669 S.E.2d at 339 (quoting *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560-61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992) (internal citations omitted)); *see also Youngblood v. S.C. Dept. of Social Services*, 402 S.C. 311, 317, 741 S.E.2d 515, 518 (2013).

A. Injury in Fact.

First, Opternative must show that it has suffered an "injury in fact," which is an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not 'conjectural' or 'hypothetical." From its Complaint, Opternative appears to argue that its "injury in fact" is its loss of business and belief that the ECCPL prevents South Carolina-licensed ophthalmologists from being "willing to work with Opternative to provide corrective-lens prescriptions for South Carolina residents," and that if the ECCPL were struck down, they presumably would be willing to use Opternative's technology to write corrective-lens prescriptions. (Plaintiff's Complaint, ¶¶ 83, 86). The ECCPL does not appear to forbid a South Carolina-licensed ophthalmologist from using Opternative's technology to assist in his or her work. Opternative alleges that it hast lost business in South Carolina and has been forced to shut down business. (Plaintiff's Complaint, ¶¶ 80). Opternative's allegations make it clear that the law directly affects their business model, but it is unclear that the Defendants are perpetuating the injury. (Plaintiff's Complaint, ¶¶ 80-86)

Although Plaintiffs present the argument that the ECCPL directly affects its business, Plaintiffs are not regulated under the act by the Defendants. *See Joytime Distrib. and Amusement Co., Inc. v. State*, 338 S.C. 634, 640 528 S.E.2d 647, 650 (1999) (holding the Plaintiffs had standing to sue the State alleging the unconstitutionality of a law that directly affected Plaintiff's business and required the Plaintiffs to pay a license surcharge fee under the law). Professionals under the authority of the Board are not forbidden by the ECCPL – and not by any action of the Board or LLR – from using Opternative's technology. Indeed, a South Carolina-licensed ophthalmologist may still use Opternative's technology to assist him or her in making a determination to write a prescription for spectacles or contact lenses. He or she simply cannot solely base the prescription on the refractive eye error of the human eye or be generated by a kiosk. Opternative has certainly presented evidence that the ECCPL will deter state-licensed ophthalmologists and optometrists from using its technology *within Opternative's current business model*.

In sum, Opternative has failed to show that it has suffered an "injury in fact," and instead has only raised theories of injury that are "conjectural" or "hypothetical."

B. <u>Causal Connection</u>.

Second, Opternative has not shown that there is a causal connection between the injury and the conduct complained of. The injury has to be "fairly ... trace[able] to the challenged action of the defendant, and not ... th[e] result [of] the independent action of some third party not before the court." *ATC,* 380 S.C. at 195-96, 669 S.E.2d at 339.

In the instant case, the causal connection does not exist because the injury alleged by Opternative – that South Carolina-licensed ophthalmologists are no longer "willing to work with Opternative to provide corrective-lens prescriptions for South Carolina residents" – actually

requires an act from a third party not before the court. Namely, as set forth above, Opternative alleges that South Carolina-licensed ophthalmologists are no longer willing to use its on-line exam because, under the ECCPL, its on-line exam cannot be the sole basis to write a prescription for spectacles or contact lenses.

South Carolina-licensed ophthalmologists can presumably make their own decisions about whether and how to use – or not use – Opternative's on-line technology to assist them in their provision of lawful corrective-lens prescriptions to their patients. In any event, that decision rests with South Carolina-licensed ophthalmologists, and not with the Board or with LLR.

C. Redress by a Favorable Decision.

Even if Plaintiff could show an "injury-in-fact" and a "causal connection," Plaintiff must also allege adequately that the particularized injury would be redressed by a favorable decision in this case. *Sea Pines Ass'n*, 345 S.C. at 602, 550 S.E.2d at 292. In its Complaint, Plaintiff appears to address this element by alleging that "[b]ut for the ECCPL, Opternative would still be facilitating corrective-lens prescriptions for South Carolina residents" and that "state-licensed ophthalmologists would be willing to work with Opternative to provide corrective-lens prescriptions for South Carolina residents." (Plaintiff's Complaint, ¶¶ 85-86).

In this regard, Plaintiff's claims appear similar to those of the plaintiffs in *Sea Pines Ass'n*, who raised a constitutional challenge to the decision of the South Carolina Department of Natural Resources ("SCDNR") to issue permits to lethally eliminate a substantial number of white-tailed deer on Hilton Head Island. The court found that the plaintiffs lacked standing in part because their alternative plan to hunting permits – use of non-lethal means to reduce the deer population – would lead to the same result, namely, the reduction of the deer population at Sea Pines. 345 S.C.

7

at 603, 550 S.E.2d at 292. For that reason, the plaintiffs failed to demonstrate standing because the proposed alternative would result in the same "injury."

In this case, Plaintiff's showing of redress is complicated by the fact that "state-licensed ophthalmologists" can already work with Opternative to provide corrective-lens prescriptions for South Carolina residents. The true "injury" of which Opternative complains is that it wants "state-licensed ophthalmologists" to use Opternative's technology *within its current business model.* This is insufficient to demonstrate standing for a constitutional challenge.

* * *

To show standing, Plaintiff must satisfy each of the three elements referenced above. Plaintiff has failed to demonstrate that it can satisfy any of them. For this reason, Plaintiff's lawsuit must be dismissed.

CONCLUSION

As set forth above, Plaintiff has failed to demonstrate that it has standing to bring this claim. The Court declines to address any equal protection and due process arguments in light of its conclusion that Plaintiffs fail to demonstrate standing.

For these reasons, the motion of the Board and LLR is GRANTED as to the issue of standing, the motion of Opternative is DENIED, and this action is dismissed with prejudice, with each side to bear its own costs and fees.

AND IT IS SO ORDERED.

The Honorable DeAndrea Gist Benjamin
Presiding Judge
Fifth Judicial Circuit

January 25, 2018
Columbia, South Carolina.

FORM 4

STATE OF SOUTH CAROLINA
COUNTY OF RICHLAND
IN THE COURT OF COMMON PLEAS

JUDGMENT IN A CIVIL CASE

CASE NUMBER: 2016CP4006276

Opternative Inc

PLAINTIFF(S)

South Carolina Board Of Medical Examiners
South Carolina Dept Of Labor Licensing And Regulation

DEFENDANT(S)

Submitted by: _____	Attorney for : ☐ Plaintiff ☐ Defendant or ☐ Self-Represented Litigant

DISPOSITION TYPE (CHECK ONE)

☐ **JURY VERDICT.** This action came before the court for a trial by jury. The issues have been tried and a verdict rendered.

☐ **DECISION BY THE COURT.** This action came to trial or hearing before the court. The issues have been tried or heard and a decision rendered.

☐ **ACTION DISMISSED** (*CHECK REASON*): ☐ Rule 12(b), SCRCP; ☐ Rule 41(a), SCRCP (Vol. Nonsuit); ☐ Rule 43(k), SCRCP (Settled); ☐ Other _____

☐ **ACTION STRICKEN** (*CHECK REASON*): ☐ Rule 40(j), SCRCP; ☐ Bankruptcy; ☐ Binding arbitration, subject to right to restore to confirm, vacate or modify arbitration award; ☐ Other _____

☐ **DISPOSITION OF APPEAL TO THE CIRCUIT COURT** (*CHECK APPLICABLE BOX*): ☐ Affirmed; ☐ Reversed; ☐ Remanded; ☐ Other _____

NOTE: ATTORNEYS ARE RESPONSIBLE FOR NOTIFYING LOWER COURT, TRIBUNAL, OR ADMINISTRATIVE AGENCY OF THE CIRCUIT COURT RULING IN THIS APPEAL.

IT IS ORDERED AND ADJUDGED: ☐ See attached order (formal order to follow) ☐ Statement of Judgment by the Court:

RICHLAND COUNTY
2017 FEB 22 AM 9:02

ORDER INFORMATION

This order ☐ ends ☑ does not end the case.
Additional Information for the Clerk : Motion to Intervene Granted – formal order to follow

INFORMATION FOR THE JUDGMENT INDEX

Complete this section below when the judgment affects title to real or personal property or if any amount should be enrolled. If there is no judgment information, indicate "N/A" in one of the boxes below.

Judgment in Favor of (List name(s) below)	Judgment Against (List name(s) below)	Judgment Amount To be Enrolled
		$
		$
		$

If applicable, describe the property, including tax map information and address, referenced in the order:

The judgment information above has been provided by the submitting party. Disputes concerning the amounts contained in this form may be addressed by way of motion pursuant to the SC Rules of Civil Procedure. Amounts to be computed such as interest or additional taxable costs not available at the time the form and final order are submitted to the judge may be provided to the clerk. **Note: Title abstractors and researchers should refer to the official court order for judgment details.**

Circuit Court Judge _____ **Judge Code** 2061 **Date** 2-15-17

For Clerk of Court Office Use Only

This judgment was entered on the ___ day of _____, 20___ and a copy mailed first class or placed in the appropriate attorney's box on this 22 day of Feb, 2017 to attorneys of record or to parties (when appearing pro se) as follows:

Miles Edward Coleman

Eugene Hamilton Matthews
Lyndey Ritz Zwingelberg

Kirby Darr Shealy III

ATTORNEY(S) FOR THE PLAINTIFF(S)

ATTORNEY(S) FOR THE DEFENDANT(S)

Court Reporter _____

Clerk of Court Jeanette W. McBride

SCRCP Form 4C (10/2011)

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND Opternative, Inc., Plaintiff, vs. South Carolina Board of Medical Examiners, and South Carolina Department of Labor, Licensing, and Regulation, Defendants.	IN THE COURT OF COMMON PLEAS FIFTH JUDICIAL CIRCUIT Civil Action No. 2016-CP-40-06276 **SUMMONS FOR DEFENDANT SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS**

RICHLAND COUNTY FILED
2016 OCT 20 AM 9:32
JEANNETTE W. MCBRIDE C.C.P. & G.S.

TO THE DEFENDANTS ABOVE-NAMED:

YOU ARE HEREBY SUMMONED and required to answer the Complaint of which a copy is herewith served upon you and to serve a copy of your Answer to the Complaint on the Attorneys for the Plaintiff to Miles E. Coleman, 1320 Main Street, 17th Floor, Meridian Building, Columbia, South Carolina, 29201, within thirty (30) days after service hereof, exclusive of the day of such service; and if you fail to answer the Complaint within the time aforesaid, the Plaintiff in this action will apply to the Court for the relief demanded in this Complaint and judgment by default will be rendered against you for the relief demanded in the Complaint.

<< Signature on Next Page >>

INSTITUTE FOR JUSTICE

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Attorneys for Plaintiff Opternative, Inc.

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October 20, 2016.

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND Opternative, Inc., Plaintiff, vs. South Carolina Board of Medical Examiners, and South Carolina Department of Labor, Licensing, and Regulation, Defendants.	IN THE COURT OF COMMON PLEAS FIFTH JUDICIAL CIRCUIT Civil Action No. 2016-CP-40-06276 **SUMMONS FOR DEFENDANT SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING, AND REGULATION**

RICHLAND COUNTY FILED
2016 OCT 20 AM 9:32
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Attorneys for Plaintiff Opternative, Inc.

Columbia, South Carolina
October 20, 2016.

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND	IN THE COURT OF COMMON PLEAS FIFTH JUDICIAL CIRCUIT
Opternative, Inc., Plaintiff, vs. South Carolina Board of Medical Examiners, and South Carolina Department of Labor, Licensing, and Regulation, Defendants.	Civil Action No. 2016-CP-40-06276 **COMPLAINT**

RICHLAND COUNTY
FILED
2016 OCT 20 AM 9:33
JEANNETTE W. MCBRIDE
C.C.P. & G.S.

INTRODUCTION

1. This civil-rights lawsuit seeks to vindicate the rights of consumers, doctors, and entrepreneurs to use innovative technology to enhance access to care for people in need of corrective lenses. Plaintiff Opternative, Inc., has developed an online technology (the "Technology") that enables licensed ophthalmologists to conduct refractive examinations,[1] establish a diagnosis, and determine the correct prescription for many patients (an "Exam"). This Technology has been used across the country—including in South Carolina—but a recent law effectively prohibits South Carolina-licensed ophthalmologists from using the Technology to issue any prescriptions at all. The purpose of this new law is not to protect the public health or safety but instead to protect the profits of established businesses. Because the South Carolina Constitution forbids regulation for no purpose beyond economic protectionism, Defendants must

[1] Refractive examinations determine the refractive error of a person's eye and therefore the proper corrective-lens prescription for that person.

be enjoined from enforcing the new law that has banned Opternative (and businesses like it) from continuing their work in South Carolina.

JURISDICTION AND VENUE

2. Plaintiff brings this action under Article I, Section 3 of the South Carolina Constitution, and the Uniform Declaratory Judgments Act, S.C. Code Ann. §§ 15-53-20, 15-53-30, and 15-53-120.

3. Plaintiff seeks declaratory and injunctive relief against enforcement of provisions of South Carolina's Eye Care Consumer Protection Law ("ECCPL"), South Carolina Code sections 40-24-10(9), 40-24-20(C) and (D), which violate Plaintiff's constitutional rights to equal protection and due process of law.

4. This Court has jurisdiction and venue lies pursuant to South Carolina Code section 15-77-50.

THE PARTIES

5. Plaintiff Opternative, Inc. ("Opternative") is a Delaware corporation with its headquarters in Illinois.

6. Defendant South Carolina Board of Medical Examiners ("the BME") is the state agency responsible for licensing physicians and for enforcing much of South Carolina's eye care regulatory regime—including the ECCPL.

7. Defendant South Carolina Department of Labor, Licensing, and Regulation is the department of the South Carolina government which is responsible for administering the BME and in which the BME is incorporated. *See* S.C. Code Ann. § 1-30-65.

STATEMENT OF FACTS

South Carolina's Eye-Care Regulatory Regime

8. Title 40 of the South Carolina Code authorizes the state to regulate certain professionals for the "health, safety, and welfare of the public." S.C. Code Ann. § 40-1-10.

9. Among these are physicians and other miscellaneous healthcare professionals, who fall under the specific authority of the South Carolina Board of Medical Examiners. S.C. Code Ann. § 40-47-10.

10. Ophthalmologists are medical doctors specializing in eye and vision care, who by study and training are qualified chiefly to diagnose and treat ocular diseases, perform eye exams and surgeries, and prescribe lenses to correct vision problems.

11. As physicians, ophthalmologists are licensed and regulated by the BME. *Id.* The BME has broad powers to restrict the practice of ophthalmology, including the setting of minimum standards of professional care and the promulgation of rules of professional conduct. *Id.* The BME is also empowered to take disciplinary action—including suspension and even revocation of a physician's license to practice ophthalmology—against those it deems guilty of professional misconduct. S.C. Code Ann. § 40-47-110.

12. Continuing to practice ophthalmology with a suspended or revoked license is a misdemeanor. S.C. Code Ann. § 40-27-200.

13. Unlike ophthalmologists, optometrists are not medical doctors. Rather, optometrists are more limited medical professionals who by study and training are qualified chiefly to detect and treat certain ocular diseases, perform eye exams and vision tests, and prescribe and dispense corrective lenses.

14. While optometrists provide professional medical care and fall under South Carolina's Title 40 regulatory powers, they are not governed by the BME. Instead, optometrists are licensed and regulated exclusively by the South Carolina Board of Examiners in Optometry. S.C. Code Ann. § 40-37-10.

15. South Carolina's regulatory regime provides that the only way to obtain a prescription for corrective lenses in the state is through a licensed ophthalmologist or optometrist. S.C. Code Ann. § 37-25-20. Prescriptions must be based on "medical findings made and refractive error discovered during [an] eye examination." S.C. Code Ann. § 40-24-20.

Opternative's Innovative Eye Care Services

16. Opternative is a healthcare technology company founded in 2012 by optometrist Steven Lee and entrepreneur Aaron Dallek out of their sincere belief that appropriate eye care and corrective-lens prescriptions should be accessible and affordable to everyone.

17. As a practicing optometrist who had completed over 20,000 refractive exams, experience taught Steven that refractive eye exams—conducted by brick-and-mortar providers, typically through use of a phoropter[2]—were needlessly time-consuming, inconvenient, and expensive for patients.

18. Traditional refractive eye exams rely on patient self-reporting: An individual sits in a chair and reports to the administering optometrist or ophthalmologist what they perceive as they are shown a series of images using a phoropter.

19. Traditional refractive eye exams are *subjective*, in that they rely on an individual's self-reporting of what they see, as distinct from *objective* exams that rely on physically measuring an individual's eyes.

[2] A phoropter is a mechanical device that switches multiple lenses in front of a patient's eyes.

20. An Exam conducted using Opternative's Technology relies on exactly the same self-reporting principle as a traditional exam.

21. Opternative's Technology is accessed through the Opternative website.

22. At the outset, an individual uses the Technology to answer a detailed list of questions, including (but not limited to) questions about their existing eyeglass prescription (if any) and their relevant medical history.

23. The Technology then presents a set of written and audio instructions that guides the individual through a self-administered vision assessment.

24. Opternative's Technology is interactive in nature: An individual observes a series of individually calibrated ophthalmological images on a computer screen and uses a smartphone to self-report what they perceive.

25. As with a traditional in-person examination, the Technology relies on individuals' honestly reporting what they perceive. Throughout the process, individuals are reminded that the correct answer is an honest answer, and the Technology employs a specialized algorithm to detect inconsistent responses.

26. A user's interaction with the Technology—from answering the initial medical-history questions to self-reporting responses to the various images—generally takes 20–25 minutes.

27. The Technology automatically collects and generates data based on the patient's interactive responses, which Opternative then shares with an ophthalmologist licensed to practice in the relevant state.

28. A licensed ophthalmologist reviews the data collected and generated by the Technology (which includes both the individual's medical-history responses and their responses

to the ophthalmological images) and decides either to write an appropriate prescription for corrective lenses or that no appropriate prescription can be written based on the data.

29. If a licensed ophthalmologist writes a prescription based on the data collected and generated by the Exam, the prescription is made available to the patient via Opternative's website. The patient can then use the prescription to purchase corrective lenses wherever they please.

30. While Opternative makes the Technology available on its website freely available to everyone, ophthalmologists working with Opternative will only conduct an Exam and write prescriptions for corrective lenses for individuals who meet certain criteria, which include age-, health-, and prescription-based considerations.

31. Opternative only charges a fee for an Exam—that is, for a doctor to review an individual's results; there is no fee for simply trying the Technology itself.

32. The Exam is designed to determine a patient's refractive error (and therefore the appropriate corrective prescription). It is not designed to be a comprehensive eye exam.

33. The American Academy of Ophthalmology recommends that otherwise-healthy patients (patients who do not have symptoms of disease or other risk factors for eye disease) who are between 18 and 39 years old receive a comprehensive eye-health exam once every 5–10 years. *See* American Academy of Ophthalmology, *Comprehensive Adult Medical Eye Evaluation*, at P216 (2015), *available at* www.aaojournal.org/article/S0161-6420(15)01269-5/pdf.

34. The American Academy of Ophthalmology recommends that otherwise-healthy patients who are between 40 and 54 years old receive a comprehensive eye exam once every 2–4 years. *Id.*

35. The American Academy of Ophthalmology recommends that otherwise-healthy patients who are between 55 and 64 years old receive a comprehensive eye health exam once every 1–3 years. *Id.*

36. In order to encourage compliance with these guidelines, Opternative asks a series of preliminary questions before examining any patient to ensure compliance with its strict eligibility requirements, which are displayed on its website at www.opternative.com:

> Opternative **is not a replacement** for a comprehensive eye examination. Our licensed Ophthalmologists use Opternative's on-line technology to evaluate a patient's visual acuity and a portion of the ocular health profile, diagnose refractive error, and issue a prescription for corrective eyewear, where clinically appropriate. Our services are limited to patients between the ages of 18 and 50 who are in good health. All examinations are conducted and all prescriptions are issued based on the independent clinical judgment of an ophthalmologist. Because our services are not a replacement for an eye health examination, we encourage everyone to obtain a comprehensive eye health exam at least once every 2 years. We prohibit patients from taking an Opternative exam more than 4 consecutive years without certifying that they have received a comprehensive eye health exam first. If you need help finding an eye care professional near you, please contact us at info@opternative.com.

37. The instructions on Opternative's website regarding the importance of comprehensive eye exams far exceed the minimum recommendations of the American Academy of Ophthalmology.

38. Eyeglass prescriptions in South Carolina expire after only one year. S.C. Code Ann. § 40-24-20(B).

39. An ophthalmologist in South Carolina is not required to conduct a comprehensive eye-health exam in order to write a prescription for corrective lenses.

40. For eligible patients, an Exam using the Technology is just as effective in the diagnosis of refractive error as traditional exams performed by ophthalmologists and optometrists using phoropters in brick-and-mortar offices.

41. In a side-by-side clinical trial, Exams that used Opternative's Technology proved just as accurate as a traditional refractive exam performed by an optometrist or ophthalmologist using a phoropter.

42. Upon information and belief, Defendants have no evidence that Exams using Opternative's Technology are any less accurate than a traditional in-person refractive exam.

43. Upon information and belief, Defendants have no reason to believe that Exams using Opternative's Technology are any less accurate than a traditional in-person refractive exam.

44. For eligible patients, an Exam using Opternative's Technology is quicker, more convenient, and more affordable than traditional exams performed by ophthalmologists and optometrists using phoropters in brick-and-mortar offices.

45. For eligible patients, an Exam using Opternative's Technology expands access to prescriptions for corrective lenses for those who can least afford to visit traditional brick-and-mortar offices.

46. Upon information and belief, Defendants possess no evidence that Exams using Opternative's Technology result in lower patient satisfaction than a traditional in-person refractive exam.

47. Upon information and belief, Defendants have no reason to believe that Exams using Opternative's Technology result in lower patient satisfaction than a traditional in-person refractive exam.

South Carolina's Unconstitutional Ban on Online Eye Care

48. Upon information and belief, many professional optometrists make the majority of their revenue from selling expensive frames in their brick-and-mortar offices rather than from professional fees earned from conducting traditional in-person eye examinations.

49. Upon information and belief, Opternative's service model disrupts this bundling of in-person eye examinations and frame sales, allowing patients the option of taking an eye exam and obtaining a prescription from the comfort of their own homes without ever having to see or consider buying expensive eyeglass frames in a brick-and-mortar office.

50. Upon information and belief, since almost immediately after Opternative's founding in 2012, the American Optometric Association ("the AOA") and related local optometric groups have conducted both a public media and private lobbying campaign to drive Opternative out of business.

51. Upon information and belief, almost immediately after Opternative began providing its services in South Carolina, the AOA and related South Carolina optometric groups conducted both a public media and private lobbying campaign to drive Opternative out of the state. These efforts culminated in the passage of the aforementioned Eye Care Consumer Protection Law on May 11, 2016.

52. The ECCPL provides that vision assessments "may not be based solely on objective refractive data or information generated by an automated testing device, including an auto refractor or other electronic refractive-only testing device, to provide a medical diagnosis or to establish a refractive error for a patient as part of an eye examination." S.C. Code Ann. § 40-24-10(9).

53. The ECCPL specifically targets "kiosks," or "automated equipment or an automated application, which is designed to be used on a phone, computer, or Internet-based device that can be used in person or remotely to provide refractive data or information." S.C. Code Ann. § 40-24-10(4).

54. The ECCPL effectively prohibits ophthalmologists from conducting Exams or writing prescriptions based on Opternative's Technology by providing that "[a] prescription for spectacles or contact lenses may not be based solely on the refractive eye error of the human eye or be generated by a kiosk." S.C. Code Ann. § 40-24-20(C).

55. Opternative's Technology is not a purely automated system; instead, Opternative's Technology uses an interactive and adaptive system to elicit responses from a patient. As part of this system, Opternative's Technology automatically collects and generates refractive data and information, which is transmitted to a participating ophthalmologist, who uses his training and judgment to write a prescription based on this data if it is appropriate to do so.

56. It is illegal to write a corrective-lens prescription based on an Exam using Opternative's Technology in South Carolina because the patient responses on which the ultimate prescription is based are being automatically recorded and compiled by a computer system designed for use on a phone, computer, or Internet-based device instead of (for example) being written down by a human being holding a clipboard.

57. Writing a prescription based on a system similar to Opternative's—which asked the same questions and showed the patient the same images—would be generally legal in South Carolina as long as the patient's responses were written down by a human being instead of being automatically recorded and compiled by a computer system.

58. The purpose of the ECCPL is to prohibit South Carolina-licensed ophthalmologists from working with Opternative (or anyone providing technology like Opternative's).

59. The effect of the ECCPL is to prohibit South Carolina-licensed ophthalmologists from working with Opternative (or anyone providing technology like Opternative's).

60. Defendants have no authority or ability to interpret the ECCPL in a way that would allow South Carolina-licensed ophthalmologists to work with Opternative (or anyone providing technology like Opternative's).

61. Therefore, asking Defendants to issue an interpretation or regulation that would permit South Carolina-licensed ophthalmologists to work with Opternative (or anyone providing technology like Opternative's) would be futile.

62. The ECCPL threatens Opternative—and specifically, state-licensed ophthalmologists who work with Opternative—with the full range of penalties covered in ¶¶ 11-12 above. *Id.* § 40-24-20(D).

63. The ECCPL's ban on prescribing corrective lenses based on information that is automatically collected or generated is unrelated to the quality or accuracy of a prescription.

64. The ECCPL prohibits prescribing corrective lenses based solely on information generated through any computerized process, whether that process is Opternative's more traditional subjective exam or a meticulously accurate objective scan of a patient's eye.

65. South Carolina law does not require that ophthalmologists or optometrists physically examine patients for risk factors or diseases before writing a prescription for corrective lenses.

66. South Carolina law does not require that ophthalmologists or optometrists take into account any particular medical facts not generated by an eye exam before writing a prescription for corrective lenses.

67. South Carolina law does not require that patients obtain a comprehensive eye-health exam once per year, once every five years, or even at all, in order to obtain a prescription for corrective lenses.

68. An ophthalmologist who writes a corrective-lens prescription without conducting a comprehensive eye-health exam has not necessarily violated any standard of care.

69. The ECCPL has no valid public health or safety purpose.

70. Upon information and belief, Defendants possess no evidence that the ECCPL serves any valid public health or safety purpose.

71. The sole purpose of the ECCPL is economic protectionism.

72. The ECCPL, in purpose and effect, reduces access to online eye care in South Carolina in order to prop up professional optometrists' outdated business model.

73. On May 16, 2016, Governor Nikki Haley vetoed the ECCPL for precisely these reasons, specifically condemning its protectionist and anti-competitive nature.

74. Governor Haley's veto statement reads, in full:

> **I am vetoing this bill because it uses health practice mandates to stifle competition for the benefit of a single industry,** effectively banning eye care kiosks statewide.
>
> During my administration, South Carolina has expanded access to health care, including mental health services, to rural and underserved regions of our state using telemedicine. Unfortunately, a small group of eyecare professionals is seeking to block new technologies that expand low-cost access to vision correction services, using two basic arguments.

> First, advocates state that kiosks pose a public health risk, which is simply untrue. Individuals can, and should, continue to see their doctor for comprehensive medical exams, and these kiosks do not offer medical evaluations or advice. Second, optometrists argue that kiosks create an uneven playing field because licensed practitioners cannot take advantage of this technology and charge patients for its use in a medical practice. The answer to this problem is not to ban a new technology, but rather to expand its use. **Send a bill to my desk that allows for the expanded use of automated vision evaluations in all settings, and I will sign it.**
>
> If [the ECCPL were] allowed to become law, South Carolina would become the eighth state to impose such a ban, putting us on the leading edge of protectionism, not innovation. This is the wrong message to send to the business community. **I urge you to continue promoting South Carolina's use of innovative technologies to expand access to medical care and sustain this veto.**

Veto Message of Governor Nikki Haley, March 16, 2016, *available at* http://www.governor.sc.gov/ExecutiveOffice/Documents/R.178,%20S.1016%20-%20Eye%20Care.pdf.

75. The assertions in Governor Haley's May 16 veto statement are true.

76. On May 18, 2016, the South Carolina General Assembly voted to override Governor Haley's veto of the ECCPL.

77. The ECCPL stands in stark contrast to how South Carolina regulates telemedicine overall. On June 3, 2016, the South Carolina Telemedicine Act legalized telemedicine generally throughout the state. S.C. Code Ann. § 40-47-37.

78. Under the South Carolina Telemedicine Act, a medical doctor may use online tools to provide medical care provided the doctor otherwise meets the relevant standard of care.

79. Under the ECCPL, however, an ophthalmologist may not use online tools like Opternative's Technology to write corrective-lens prescriptions, even if they otherwise meet the relevant standard of care.

INJURY TO PLAINTIFF

80. As a direct result of the passage of the ECCPL, the use of Opternative's Technology has been effectively prohibited in South Carolina.

81. Prior to the adoption of the ECCPL, Opternative could (and did) allow a South Carolina-licensed ophthalmologist to write corrective-lens prescriptions for South Carolina residents.

82. As a direct result of the passage of the ECCPL, South Carolina-licensed ophthalmologists are legally prohibited from working with Opternative to provide corrective-lens prescriptions for South Carolina residents.

83. As a direct result of the passage of the ECCPL, South Carolina-licensed ophthalmologists are no longer willing to work with Opternative to provide corrective-lens prescriptions for South Carolina residents.

84. As a direct result of the passage of the ECCPL, Opternative has ceased its business operations in South Carolina.

85. But for the ECCPL, Opternative would still be facilitating corrective-lens prescriptions for South Carolina residents.

86. But for the ECCPL, state-licensed ophthalmologists would be willing to work with Opternative to provide corrective-lens prescriptions for South Carolina residents.

COUNT I: DUE PROCESS VIOLATION

87. Opternative re-alleges and incorporates by reference each and every allegation set forth in ¶ 1 through ¶ 86 of this Complaint as if fully set forth herein.

88. Article I, Section 3 of the South Carolina Constitution protects Opternative's right to pursue an honest living free from arbitrary, irrational, and protectionist regulation and the

rights of doctors and patients to make responsible decisions about medical care by providing that "[t]he privileges and immunities of citizens of this State and of the United States under this Constitution shall not be abridged, nor shall any person be deprived of life, liberty, or property without due process of law." S.C. Const. art I, § 3.

89. South Carolina's eye-care regulatory regime—specifically, the ECCPL provisions described above and codified at South Carolina Code sections 40-24-10(9), and 40-24-20(C) and (D)—does not further any valid public health or safety purpose, and therefore violates Opternative's right to pursue an honest living free from arbitrary, irrational, and protectionist regulation.

90. The ECCPL is a purely protectionist piece of legislation, and protectionism is not a legitimate basis under the South Carolina Constitution for depriving Opternative of its constitutional right to pursue an honest living by providing innovative eye-care solutions to patients who need them.

91. Unless Defendants are enjoined from enforcing the ECCPL, Opternative will suffer continuing and irreparable harm.

COUNT II: EQUAL PROTECTION VIOLATION

92. Opternative re-alleges and incorporates by reference each and every allegation set forth in ¶ 1 through ¶ 86 of this Complaint as if fully set forth herein.

93. Article I, Section 3 of the South Carolina Constitution further protects the rights of South Carolinians by providing "nor shall any person be denied the equal protection of the laws." S.C. Const. art I, § 3.

94. The ECCPL has no valid public health or safety purpose but is a purely protectionist piece of legislation, and therefore serves no legitimate state end.

95. The ECCPL draws an arbitrary and irrational distinction between ophthalmologists who write corrective-lens prescriptions based on an in-person refractive examination and ophthalmologists who write corrective-lens prescriptions based on Opternative's Exam.

96. The ECCPL draws an arbitrary and irrational distinction between ophthalmologists, who are not allowed to use their medical judgment to use online tools like Opternative to provide medical services that otherwise meet the general standard of care, and other kinds of medical doctors, who are allowed to use their medical judgment to use online tools to provide medical services that otherwise meet the general standard of care.

97. Unless Defendants are enjoined from enforcing the ECCPL, Opternative will suffer continuing and irreparable harm.

PRAYER FOR RELIEF

WHEREFORE, Opternative respectfully requests that this Court:

A. Enter a declaratory judgment that the Eye Care Consumer Protection Law, S.C. Code Ann. §§ 40-24-10(9), and 40-24-20(C) and (D), violates Article I, Section 3 of the South Carolina Constitution;

B. Enter a declaratory judgment that Defendants cannot legally penalize South Carolina-licensed ophthalmologists solely on the basis that they have written corrective-lens prescriptions using Opternative's Technology;

C. Enter an order permanently enjoining Defendants from enforcing the ECCPL;

D. Award Opternative its reasonable costs and attorneys' fees in this action;

E. Award Opternative any other legal or equitable relief to which Opternative is justly entitled.

Respectfully submitted,

INSTITUTE FOR JUSTICE

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Attorneys for Plaintiff Opternative, Inc.

Columbia, South Carolina
October 20, 2016.

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FIFTH JUDICIAL CIRCUIT
COUNTY OF RICHLAND	)	
		Civil Action No. 2016-CP-40-06276
Opternative, Inc.,	)	
Plaintiff,	)	
v.	)	**ANSWER OF DEFENDANT-INTERVENOR SOUTH CAROLINA OPTOMETRIC PHYSICIANS ASSOCIATION**
South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation,	)	
Defendants,	)	
and	)	
South Carolina Optometric Physicians Association,	)	
Defendant-Intervenor.	)	

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Defendant-Intervenor South Carolina Optometric Physicians Association ("SCOPA"), by and through its undersigned attorneys, hereby answers the Complaint of Opternative, Inc. ("Plaintiff"), filed October 20, 2016, as follows.

FOR A FIRST DEFENSE

1. Each and every paragraph of Plaintiff's Complaint not specifically admitted, qualified, or explained herein is denied.

2. The allegations in Paragraph One (1) of Plaintiff's Complaint state legal conclusions to which no response is required. To the extent a response is required, SCOPA admits Plaintiff claims rights and interests in certain online technology (the "Technology") alleged in this Paragraph. Further answering the allegations in this paragraph, SCOPA denies Plaintiff's characterization of the South Carolina Eye Care Consumer Protection Law, S.C. Code

Ann. §§ 40-24-10, et seq. and denies Plaintiff's entitlement to a declaratory judgment and demands strict proof thereof.

3. The allegations in Paragraph Two (2) of Plaintiff's Complaint state legal conclusions to which no response is required. To the extent a response is required, SCOPA does not contest jurisdiction.

4. The allegations in Paragraph Three (3) of Plaintiff's Complaint state legal conclusions to which no response is required. To the extent a response is required, SCOPA admits Plaintiff seeks a declaratory judgment and injunctive relief. SCOPA denies Plaintiff's characterization of the South Carolina Eye Care Consumer Protection Law, S.C. Code Ann. §§ 40-24-10, et seq. and denies Plaintiff's entitlement to a declaratory judgment.

5. The allegations in Paragraph Four (4) of Plaintiff's Complaint state legal conclusions to which no response is required. To the extent a response is required, SCOPA does not contest jurisdiction.

6. Upon information and belief, SCOPA admits the allegations in Paragraph Five (5) of Plaintiff's Complaint.

7. Upon information and belief, SCOPA admits the allegations in Paragraphs Six (6) and Seven (7) of Plaintiff's Complaint.

8. The allegations in Paragraphs Eight (8) and Nine (9) of Plaintiff's Complaint state legal conclusions to which no response is required.

9. SCOPA admits the allegations in Paragraph Ten (10) of Plaintiff's Complaint.

10. The allegations in Paragraphs Eleven (11) and Twelve (12) of Plaintiff's Complaint state legal conclusions to which no response is required.

11. SCOPA admits the allegations in Paragraph Thirteen (13) of Plaintiff's Complaint.

12. The allegations in Paragraphs Fourteen (14) and Fifteen (15) of Plaintiff's Complaint state legal conclusions to which no response is required.

13. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraphs Sixteen (16) and Seventeen (17) of Plaintiff's Complaint.

14. SCOPA admits the allegations in Paragraphs Eighteen (18) and Nineteen (19) of Plaintiff's Complaint.

15. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraphs Twenty (20), Twenty-One (21), Twenty-Two (22), Twenty-Three (23), Twenty-Four (24), Twenty-Five (25), Twenty-Six (26), Twenty-Seven (27), Twenty-Eight (28), Twenty-Nine (29), Thirty (30), Thirty-One (31), and Thirty-Two (32) of Plaintiff's Complaint.

16. SCOPA admits the allegations in Paragraphs Thirty-Three (33), Thirty-Four (34), and Thirty-Five (35) of Plaintiff's Complaint.

17. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraphs Thirty-Six (36) and Thirty-Seven (37) of Plaintiff's Complaint.

18. The allegations in Paragraphs Thirty-Eight (38) and Thirty-Nine (39) of Plaintiff's Complaint state legal conclusions to which no response is required.

19. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraphs Forty (40), Forty-One (41), Forty-Two (42), Forty-Three (43), Forty-Four (44), Forty-Five (45), Forty-Six (46), and Forty-Seven (47) of Plaintiff's Complaint.

20. Upon information and belief, SCOPA admits the allegations in Paragraph Forty-Eight (48) of Plaintiff's Complaint.

21. SCOPA denies the allegations in Paragraphs Forty-Nine (49), Fifty (50), and Fifty-One (51) of Plaintiff's Complaint as stated.

22. The allegations in Paragraphs Fifty-Two (52), Fifty-Three (53), and Fifty-Four (54) of Plaintiff's Complaint state legal conclusions to which no response is required.

23. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraph Fifty-Five (55) of Plaintiff's Complaint.

24. The allegations in Paragraphs Fifty-Six (56), Fifty-Seven (57), Fifty-Eight (58), Fifty-Nine (59), Sixty (60), Sixty-One (61), Sixty-Two (62), Sixty-Three (63), Sixty-Four (64), Sixty-Five (65), Sixty-Six (66), Sixty-Seven (67), Sixty-Eight (68), Sixty-Nine (69), Seventy (70), Seventy-One (71), Seventy-Two (72), Seventy-Three (73), Seventy-Four (74), Seventy-Five (75), Seventy-Six (76), Seventy-Seven (77), Seventy-Eight (78), and Seventy-Nine (79) of Plaintiff's Complaint state legal conclusions to which no response is required.

25. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraphs Eighty (80), Eighty-One (81), Eighty-Two (82), Eighty-Three (83), Eighty-Four (84), Eighty-Five (85), and Eighty-Six (86) of Plaintiff's Complaint.

26. In response to the allegations in Paragraph Eighty-Seven (87) of Plaintiff's Complaint, SCOPA hereby reincorporates the preceding allegations of this Answer as if fully restated herein verbatim.

27. The allegations in Paragraphs Eighty-Eight (88), Eighty-Nine (89), and Ninety (90) of Plaintiff's Complaint state legal conclusions to which no response is required.

28. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraph Ninety-One (91) of Plaintiff's Complaint.

29. In response to the allegations in Paragraph Ninety-Two (92) of Plaintiff's Complaint, SCOPA hereby reincorporates the preceding allegations of this Answer as if fully restated herein verbatim.

30. The allegations in Paragraphs Ninety-Three (93), Ninety-Four (94), Ninety-Five (95), and Ninety-Six (96) of Plaintiff's Complaint state legal conclusions to which no response is required.

31. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraph Ninety-Seven (97) of Plaintiff's Complaint.

32. SCOPA denies the allegations in the Plaintiff's Prayer for Relief.

WHEREFORE, having fully answered Plaintiff's Complaint, Defendant-Intervenor South Carolina Optometric Physicians Association prays that it be dismissed with prejudice, for the taxable costs of this action, and for such other and further relief as the Court may deem just and proper.

Respectfully submitted,

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Attorneys for South Carolina Optometric Physicians Association

March 7, 2017.

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FIFTH JUDICIAL CIRCUIT
COUNTY OF RICHLAND	)	
		Civil Action No. 2016-CP-40-06276
Opternative, Inc.,	)	
	)	
Plaintiff,	)	**MOTION TO INTERVENE**
v.	)	
	)	
South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation,	)	
	)	
Defendants.	)	

RICHLAND COUNTY
FILED
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JEANNETTE W. MCBRIDE
C.C.P. & G.S.

Pursuant to Rule 24 of the *South Carolina Rules of Civil Procedure*, South Carolina Optometric Physicians Association ("SCOPA") hereby moves to intervene as a defendant in this action to assert the defenses set forth in its proposed answer, a copy of which is attached as **Exhibit 1**. This motion is further supported by the affidavit of Dr. Jennifer Zolman, President of SCOPA, a copy of which is attached hereto as **Exhibit 2**.

BACKGROUND

Plaintiff Opternative, Inc. initiated this action on October 20, 2016, seeking a declaratory judgment finding portions of the Eye Care Consumer Protection Law, S.C. Code Ann. §§ 40-24-10, *et seq.*, enacted on May 11, 2016 ("ECCPL"). Specifically, Opternative challenges sections 40-24-10(9) and 40-24-20(C) and (D) of the ECCPL, alleging these provisions violate Article I, Section 3 of the South Carolina Constitution.

Opternative is a healthcare technology company that has allegedly produced certain technology which allows ophthalmologists and optometrists to conduct a refractive eye

examination using a computer. *See* Complaint at ¶¶ 16, 21-28. Opternative challenges section 40-24-10(9) of the ECCPL, which provides that vision assessments

> may not be based solely on objective refractive data or information generated by an automated testing device, including an auto refractor or other electronic refractive-only testing device, to provide a medical diagnosis or to establish a refractive error for a patient as part of an eye examination.

Opternative claims the ECCPL "effectively prohibits ophthalmologists from conducting Exams or writing prescriptions based on Opternative's Technology." Complaint at ¶ 54 (citing S.C. Code Ann. § 40-24-20(C) (barring the issuance of "prescription[s] for spectacles or contact lenses ... based solely on the refractive eye error of the human eye or be generated by a kiosk."). Opternative seeks a ruling prohibiting Defendants South Carolina Board of Medical Examiners and South Carolina Department of Labor, Licensing, and Regulation from penalizing South Carolina-licensed ophthalmologists pursuant to Section 40-24-40(D) of the ECCPL.

Movant is an association of optometric physicians practicing in South Carolina. Optometrists are healthcare professionals who provide primary vision care ranging from sight testing and correction to diagnosis, treatment, and management of vision changes. *See* Exhibit 2 at ¶ 5. Optometrists are different from ophthalmologists in that ophthalmologists are medical professionals or osteopathic doctors who specialize in eye and vision care. *Id.* at ¶ 6.

The ECCPL affects both ophthalmologists and optometrists because it expressly provides that the only way to obtain a prescription for corrective lenses in the state is through a licensed ophthalmologist or optometrist. S.C. Code Ann. § 37-25-20. Plaintiff acknowledges as much in its Complaint. *See* Complaint at ¶¶ 9, 13-15. Prescriptions must be based on "medical findings made and refractive error discovered during [an] eye examination," which may be conducted by either an ophthalmologist or optometrist. S.C. Code Ann. § 40-24-20; S.C. Code Ann. § 37-25-20. SCOPA's members are directly affected by the ECCPL and, potentially, the outcome of this

litigation. If Plaintiff prevails in this case, SCOPA's members and the patients they treat could be affected. For the reasons that follow, SCOPA's intervention should be permitted.

ARGUMENTS

The Rules of Civil Procedure provide for intervention as of right as well as permissive intervention. Intervention as of right is governed by Rule 24(a), SCRCP. Rule 24(a)(2) provides

> anyone shall be permitted to intervene in an action: ... (2) when the applicant claims an interest relating to the property or transaction which is the subject of the action and he is so situated that the disposition of the action may as a practical matter impair or impede his ability to protect that interest, unless the applicant's interest is adequately represented by existing parties.

Rule 24(a) is a counterpart to Rule 19(a), SCRCP, regarding joinder of persons needed for a just adjudication. Under Rule 19(a), upon motion of a party to the action, a non-party should be joined so that he may protect his interest which, as a practical matter, may be substantially impaired by the disposition of the action. Pursuant to Rule 24(a), that same non-party has a right to intervene in the action on his own motion. Case law interpreting both rules hold admission of a non-party who is necessary to adjudication of the action should be liberally granted. *See Government Employee's Ins. Co., Ex Parte*, 373 S.C. 132, 136, 644 S.E.2d 699, 701 (2007); *Berkeley Electric v. Town of Mt. Pleasant*, 302 S.C. 186, 189, 394 S.E.2d 712, 714 (1990).

Permissive intervention is governed by Rule 24(b), SCRCP, which provides for intervention: (1) when a statute confers a conditional right to intervene; or (2) when an applicant's claim or defense and the main action have a question of law or fact in common." "Rule 24(b) intervention is premised on the theory that when claims or defenses have a question of law or fact common to each other, sound administrative procedures encourage the disposition of all of the claims or defenses in one action rather than a multiplicity of actions." *S.C. Tax Comm'n v. Union City Treasurer*, 295 S.C. 257, 263, 368 S.E.2d 72, 75 (Ct. App. 1988).

Courts interpret Rule 24 "to permit liberal intervention particularly where, as here, judicial economy will be promoted by the declaration of the rights of all parties who may be affected." *Berkeley Electric*, 302 S.C. at 189, 394 S.E.2d at 714. *See also TPI Corp. v. Merchandise Mart of South Carolina, Inc.*, 61 F.R.D. 684, 690 (D.S.C. 1974) ("most cases call for a liberal construction of Rule 24") (citations omitted). Granting intervention is wholly discretionary with the court. *See* Rule 24(b), SCRCP; *Berkeley Electric*, 302 S.C. at 189, 394 S.E.2d at 714. "In exercising its discretion the court shall consider whether the intervention will unduly delay or prejudice the adjudication of the rights of the original parties." *Id.*

I. SCOPA IS ENTITLED TO INTERVENE AS OF RIGHT UNDER RULE 24(A).

In order to establish intervention as of right, a proposed intervenor must: (1) establish timely application; (2) assert an interest relating to the property or transaction which is the subject of the action; (3) demonstrate it is in a position such that without intervention, disposition of the action may impair or impede his ability to protect that interest; and (4) demonstrate its interest is inadequately represented by other parties." *Berkeley Electric*, 302 S.C. at 189, 394 S.E.2d at 714; *Ex Parte Reichlyn*, 310 S.C. 495, 498, 427 S.E.2d 661, 663 (1993). The court "must consider the pragmatic consequences of a decision to permit or deny intervention" and should "avoid setting up rigid applications of Rule 24(a)(2)." *Id.* at 189, 394 S.E.2d at 714.

A. SCOPA's intervention is reasonable and timely.

SCOPA's motion to intervene is timely. The Supreme Court has set forth a four-part test to determine timeliness of a motion to intervene: (1) the time that has passed since the applicant knew or should have known of his or her interest in the suit; (2) the reason for the delay; (3) the stage to which litigation has progressed; and (4) the prejudice the original parties would suffer from granting intervention and the applicant would suffer from denial. *Davis v. Jennings*, 304

S.C. 502, 504, 405 S.E.2d 601, 603 (1991) (reversing trial court's denial of newspaper's motion to intervene for limited purpose of challenging a protective order, rejecting respondents' contention that motion was untimely).

Rule 24 provides no definition of what constitutes a "timely" motion. Rather, "the question must . . . be answered in each case by the exercise of the sound discretion of the court." *Black v. Central Motor Lines*, 500 F.2d 407, 408 (4th Cir. 1974); *Berkeley Electric*, 302 S.C. at 189, 394 S.E.2d at 714 ("Each case will be examined in the context of its unique facts and circumstances"). It is clear here, based on the stage of litigation, SCOPA's motion to intervene is timely and would not prejudice the rights of the original parties. The above-captioned action was filed on October 20, 2016. *See generally* Complaint. SCOPA received notice of the action on the date it was initiated through its relationship with the American Optometric Association. Exhibit 2 at ¶ 14. On November 21, 2016, the original defendants in the action answered Plaintiff's Complaint.

When evaluating prejudice to the original parties, "[p]articular focus must be had on the posture of th[e] litigation at the time the motion is made." *U.S. v. Pitney Bowes, Inc.*, 25 F.3d 66, 72 (2d Cir. 1994) (citation omitted). A motion to intervene is timely when it causes no delay in the resolution of the action or otherwise prejudices a party. *Butler, Fitzgerald & Potter v. Sequa Corp.*, 250 F.3d 171 (2d Cir. 2001); *Jet Traders Investment Corp. v. Tekair, Ltd.*, 89 F.R.D. 560 (D. Del. 1981). Any delay that may result from SCOPA's intervention would be minimal, as SCOPA's involvement would not disturb or challenge existing orders or upset past discovery. SCOPA's intervention is both reasonable and timely.

B. SCOPA has a real and substantial interest relating to the subject of this action.

To meet the second prong of Rule 24(a)(2), SCRCP, a party must have a real and protectable interest in the property or transaction that is the subject matter of the lawsuit. "A real party in interest . . . ordinarily is one who has a real, actual, material, or substantial interest in the subject matter of the action, as distinguished from one who has only a nominal, formal, or technical interest in, or connection with, the action." *Dockside Ass'n, Inc. v. Detyens, Simmons and Carlisle*, 285 S.C. 565, 568-69, 330 S.E.2d 537, 539 (Ct. App. 1985), *aff'd as modified by* 287 S.C. 287, 337 S.E.2d 887 (1985). "It is well settled that the only interest which will entitle a person to the right of intervention in a case is a legal interest as distinguished from interests of a general and indefinite character which do not give rise to definite legal rights." *Allen v. County Sch. Board*, 28 F.R.D. 358, 362 (D. Va. 1961) (citation omitted); *Radford Iron Co. Inc. v. Appalachian Elec. Power Co.*, 62 F.2d 940 (4th Cir. 1933)).

The court's analysis under the second prong of the applicable test for intervention as of right under Rule 24(a) amounts to a determination of a party's standing, a fundamental requirement for instituting a civil action. Standing requires a party to have an interest in the subject matter of the action and a personal stake in the outcome of the litigation. *Furman Univ. v. Livingston*, 244 S.C. 200, 204, 136 S.E.2d 254, 256 (1964); *Duke Power Co. v. S.C. Pub. Serv. Com'n*, 284 S.C. 81, 96, 326 S.E.2d 394, 404 (1985). In declaratory judgment actions, the interest of the parties to the subject matter of the controversy must be more than merely general; it must be a substantial, direct, and legally protected interest in the relief sought. S.C. Code Ann. § 15-53-30; *Carolina Alliance for Fair Employment v. S.C. Dept. of Labor, Licensing, and Regulation*, 337 S.C. 476, 523 S.E.2d 795 (Ct. App. 1999).

"An association has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests at stake are germane to the

organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Friends of the Earth Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 181, 120 S.Ct. 693, 704, 145 L.Ed.2d 610 (2000) (citing *Hunt v. Washington State Apple Advertising Com'n*, 432 U.S. 333, 343, 97 S.Ct. 2434, 53 L.Ed.2d 383 (1977)). In *Carnival Corp. v. Historic Ansonborough Neighborhood Ass'n*, the South Carolina Supreme Court recognized the three-part *Laidlaw* test for associational standing applied in this state. 407 S.C. 67, 76-77, 753 S.E.2d 846, 851-52 (2014).

SCOPA meets the three-part test for associational standing. First, SCOPA's members, optometrists practicing in the State of South Carolina, would otherwise have standing to intervene in this action in their own right. As acknowledged by Plaintiff in its Complaint, both ophthalmologists and optometrists are affected by the ECCPL. *See also* Exhibit 2 at ¶ 8 (stating the ECCPL directly regulates SCOPA's members). A declaration in Plaintiff's favor in the subject action would substantially and materially change the manner in which optometrists treat their patients, conduct refractive eye examinations, and prescribe spectacles or contact lenses. *See* Exhibit 2 at ¶ 16.

In *New York Public Interest Research Group, Inc. v. Regents of University of State of N.Y.*, 516 F.2d 350 (2d Cir. 1975), the Court of Appeals for the Second Circuit reversed a district court's order refusing to allow a pharmaceutical association from intervening in a consumer action challenging a prohibition on advertising prescription drugs. The appellate court recognized: "Clearly the pharmacists have an interest in the transaction which is the subject of the action." *Id.* at 351. "Pharmacists also have an interest in the action as professionals since any lifting of the prohibition against advertising prescription drug prices might well lead to significant changes in the profession and in the way pharmacists conduct their businesses." *Id.*

For similar reasons, SCOPA's members have an interest in the subject matter of the subject action and have a personal stake in the outcome of the litigation because any declaratory judgment that may be issued in this case could materially change the manner in which SCOPA's members treat their patients. Because SCOPA's members would have personal standing to intervene in this matter, SCOPA has standing to intervene.

Second, SCOPA has standing to intervene because the interests at stake are germane to the organization's purpose. SCOPA operates for the purpose of representing optometrists in South Carolina and advocating for patient care. Exhibit 2 at ¶ 11. To the extent the subject litigation may affect the statutory and regulatory regime under which SCOPA's members operate, SCOPA has an organizational interest in the outcome of the action. *See New York Public Interest Research Group, Inc.*, 516 F.2d at 352 ("With respect to the association of pharmacists, we hold that it has a sufficient interest to permit it to intervene since the validity of a regulation from which its members benefit is challenged."); *Sierra Club v. Ruckelshaus*, 602 F.Supp. 892, 896 (N.D. Cal. 1984) ("Because Association members mine phosphorus, they will be directly affected by final radionuclide emission standards"). Accordingly, the interests at stake in this case are germane to SCOPA's organizational purpose and SCOPA should be allowed to intervene.

Finally, SCOPA has standing to intervene because neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. The potential declaration in this case has the effect of determining whether certain provisions of the ECCPL are valid or invalid. Should Plaintiff prevail in this suit, portions of the ECCPL under which SCOPA's members are currently regulated and required to follow would be set aside or materially rewritten and enforced. The effect of such a declaration would impact all of SCOPA's

members and the patients SCOPA treats, rather than affecting only a limited number. Further, requiring intervention by SCOPA's individual members, more than 425 optometrists in the State of South Carolina, *see* Exhibit 2 at ¶ 10, would be a waste of judicial time and resources and would be antithetical to this court's interest in promoting judicial economy.

Similarly, in *Berkeley Electric*, the Supreme Court held a proposed intervenor, SCE&G, had a substantial interest in the litigation and was allowed to intervene under Rule 24(a) where SCE&G showed it "may be impaired or impeded in its ability to protect its asserted interests." 302 S.C. at 191, 394 S.E.2d at 715. The Court recognized, "[a] declaration by the trial judge in favor of [the plaintiff] would, as a practical matter, prevent [SCE&G] from serving customers that it believes it is legally entitled to serve . . . ." *Id.* Similarly, here, SCOPA believes the provisions of the ECCPL are reasonably necessary to protect and uphold the applicable standard of care for SCOPA's members' patients. SCOPA's members are under an affirmative obligation to look after the best interests and health of their patients. *See* Exhibit 2 at ¶ 13 (citing American Optometric Association Standards of Professional Conduct). The American Optometric Association's Code of Ethics states: "It shall be the ideal, resolve, and duty of all optometrists to keep their patients' eye, vision, and general health paramount at all times." *Id.* at ¶ 13. A finding that the ECCPL's provisions are unconstitutional or illegal would directly affect the nature of services provided by SCOPA's members and the quality of care SCOPA's members' patients receive.

In cases in other jurisdictions challenging various statutory schemes as unconstitutional or improperly interpreted and applied, courts have permitted persons who are governed by those schemes to intervene. *See, e.g., Chiles v. Thornburgh*, 865 F.2d 1197, 1214 (11th Cir. 1989) (detainees allowed to intervene as a matter of right in action brought to challenge housing of

alien felons); *Taft v. Pontarelli*, 100 F.R.D. 19 (D.R.I. 1983) (parents of children who attended religiously-affiliated schools permitted to intervene in action challenging a federal program purporting to aid children in both public and nonpublic schools nationwide). This judicial willingness to allow intervention extends to associations whose members are governed by the subject statutory or regulatory schemes. *See Great Atl. & Pac. Tea Co. v. Town of East Hampton*, 178 F.R.D. 39 (D.N.Y. 1998) (group dedicated to preserving the rural character of a municipality permitted to intervene in action contesting the continued existence of an ordinance restricting commercial activities outside of the central business district); *Stevenson v. Rominger*, 905 F.Supp. 836 (D.Wash. 1995) (environmental group allowed to intervene as of right in landowner's action challenging Forest Service regulation); *Sierra Club v. Ruckelshaus*, 602 F.Supp. 892 (D.Cal. 1984) (mining association permitted to intervene in environmental organization's suit against EPA arising out of agency's failure to timely promulgate regulations concerning radionuclide emission standards).

For these reasons, SCOPA has a real and substantial interest relating to the subject of this action and should be permitted to intervene.

C. Without intervention, disposition of the action could impair SCOPA's ability to protect its interest.

In order to show that its interest will be impaired or impeded, "a party need not prove that it would be bound in a *res judicata* sense by the judgment, only that it would have difficulty adequately protecting its interests if not allowed to intervene." *Berkeley*, 302 S.C. at 189, 394 S.E.2d at 714. It is not a sufficient ground to deny intervention in a declaratory judgment case that the proposed intervenor "protect [its] interests after an adverse decision in the instant case by attacking any new regulation on constitutional, antitrust or unfair competition grounds." *New*

York Public Interest Research Group, Inc., 516 F.2d at 352. In *Sierra Club v. Ruckelshaus*, 602 F.Supp. at 896, a federal district court recognized,

> Although the Association ... would have the opportunity to litigate the merits of the regulations at a later date, such an after-the-fact remedy "may, 'as a practical matter,' afford much less protection than the opportunity to participate in ... proceedings that seek to ensure sustainable regulations in the first place, with no need for judicial review. ..." Thus, the Association's interests might be impaired if intervention in th[e] action were not allowed.

602 F.Supp. at 896 (quoting *Natural Resources Defense Council v. Costle*, 561 F.2d 904, 909 (D.C. Cir. 1977). For the same reasons, judicial economy would be served by permitting SCOPA to intervene in this action rather than require SCOPA to later challenge the downstream effect of a ruling in this case.

D. SCOPA's interest is not adequately represented by other parties.

The last requirement of Rule 24(a), SCRCP, is met upon a showing by the party seeking intervention that "the representation of [its] interests 'may be' inadequate. *Berkeley Electric*, 302 S.C. at 191, 394 S.E.2d at 715 (quoting *Trbovich v. United Mine Workers*, 404 U.S. 528, 92 S.Ct. 630, 30 L.Ed2d 686 (1972)). "This burden is minimal." *Id.* In order to determine whether another party will adequately protect the interest of an intervenor, the Court should consider three factors: (1) whether the existing parties will undoubtedly make all of the intervenor's arguments; (2) whether the existing parties are capable and willing to make such arguments; and (3) whether the intervenor offers different knowledge, experience, or perspective on the proceedings that would otherwise be absent. *In re Horry County State Bank*, 361 S.C. 503, 508-09, 604 S.E.2d 723, 726 (Ct. App. 2004); *Berkeley Electric*, 302 S.C. at 191, 394 S.E.2d at 715.

Even though the Board and SCLLR are parties to the subject action, and may at this stage have similar interests to SCOPA, courts have recognized "even when a governmental agency's interests appear aligned with those of a particular private group at a particular moment in time,

'the government's position is defined by the public interest, [not simply] the interests of a particular group of citizens." *Fellerv. Brock*, 802 F.2d 722, 730 (4th Cir. 1986); *In re Sierra Club*, 945 F.2d 776, 780 (4th Cir. 1991); *see also New York Public Interest Research Group, Inc.*, 516 F.2d at 352 ("[W]e are satisfied that there is a likelihood that the pharmacists will make a more vigorous presentation of the economic side of the argument than would [the existing parties] ... [as] their interests 'may significantly differ.'").

Moreover, should SCOPA's intervention be denied, there is a risk that the original defendants could settle the case in a manner that could harm SCOPA's interests. Thus, if SCOPA is not permitted to intervene, it would be precluded from protecting its interests as well as the interests of its members, as it would have no meaningful way to attempt to affect the outcome of this case.

II. ALTERNATIVELY, PERMISSIVE INTERVENTION IS APPROPRIATE.

As an alternative, SCOPA should be allowed permissive intervention pursuant to Rule 24(b)(2), SCRCP. Under Rule 24(b)(2), permissive intervention is appropriate where "an applicant's claim or defense and the main action have a question of law or fact in common" and the intervention does not "unduly delay or prejudice" the rights of the original parties. *Id.* The commonality requirement for permissive intervention is satisfied where the "petitioner-intervenor's claims and the main action arose out of the same transaction." *TPI Corp. v. Merchandise Mart of South Carolina, Inc.*, 61 F.R.D. 684, 689 (D.S.C. 1974).

When considering a request for permissive intervention, the court must "consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." *Stuart v. Huff*, 706 F.3d 345, 349 (4th Cir. 2013) (internal quotation omitted). Additional relevant factors "include the nature and extent of the intervenors' interests," the degree to which

those interests are "adequately represented by other parties," and "whether parties seeking intervention will significantly contribute to full development of the underlying factual issues in the suit and to the just and equitable adjudication of the legal questions presented." *H.L. Hayden Co. of New York, Inc. v. Siemens Medical Systems, Inc.*, 797 F.2d 85, 89 (citation omitted).

The same reasons that call for an order permitting SCOPA to intervene under Rule 24(a), SCRCP, provide equally compelling grounds for an order permitting SCOPA to intervene under Rule 24(b), SCRCP.

CONCLUSION

Because SCOPA has met each requisite element for intervention, SCOPA respectfully requests this Court grant it leave to intervene in this action pursuant to Rule 24, SCRCP.

Respectfully submitted,

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Attorneys for South Carolina Optometric Physicians Association

January 12, 2017.

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FIFTH JUDICIAL CIRCUIT
COUNTY OF RICHLAND	)	
		Civil Action No. 2016-CP-40-06276
Opternative, Inc.,	)	
Plaintiff,	)	
v.	)	**ANSWER OF DEFENDANT-INTERVENOR SOUTH CAROLINA OPTOMETRIC PHYSICIANS ASSOCIATION**
	)	
South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation,	)	
	)	
Defendants,	)	
and	)	
	)	
South Carolina Optometric Physicians Association,	)	
	)	
Defendant-Intervenor.	)	

Defendant-Intervenor South Carolina Optometric Physicians Association ("SCOPA"), by and through its undersigned attorneys, hereby answers the Complaint of Opternative, Inc. ("Plaintiff"), filed October 20, 2016, as follows.

FOR A FIRST DEFENSE

1. Each and every paragraph of Plaintiff's Complaint not specifically admitted, qualified, or explained herein is denied.

2. The allegations in Paragraph One (1) of Plaintiff's Complaint state legal conclusions to which no response is required. To the extent a response is required, SCOPA admits Plaintiff claims rights and interests in certain online technology (the "Technology") alleged in this Paragraph. Further answering the allegations in this paragraph, SCOPA denies Plaintiff's characterization of the South Carolina Eye Care Consumer Protection Law, S.C. Code

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Ann. §§ 40-24-10, et seq. and denies Plaintiff's entitlement to a declaratory judgment and demands strict proof thereof.

3. The allegations in Paragraph Two (2) of Plaintiff's Complaint state legal conclusions to which no response is required. To the extent a response is required, SCOPA does not contest jurisdiction.

4. The allegations in Paragraph Three (3) of Plaintiff's Complaint state legal conclusions to which no response is required. To the extent a response is required, SCOPA admits Plaintiff seeks a declaratory judgment and injunctive relief. SCOPA denies Plaintiff's characterization of the South Carolina Eye Care Consumer Protection Law, S.C. Code Ann. §§ 40-24-10, et seq. and denies Plaintiff's entitlement to a declaratory judgment.

5. The allegations in Paragraph Four (4) of Plaintiff's Complaint state legal conclusions to which no response is required. To the extent a response is required, SCOPA does not contest jurisdiction.

6. Upon information and belief, SCOPA admits the allegations in Paragraph Five (5) of Plaintiff's Complaint.

7. Upon information and belief, SCOPA admits the allegations in Paragraphs Six (6) and Seven (7) of Plaintiff's Complaint.

8. The allegations in Paragraphs Eight (8) and Nine (9) of Plaintiff's Complaint state legal conclusions to which no response is required.

9. SCOPA admits the allegations in Paragraph Ten (10) of Plaintiff's Complaint.

10. The allegations in Paragraphs Eleven (11) and Twelve (12) of Plaintiff's Complaint state legal conclusions to which no response is required.

11. SCOPA admits the allegations in Paragraph Thirteen (13) of Plaintiff's Complaint.

12. The allegations in Paragraphs Fourteen (14) and Fifteen (15) of Plaintiff's Complaint state legal conclusions to which no response is required.

13. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraphs Sixteen (16) and Seventeen (17) of Plaintiff's Complaint.

14. SCOPA admits the allegations in Paragraphs Eighteen (18) and Nineteen (19) of Plaintiff's Complaint.

15. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraphs Twenty (20), Twenty-One (21), Twenty-Two (22), Twenty-Three (23), Twenty-Four (24), Twenty-Five (25), Twenty-Six (26), Twenty-Seven (27), Twenty-Eight (28), Twenty-Nine (29), Thirty (30), Thirty-One (31), and Thirty-Two (32) of Plaintiff's Complaint.

16. SCOPA admits the allegations in Paragraphs Thirty-Three (33), Thirty-Four (34), and Thirty-Five (35) of Plaintiff's Complaint.

17. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraphs Thirty-Six (36) and Thirty-Seven (37) of Plaintiff's Complaint.

18. The allegations in Paragraphs Thirty-Eight (38) and Thirty-Nine (39) of Plaintiff's Complaint state legal conclusions to which no response is required.

19. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraphs Forty (40), Forty-One (41), Forty-Two (42), Forty-Three (43), Forty-Four (44), Forty-Five (45), Forty-Six (46), and Forty-Seven (47) of Plaintiff's Complaint.

20. Upon information and belief, SCOPA admits the allegations in Paragraph Forty-Eight (48) of Plaintiff's Complaint.

21. SCOPA denies the allegations in Paragraphs Forty-Nine (49), Fifty (50), and Fifty-One (51) of Plaintiff's Complaint as stated.

22. The allegations in Paragraphs Fifty-Two (52), Fifty-Three (53), and Fifty-Four (54) of Plaintiff's Complaint state legal conclusions to which no response is required.

23. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraph Fifty-Five (55) of Plaintiff's Complaint.

24. The allegations in Paragraphs Fifty-Six (56), Fifty-Seven (57), Fifty-Eight (58), Fifty-Nine (59), Sixty (60), Sixty-One (61), Sixty-Two (62), Sixty-Three (63), Sixty-Four (64), Sixty-Five (65), Sixty-Six (66), Sixty-Seven (67), Sixty-Eight (68), Sixty-Nine (69), Seventy (70), Seventy-One (71), Seventy-Two (72), Seventy-Three (73), Seventy-Four (74), Seventy-Five (75), Seventy-Six (76), Seventy-Seven (77), Seventy-Eight (78), and Seventy-Nine (79) of Plaintiff's Complaint state legal conclusions to which no response is required.

25. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraphs Eighty (80), Eighty-One (81), Eighty-Two (82), Eighty-Three (83), Eighty-Four (84), Eighty-Five (85), and Eighty-Six (86) of Plaintiff's Complaint.

26. In response to the allegations in Paragraph Eighty-Seven (87) of Plaintiff's Complaint, SCOPA hereby reincorporates the preceding allegations of this Answer as if fully restated herein verbatim.

27. The allegations in Paragraphs Eighty-Eight (88), Eighty-Nine (89), and Ninety (90) of Plaintiff's Complaint state legal conclusions to which no response is required.

28. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraph Ninety-One (91) of Plaintiff's Complaint.

29. In response to the allegations in Paragraph Ninety-Two (92) of Plaintiff's Complaint, SCOPA hereby reincorporates the preceding allegations of this Answer as if fully restated herein verbatim.

30. The allegations in Paragraphs Ninety-Three (93), Ninety-Four (94), Ninety-Five (95), and Ninety-Six (96) of Plaintiff's Complaint state legal conclusions to which no response is required.

31. SCOPA is without sufficient information or knowledge to respond to the allegations in Paragraph Ninety-Seven (97) of Plaintiff's Complaint.

32. SCOPA denies the allegations in the Plaintiff's Prayer for Relief.

WHEREFORE, having fully answered Plaintiff's Complaint, Defendant-Intervenor South Carolina Optometric Physicians Association prays that it be dismissed with prejudice, for the taxable costs of this action, and for such other and further relief as the Court may deem just and proper.

Respectfully submitted,

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Attorneys for South Carolina Optometric Physicians Association

January _____, 2017.

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND Opternative, Inc., Plaintiff, v. South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation, Defendants.	)	IN THE COURT OF COMMON PLEAS FOR THE FIFTH JUDICIAL CIRCUIT Civil Action No. 2016-CP-40-06276 **AFFIDAVIT OF DR. JENNIFER ZOLMAN**

RICHLAND COUNTY
FILED
2017 JAN 12 PM 4:14
JEANNETTE W. MCBRIDE
C.C.P. & G.S.

PERSONALLY appeared before me, Dr. Jennifer Zolman, who, being duly sworn, deposes and states that:

1. I am over the age of eighteen and am of sound mind to give the testimony provided in this affidavit.

2. I have personal knowledge of and am competent to swear to the facts set forth in this affidavit.

3. South Carolina Optometric Physicians Association ("SCOPA") is an association of optometric physicians who practice in the State of South Carolina.

4. I currently serve as the President of SCOPA and have served in that role since August 2016.

5. Doctors of optometry are the primary health care professionals for the eye. Optometrists examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures as well as identify related systemic conditions affecting the eye.

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6. Optometrists are different from ophthalmologists in that ophthalmologists are medical professionals or osteopathic doctors who specialize in eye and vision care. Optometrists' scope of practice is defined in S.C. Code Ann. § 40-37-30.

7. Optometrists are licensed and regulated exclusively by the South Carolina Board of Examiners in Optometry pursuant to S.C. Code Ann. § 40-37-10.

8. The South Carolina Eye Care Consumer Protection Law, S.C. Code Ann. §§ 40-24-10, *et seq.* ("ECCPL") governs medical care and treatment provided by optometrists in the State of South Carolina.

9. SCOPA was created in 1903 with the organizational purposes of providing education.

10. Currently, SCOPA has 427 members.

11. SCOPA's primary organizational duties are to ensure the visual welfare and ocular health of the citizens of South Carolina by advancing the profession of optometry through legislation, education, cooperation and inter-professional relations.

12. SCOPA is affiliated with the American Optometric Association ("AOA"), a nationwide organization of optometric physicians. All members of SCOPA are automatically enrolled as members of AOA.

13. SCOPA members follow both the AOA's Standards of Professional Conduct, attached hereto as **Exhibit A**, and Code of Ethics, attached hereto as **Exhibit B**.

14. On October 20, 2016, I received an email from Daniel Carey, Director of State Government Relations for the AOA, advising me of a press release by the Institute for Justice regarding a lawsuit filed in South Carolina, the outcome of which could have a direct effect on SCOPA's members and their patients. The press release is available online at http://ij.org/press-release/lawsuit-challenges-south-carolinas-shutdown-innovative-online-eye-exam-company/ (last

accessed November 22, 2016). The lawsuit referenced in the press release was the subject action, *Opternative, Inc. v. South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation*, C/A No. 2016-CP-40-06276.

15. I am informed and believe SCOPA and its members have a real, actual, material, or substantial interest in the subject matter of the pending litigation.

16. I am informed and believe that an outcome in this action in Plaintiff's favor would materially and substantially affect the manner in which SCOPA's members treat their patients.

17. I am informed and believe the ECCPL provisions are in the best interest of SCOPA's members and their patients.

FURTHER AFFIANT SAYETH NAUGHT.

Jennifer Zolman, O.D.

SWORN TO BEFORE ME THIS 11th

DAY OF January 2017.

NOTARY PUBLIC FOR SOUTH CAROLINA

MY COMMISSION EXPIRES: 12/3/2017

American Optometric Association
243 N. Lindbergh Blvd • St. Louis, MO 63141 • (314) 991-4100
FAX: (314) 991-4101

Standards of Professional Conduct

Adopted by the House of Delegates, June 2011

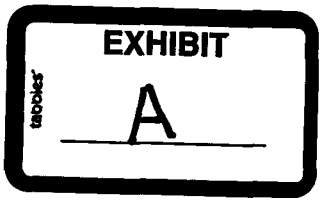
Background:

The profession of optometry is privileged to serve the eye care needs of the public and is entrusted by society to do so in a professional and ethical manner. The placement of the patient's interests above self-interest is referred to as fiduciary duty and is the primary ethical responsibility of all health care professionals. Specifically, optometrists have the duty to look after the best interests of their patients with regard to the patient's eye, vision and general health. Additionally, the ethical optometrist strives to protect and enhance the health and welfare of the public in general.

The American Optometric Association (AOA) has adopted a Code of Ethics and Standards of Professional Conduct to guide optometrists in their professional and ethical duties. These documents are supplemented by The Optometric Oath, and certain AOA House of Delegates' resolutions and Board of Trustees' policy statements. The content of these ethical documents and pronouncements is the result of a continually evolving relationship between the profession of optometry and the society it serves. While the Code of Ethics of the American Optometric Association sets forth the basic tenets of ethical behavior for optometrists, the Standards of Professional Conduct is a more evolving document that amplifies the Code of Ethics and describes appropriate ethical and professional behaviors in greater detail. It is the intent of the American Optometric Association that the Code of Ethics and the Standards of Professional Conduct be written expressions of and a continuing commitment to professional and ethical behavior for all optometrists.

Discussions of biomedical ethics traditionally identify four categories or fundamental principles of ethical behavior: patient autonomy, non-maleficence, beneficence, and justice. These principles provide the underlying support for specific ethical behaviors within the health care professions. Each of the topic areas within the AOA Standards of Professional Conduct is arranged under one of these principles. While each topic area can be identified and justified under several if not all of the principles, they are arranged here under what could be considered the most compelling principle for each. A fifth category, Non-patient Professional Relationships, is added to complete the content of the AOA Standards of Professional Conduct. It should be noted that these ethical documents and pronouncements are expressions of many but not all of the ethical ideals of the profession and are not necessarily expressions of legal obligations.

Ethics and the law are two different entities, although many times these may overlap. The law sets minimum standards for societal behavior that all persons must comply with. Ethics generally sets higher than minimum standards for behavior that people should strive for as the ideal.



Standards of Professional Conduct:

A – Patient Autonomy ("self-determination")

The optometrist has the duty to involve the patient in care and treatment decisions in a meaningful way, with due consideration of the patient's needs, desires, abilities and understanding, while safeguarding the patient's privacy.

1. **Patient Participation**: Optometrists have a duty to respect the right of their patients to be active participants in decisions affecting their health care. This duty should be reinforced and supported through patient education and effective communication.
2. **Confidentiality:** Optometrists and their staff should hold in confidence all protected health and other personal information. This is an essential element of the doctor-patient relationship that is necessary to build and maintain trust. The optometrist may reveal protected health and other personal information only with the written consent of the patient as defined under the Health Insurance Portability and Accountability Act (HIPAA). However, exceptions to confidentiality do exist that are ethically justified. These exceptions occur either when it is necessary to protect the welfare of the patient or others when faced with a significant threat, or when the release of information is required by law. It should be noted that an ethical imperative of an optometrist to release information to protect the welfare of the patient or others without the patient's consent may have legal considerations.
3. **Truthfulness:** Telling the truth is a necessary component of a trusting optometrist-patient relationship. From an ethical standpoint, there are two levels of truthfulness, veracity and candor. Simply put, veracity is "telling the truth" and candor is "telling the whole truth." Optometrists should always practice veracity and strive to tell the truth. While candor is usually required from an ethical standpoint, exceptions are only justifiable out of kindness to the patient or to protect the overall best interests of the patient. Since breaching candor would be a violation of the basic principle of patient autonomy, it should only be considered after careful reflection and weighing the alternatives.
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Finally, optometrists should make the effort to ensure that the patient or guardian has a reasonable understanding of the information presented.

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The optometrist has the duty to avoid acts of omission or commission that would harm the patient.

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The optometrist has the duty to proactively serve the needs of the patient and the public at large regarding eye, vision and general health.

1. **Character:** Optometrists should conduct themselves with good character in all of their actions to build trust and respect with patients, the public, and colleagues. Good character includes but is not limited to honesty, integrity, fairness, kindness, and compassion.
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3. **Advertising:** Advertising by optometrists should be truthful and in accordance with prevailing federal and state laws and regulations. Optometrists who advertise should identify their professional degree and/or their profession in all forms of advertising and should never mislead the public regarding their expertise or competency. Optometrists should not hold themselves as having superior knowledge or credentials other than their earned degrees, certifications or license types.
4. **Economic Interests:** Fees for optometric services should be reasonable and accurately reflect the care delivered to the patient.

E – Non - patient Professional Relationships

Optometrists have an obligation to conduct themselves with integrity and without conflicts of interest in all of their professional relationships.

1. **Relationships with Industry:** In their interactions with industry, optometrists are expected to maintain the highest level of ethical conduct in order to retain their professional autonomy and clinical integrity. Optometrists have a responsibility to provide the best care possible for their patients and to continuously advance their

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TO ENSURE confidentiality and privacy of patients' protected health and other personal information;

TO STRIVE to ensure that all persons have access to eye, vision, and general health care;

TO ADVANCE their professional knowledge and proficiency to maintain and expand competence to benefit their patients;

TO MAINTAIN their practices in accordance with professional health care standards;

TO PROMOTE ethical and cordial relationships with all members of the health care community;

TO RECOGNIZE their obligation to protect the health and welfare of society; and

TO CONDUCT themselves as exemplary citizens and professionals with honesty, integrity, fairness, kindness and compassion.

Adopted by the House of Delegates as
Substance of Motion 1944-1, June 1944. Modified June 2005. Repealed June 2007.
Re-Adopted as Resolution #1005, June 2007.

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Optometry's Meeting

OPTOMETRY CARES
The AOA Foundation

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American Optometric Association 243 N. Lindbergh Blvd., St. Louis, MO 63141
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STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FIFTH JUDICIAL CIRCUIT
COUNTY OF RICHLAND	)	
		Civil Action No. 2016-CP-40-06276
Opternative, Inc.,	)	
	)	
Plaintiff,	)	**AFFIDAVIT OF DR. JENNIFER ZOLMAN**
v.	)	
	)	
South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation,	)	
	)	
Defendants.	)	

RICHLAND COUNTY
FILED
2017 JAN 12 PM 4:14
JEANNETTE W. MCBRIDE
C.C.P. & G.S.

PERSONALLY appeared before me, Dr. Jennifer Zolman, who, being duly sworn, deposes and states that:

1. I am over the age of eighteen and am of sound mind to give the testimony provided in this affidavit.

2. I have personal knowledge of and am competent to swear to the facts set forth in this affidavit.

3. South Carolina Optometric Physicians Association ("SCOPA") is an association of optometric physicians who practice in the State of South Carolina.

4. I currently serve as the President of SCOPA and have served in that role since August 2016.

5. Doctors of optometry are the primary health care professionals for the eye. Optometrists examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures as well as identify related systemic conditions affecting the eye.

EXHIBIT 2

6. Optometrists are different from ophthalmologists in that ophthalmologists are medical professionals or osteopathic doctors who specialize in eye and vision care. Optometrists' scope of practice is defined in S.C. Code Ann. § 40-37-30.

7. Optometrists are licensed and regulated exclusively by the South Carolina Board of Examiners in Optometry pursuant to S.C. Code Ann. § 40-37-10.

8. The South Carolina Eye Care Consumer Protection Law, S.C. Code Ann. §§ 40-24-10, *et seq.* ("ECCPL") governs medical care and treatment provided by optometrists in the State of South Carolina.

9. SCOPA was created in 1903 with the organizational purposes of providing education.

10. Currently, SCOPA has 427 members.

11. SCOPA's primary organizational duties are to ensure the visual welfare and ocular health of the citizens of South Carolina by advancing the profession of optometry through legislation, education, cooperation and inter-professional relations.

12. SCOPA is affiliated with the American Optometric Association ("AOA"), a nationwide organization of optometric physicians. All members of SCOPA are automatically enrolled as members of AOA.

13. SCOPA members follow both the AOA's Standards of Professional Conduct, attached hereto as **Exhibit A**, and Code of Ethics, attached hereto as **Exhibit B**.

14. On October 20, 2016, I received an email from Daniel Carey, Director of State Government Relations for the AOA, advising me of a press release by the Institute for Justice regarding a lawsuit filed in South Carolina, the outcome of which could have a direct effect on SCOPA's members and their patients. The press release is available online at http://ij.org/press-release/lawsuit-challenges-south-carolinas-shutdown-innovative-online-eye-exam-company/ (last

accessed November 22, 2016). The lawsuit referenced in the press release was the subject action, *Opternative, Inc. v. South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation*, C/A No. 2016-CP-40-06276.

15. I am informed and believe SCOPA and its members have a real, actual, material, or substantial interest in the subject matter of the pending litigation.

16. I am informed and believe that an outcome in this action in Plaintiff's favor would materially and substantially affect the manner in which SCOPA's members treat their patients.

17. I am informed and believe the ECCPL provisions are in the best interest of SCOPA's members and their patients.

FURTHER AFFIANT SAYETH NAUGHT.

Jennifer Zolman, O.D.

SWORN TO BEFORE ME THIS 11th

DAY OF January 2017.

NOTARY PUBLIC FOR SOUTH CAROLINA

MY COMMISSION EXPIRES: 12/3/2017

American Optometric Association
243 N. Lindbergh Blvd • St. Louis, MO 63141 • (314) 991-4100
FAX: (314) 991-4101

Standards of Professional Conduct

Adopted by the House of Delegates, June 2011

Background:

The profession of optometry is privileged to serve the eye care needs of the public and is entrusted by society to do so in a professional and ethical manner. The placement of the patient's interests above self-interest is referred to as fiduciary duty and is the primary ethical responsibility of all health care professionals. Specifically, optometrists have the duty to look after the best interests of their patients with regard to the patient's eye, vision and general health. Additionally, the ethical optometrist strives to protect and enhance the health and welfare of the public in general.

The American Optometric Association (AOA) has adopted a Code of Ethics and Standards of Professional Conduct to guide optometrists in their professional and ethical duties. These documents are supplemented by The Optometric Oath, and certain AOA House of Delegates' resolutions and Board of Trustees' policy statements. The content of these ethical documents and pronouncements is the result of a continually evolving relationship between the profession of optometry and the society it serves. While the Code of Ethics of the American Optometric Association sets forth the basic tenets of ethical behavior for optometrists, the Standards of Professional Conduct is a more evolving document that amplifies the Code of Ethics and describes appropriate ethical and professional behaviors in greater detail. It is the intent of the American Optometric Association that the Code of Ethics and the Standards of Professional Conduct be written expressions of and a continuing commitment to professional and ethical behavior for all optometrists.

Discussions of biomedical ethics traditionally identify four categories or fundamental principles of ethical behavior: patient autonomy, non-maleficence, beneficence, and justice. These principles provide the underlying support for specific ethical behaviors within the health care professions. Each of the topic areas within the AOA Standards of Professional Conduct is arranged under one of these principles. While each topic area can be identified and justified under several if not all of the principles, they are arranged here under what could be considered the most compelling principle for each. A fifth category, Non-patient Professional Relationships, is added to complete the content of the AOA Standards of Professional Conduct. It should be noted that these ethical documents and pronouncements are expressions of many but not all of the ethical ideals of the profession and are not necessarily expressions of legal obligations.

Ethics and the law are two different entities, although many times these may overlap. The law sets minimum standards for societal behavior that all persons must comply with. Ethics generally sets higher than minimum standards for behavior that people should strive for as the ideal.

EXHIBIT
tabbies
A

Standards of Professional Conduct:

A – Patient Autonomy ("self-determination")

The optometrist has the duty to involve the patient in care and treatment decisions in a meaningful way, with due consideration of the patient's needs, desires, abilities and understanding, while safeguarding the patient's privacy.

1. **Patient Participation**: Optometrists have a duty to respect the right of their patients to be active participants in decisions affecting their health care. This duty should be reinforced and supported through patient education and effective communication.
2. **Confidentiality:** Optometrists and their staff should hold in confidence all protected health and other personal information. This is an essential element of the doctor-patient relationship that is necessary to build and maintain trust. The optometrist may reveal protected health and other personal information only with the written consent of the patient as defined under the Health Insurance Portability and Accountability Act (HIPAA). However, exceptions to confidentiality do exist that are ethically justified. These exceptions occur either when it is necessary to protect the welfare of the patient or others when faced with a significant threat, or when the release of information is required by law. It should be noted that an ethical imperative of an optometrist to release information to protect the welfare of the patient or others without the patient's consent may have legal considerations.
3. **Truthfulness:** Telling the truth is a necessary component of a trusting optometrist-patient relationship. From an ethical standpoint, there are two levels of truthfulness, veracity and candor. Simply put, veracity is "telling the truth" and candor is "telling the whole truth." Optometrists should always practice veracity and strive to tell the truth. While candor is usually required from an ethical standpoint, exceptions are only justifiable out of kindness to the patient or to protect the overall best interests of the patient. Since breaching candor would be a violation of the basic principle of patient autonomy, it should only be considered after careful reflection and weighing the alternatives.
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B – Non-maleficence ("do no harm")

The optometrist has the duty to avoid acts of omission or commission that would harm the patient.

1. **Standards of Care:** Optometrists should strive to provide care that is consistent with established clinical practice guidelines such as those adopted by the American Optometric Association that are based on the latest scientific knowledge and procedures and utilize the opinions of authoritative experts and is in accordance with existing laws.
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Adopted by the House of Delegates as
Substantive Motion 1944-1, June 1944. Modified June 2005. Repealed June 2007.
Modified and Adopted as Resolution #1965, June 2007.

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STATE OF SOUTH CAROLINA

COUNTY OF RICHLAND

Opternative, Inc.,

Plaintiff,

v.

South Carolina Board of Medical Examiners and the South Carolina Department of Labor, Licensing & Regulation,

Defendants.

and

South Carolina Optometric Physicians Association,

Defendant-Intervenor.

IN THE COURT OF COMMON PLEAS
FIFTH JUDICIAL CIRCUIT

C/A No.: 2016-CP-40-06276

MOTION FOR SUMMARY JUDGMENT OF DEFENDANTS SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS AND THE SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING & REGULATION

RICHLAND COUNTY
FILED
2017 JUL 10 PM 3:43
JEANNETTE W. McBRIDE
C.C.P. & G.S.

Defendants South Carolina Board of Medical Examiners (the "Board") and the South Carolina Department of Labor, Licensing & Regulation ("LLR") (collectively the "Defendants"), by and through undersigned counsel, hereby submit their Motion for Summary Judgment under Rule 56, SCRCP, and request that this Court dismiss the lawsuit of Plaintiff Opternative, Inc. ("Plaintiff" or "Opternative").

Plaintiff has brought a declaratory judgment action to challenge the constitutionality of South Carolina's Eye Care Consumer Protection Law ("ECCPL"), S.C. Code Ann. § 40-24-10 *et seq.*, arguing that the ECCPL is "protectionist" legislation and unconstitutional on grounds of (1) due process and (2) equal protection. (Plaintiff's Complaint, ¶¶ 87-97).

The Defendants move to dismiss this Complaint on the following grounds:

- Opternative has not suffered an "injury in fact" at the hands of the Defendants, who do not do not regulate Opternative and are not proper parties in this case.

- The ECCPL is constitutional because it bears a reasonable relation to its legislative purpose that is supported by a rational basis.

For these reasons, as set forth in greater detail below, the Defendants request that this Court GRANT their motion and DISMISS the case with prejudice.

PLAINTIFF'S LAWSUIT

Plaintiff is a private foreign corporation that has developed an online technology designed to conduct eye examinations and produce prescriptions for corrective lens. (Plaintiff's Complaint, ¶¶ 1, 5). In bringing this declaratory judgment action, Plaintiff argues that the ECCPL is "protectionist" legislation and unconstitutional on grounds of (1) due process and (2) equal protection. (Plaintiff's Complaint, ¶¶ 87-97). Specifically, Plaintiff has argued that:

- Article I, Section 3 of the South Carolina Constitution forbids protectionist legislation. Because the ECCPL does not further any valid public health or safety purpose, it has no legitimate basis under the South Carolina Constitution. For that reason, the ECCPL allegedly violates the "due process" rights of Plaintiff. (Plaintiff's Complaint, ¶¶ 87-90).

- Article I, Section 3 of the South Carolina Constitution provides for "equal protection of the laws." The ECCPL violates Plaintiff's equal protection rights by drawing an "arbitrary and irrational distinction between ophthalmologists who write corrective-lens prescriptions based on an in-person refractive examination and ophthalmologists who write corrective-lens prescriptions based on Opternative's Exam." Plaintiff also argues that the ECCPL offends equal protection because it draws an "arbitrary and irrational distinction between ophthalmologists [] who are not allowed to use their medical judgment to use online tools like Opternative to provide medical services that otherwise meet the general standard of care, and other kinds of medical doctors [] who are allowed to use their medical judgment to use online tools like Opternative to provide medical services that otherwise meet the general standard of care." (Plaintiff's Complaint, ¶¶ 92-96).

- Regarding both grounds, Plaintiff alleged the "[u]nless Defendants are enjoined from enforcing the ECCPL, Opternative will suffer continuing and irreparable harm." (Plaintiff's Complaint, ¶¶ 91, 97).

THE ECCPL

The ECCPL has two parts. The first part establishes the definitions of terms that it uses, and the second establishes the substance of the act.

Importantly, the first part of the act defines "provider" as "an individual licensed by the South Carolina Board of Examiners in Optometry or the South Carolina Board of Medical Examiners." S.C. Code Ann. § 40-24-10(7). The second part of the ECCPL provides as follows:

> **SECTION 40-24-20.** Valid prescription required to dispense spectacles or contact lenses; penalties.
>
> (A) A person in this State may not dispense spectacles or contact lenses to a patient without a valid prescription from a provider.
>
> (B) To be valid, a prescription must contain an expiration date on spectacles or contact lenses of one year from the date of examination by the provider or a statement of the reasons why a shorter time is appropriate based on the medical needs of the patient. The prescription must take into consideration medical findings made and refractive error discovered during the eye examination. If a provider determines a patient is a suitable candidate for a prescription for contact lenses or spectacles, a provider may not thereafter refuse to issue a prescription for spectacles or contact lenses to a patient.
>
> (C) A prescription for spectacles or contact lenses may not be based solely on the refractive eye error of the human eye or be generated by a kiosk.
>
> (D) Violation of this section constitutes misconduct as provided for in Sections 40-37-110 and 40-47-110. A provider who violates this section is subject to the penalties authorized in Chapter 37, Title 40 or Chapter 47, Title 40, as applicable.[1]

When requested to identify the public health or safety purpose advanced by the ECCPL, and how the ECCPL is tailored to achieve that purpose, Defendant-Intervenor South Carolina Optometric Physician's Association ("SCOPA") noted that the ECCPL "protects patients of ophthalmologists and optometrists from unwittingly putting their eye health at risk by obtaining

[1] Chapter 37, Title 40 applies to optometrists. Chapter 47, Title 40 applies, among other physicians, to ophthalmologists.

a prescription for corrective lenses without a comprehensive eye examination. Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination." (Answer of SCOPA to Plaintiff's First Set of Interrogatories, p. 2). SCOPA further asserts that this assertion derives from the collective training and clinical experience of SCOPA's members. (Answer of SCOPA to Plaintiff's First Set of Interrogatories, p. 3).

THE BOARD AND LLR

The Board is the professional licensing board in South Carolina that regulates physician practice and conduct. S.C. Code Ann. § 40-47-5 *et seq*. **Notably, it does not regulate Plaintiff, as Plaintiff is not a physician licensed in the State of South Carolina**. S.C. Code Ann. § 40-1-70; S.C. Code Ann. § 40-47-10(I).

The LLR administers the Board. S.C. Code Ann. § 40-1-40(B). Like the Board, **LLR does not regulate Plaintiff, as Plaintiff is not licensed by a Board that LLR administers.** Rather, LLR merely "is responsible for all administrative, fiscal, investigative, inspectional, clerical, secretarial, and license renewal operation and activities" of the Board, and in fact does make such support available to the Board. S.C. Code Ann. § 40-1-50(A).

In any event, neither the Board nor LLR has ever taken any enforcement action against any person that it regulates for an alleged violation of the ECCPL.

LEGAL ARGUMENT

I. UNDER SOUTH CAROLINA LAW, STATUTES ARE PRESUMED TO BE CONSTITUTIONAL.

The provisions of the South Carolina Constitution are not a grant but a limitation of legislative power, so that the Legislature may enact any law not expressly, or by clear implication, prohibited by the state or federal constitution. *Segars-Andrews v. Judicial Merit Selection Comm'n*, 387 S.C. 109, 118, 691 S.E.2d 453, 458 (2010).

Moreover, when the constitutionality of a statute is challenged, every presumption will be made in favor of its validity. A statute will not be declared unconstitutional unless its invalidity appears so clearly as to leave no doubt that it violates some provision of the constitution. *Id.* A "legislative act will not be declared unconstitutional unless its repugnance to the constitution is clear and beyond a reasonable doubt." *Joytime Distribs. and Amusement Co. v. State,* 338 S.C. 634, 640, 528 S.E.2d 647, 650 (1999). The challenging party bears the burden of proving the statute unconstitutional. *Home Health Serv., Inc. v. South Carolina Tax Comm'n,* 312 S.C. 324, 440 S.E.2d 375 (1994); *In re Treatment & Care of Luckabaugh*, 351 S.C. 122, 135, 568 S.E.2d 338, 344 (2002).

II. PLAINTIFF CANNOT BRING THIS LAWSUIT BECAUSE IT DOES NOT HAVE PROPER STANDING.

Where a private party seeks to have a statue declared unconstitutional, it must first demonstrate that it has standing. *ATC v. Charleston Cty.*, 380 S.C. 191, 195–96, 669 S.E.2d 337, 339 (2008). Standing is defined as "a personal stake in the subject matter of a lawsuit." *Sea Pines Ass'n for the Prot. of Wildlife, Inc. v. S.C. Dep't of Natural Res.*, 345 S.C. 594, 600, 550 S.E.2d 287, 291 (2001) (citing *Charleston Cnty. Sch. Dist. v. Charleston Cnty. Election Comm'n*, 336 S.C. 174, 519 S.E.2d 567 (1999)).

A private person or entity does not have standing unless he has sustained, or is in immediate danger of sustaining, prejudice from an executive or legislative action. *Baird v. Charleston County,* 333 S.C. 519, 511 S.E.2d 69 (1999). Such imminent prejudice must be of a personal nature to the party laying claim to standing, and not merely of general interest common to all members of the public. *Id.* (citing *Citizens for Lee County, Inc. v. Lee County,* 308 S.C. 23, 416 S.E.2d 641 (1992)).

To make the required showing, the challenging party must satisfy the following three-part test:

> First, the plaintiff must have suffered an "injury in fact" – an invasion of a legally protected interest which is (a) concrete and particularized, and (b) "actual or imminent, not 'conjectural' or 'hypothetical,' " Second, there must be a causal connection between the injury and the conduct complained of-the injury has to be "fairly ... trace[able] to the challenged action of the defendant, and not ... th[e] result [of] the independent action of some third party not before the court." Third, it must be "likely," as opposed to merely "speculative," that the injury will be "redressed by a favorable decision."

ATC, 380 S.C. at 195-96, 669 S.E.2d at 339 (quoting *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560-61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992) (internal citations omitted)); *see also Youngblood v. S.C. Dept. of Social Services*, 402 S.C. 311, 317, 741 S.E.2d 515, 518 (2013).

In its Complaint, Opternative describes the "Injury to Plaintiff" in the following manner:

> "80. As a direct result of the passage of the ECCPL, the use of Opternative's Technology has been effectively prohibited in South Carolina.
>
> 81. Prior to the adoption of the ECCPL, Opternative could (and did) allow a South Carolina-licensed ophthalmologist to write corrective-lens prescriptions for South Carolina residents.

82. As a direct result of the passage of the ECCPL, South Carolina-licensed ophthalmologists are legally prohibited from working with Opternative to provide corrective-lens prescriptions for South Carolina residents.

83. As a direct result of the passage of the ECCPL, South Carolina-licensed ophthalmologists are no longer willing to work with Opternative to provide corrective-lens prescriptions for South Carolina residents.

84. As a direct result of the passage of the ECCPL, Opternative has ceased business operations in South Carolina.

85. But for the ECCPL, Opternative would still be facilitating corrective-lens prescriptions for South Carolina residents.

86. But for the ECCPL, state-licensed ophthalmologists would be willing to work with Opternative to provide corrective-lens prescriptions for South Carolina residents."

(Plaintiff's Complaint, ¶¶ 80-86). However, for the reasons stated below, these allegations fail to meet the standards set for establishing standing.

A. Injury in Fact.

First, Opternative must show that it has suffered an "injury in fact," which is an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not 'conjectural' or 'hypothetical." *ATC,* 380 S.C. at 195, 669 S.E.2d at 337. From its Complaint, Opternative appears to argue that its "injury in fact" is its belief that the ECCPL prevents South Carolina-licensed ophthalmologists from being "willing to work with Opternative to provide corrective-lens prescriptions for South Carolina residents," and that if the ECCPL were struck down, they presumably would be willing to use Opternative's technology to write

corrective-lens prescriptions.[2] (Plaintiff's Complaint, ¶¶ 83, 86). As an initial matter, this appears to be a conjectural or hypothetical harm rather than a concrete and particularized harm. In fact, nothing in the ECCPL appears to forbid a South Carolina-licensed ophthalmologist from using Opternative's technology to assist in his or her work. Rather, Opternative appears to argue that it is at a competitive disadvantage because a South Carolina-licensed ophthalmologist cannot base a prescription for spectacles or contact lenses solely on the refractive eye error of the human eye or be generated by a kiosk. S.C. Code Ann. § 40-24-20(C). Instead, the South Carolina-licensed ophthalmologist must also "take into consideration medical findings made and refractive error discovered during the eye examination." S.C. Code Ann. § 40-24-20(B).

On its face, this showing is insufficient to establish an "injury in fact." It is well-established that South Carolina has "rejected a competitor's assertion that standing exists when alleged damages flow from increased or perceived unfair competition." *ATC*, 380 S.C. at 196, 669 S.E.2d at 340 (citing *Connor Holdings, LLC v. Cousins,* 373 S.C. 81, 86, 644 S.E.2d 58, 60–61 (2007)). Further, our courts have observed that this is the "prevailing law throughout the country." *ATC*, 380 S.C. at 197, 669 S.E.2d at 340 (citations omitted).

This is especially apparent when Opternative is compared to the plaintiffs in *Joseph v. S.C. Dep't of Labor, Licensing & Regulation*, 417 S.C. 436, 790 S.E.2d 763 (2016), who were a physical therapist (PT) and two orthopedic surgeons challenging a 2011 position statement from the South Carolina Board of Physical Therapy that – unlike other licensed healthcare professionals – forbade PTs from providing treatment as direct employees of physicians. In

[2] More specifically, the role of a state-licensed ophthalmologist appears to be as follows: (1) the patient takes an on-line test through Opternative's website, (2) Opternative shares the test results with a state-licensed ophthalmologist, and (3) the state-licensed ophthalmologist uses the test results to determine an appropriate a corrective lens prescription, which is made available to the patient via the Opternative website. (Plaintiff's Complaint, ¶¶ 27-29). Opternative admits that its on-line test is not a "comprehensive eye exam." (Plaintiff's Complaint, ¶ 32).

Joseph, the court found that 2011 position statement – an actual act taken by the South Carolina Board of Physical Therapy – injured the PT "by the infringement on her ability to practice her chosen profession and by the adoption of a regulation that requires she and other PTs be treated differently from other health care professionals who may be employed by doctors." 417 S.C. at 449, 790 S.E.2d 770. Similarly, the court found that the surgeons were injured because "they have an interest in how the PT system works and in their ability to employ PTs." *Id.*

In this case, Opternative can justly lay claim to none of these concerns. Professionals under the authority of the Board are not forbidden by the ECCPL – and certainly not by any action of the Board or LLR – from using Opternative's technology. Indeed, a South Carolina-licensed ophthalmologist may still use Opternative's technology to assist him or her in making a determination to write a prescription for spectacles or contact lenses. He or she simply cannot solely base the prescription on the refractive eye error of the human eye or be generated by a kiosk.

In sum, Opternative has failed to show that it has suffered an "injury in fact," and instead has only raised theories of injury that are "conjectural" or "hypothetical." For this reason alone, Opternative's claim must be dismissed.

B. Causal Connection.

Second, Opternative has no show that there is a causal connection between the injury and the conduct complained of. The injury has to be "fairly ... trace[able] to the challenged action of the defendant, and not ... th[e] result [of] the independent action of some third party not before the court." *ATC,* 380 S.C. at 195-96, 669 S.E.2d at 339.

In the instant case, the causal connection does not exist because the injury alleged by Opternative – that South Carolina-licensed ophthalmologists are no longer "willing to work with

Opternative to provide corrective-lens prescriptions for South Carolina residents" – actually requires an act from a third party not before the court. Namely, as set forth above, Opternative alleges that South Carolina-licensed ophthalmologists are no longer willing to use its on-line exam because, under the ECCPL, its on-line exam cannot be the sole basis to write a prescription for spectacles or contact lenses.

Naturally, South Carolina-licensed ophthalmologists can presumably make their own decisions about whether and how to use – or not use – Opternative's on-line technology to assist them in their provision of lawful corrective-lens prescriptions to their patients. In any event, that decision rests with South Carolina-licensed ophthalmologists, and not with the Board or with LLR.

Indeed, to the extent that Opternative argues that the ECCPL places it at a competitive disadvantage because its on-line technology cannot serve as the sole basis for a corrective-lens prescription, its claim must be rejected, as "a competitor challenging legislative or executive action solely to protect its own economic interests lacks standing." *ATC*, 380 S.C. at 198, 669 S.E.2d at 340.

Furthermore, the pleadings are devoid of any "conduct complained of" by either the Board or LLR. In fact, neither the Board nor LLR have ever taken any enforcement action against Opternative, perhaps because Opternative is not an entity that is regulated by either the Board or LLR. This fact alone eviscerates Opternative's argument that either the Board or LLR has engaged in "conduct" that is causally connected to an "injury in fact" that Opternative has suffered.

C. **Redress by a Favorable Decision.**

Plaintiff must allege a particularized harm – which is denied – and it has failed to allege adequately that the injury would be redressed by a favorable decision in this case. *Sea Pines Ass'n*, 345 S.C. at 602, 550 S.E.2d at 292. In its Complaint, Plaintiff appears to address this element by alleging that "[b]ut for the ECCPL, Opternative would still be facilitating corrective-lens prescriptions for South Carolina residents" and that "state-licensed ophthalmologists would be willing to work with Opternative to provide corrective-lens prescriptions for South Carolina residents." (Plaintiff's Complaint, ¶¶ 85-86).

In this regard, Plaintiff's claims appear similar to those of the plaintiffs in *Sea Pines Ass'n*, who raised a constitutional challenge to the decision of the South Carolina Department of Natural Resources ("SCDNR") to issue permits to lethally eliminate a substantial number of white-tailed deer on Hilton Head Island. The court found that the plaintiffs lacked standing in part because their alternative plan to hunting permits – use of non-lethal means to reduce the deer population – would lead to the same result, namely, the reduction of the deer population at Sea Pines. 345 S.C. at 603, 550 S.E.2d at 292. For that reason, the plaintiffs failed to demonstrate standing because the proposed alternative would result in the same "injury."

As set forth above, Plaintiff cannot rely on the alleged "competitive disadvantage" imposed by the ECCPL on Opternative's technology to serve as the "injury in fact." In any event, there is no showing here that a favorable ruling would lead to state-licensed ophthalmologists using Opternative's technology to provide corrective-lens prescriptions for South Carolina residents.

* * *

To show standing, Plaintiff must satisfy each of the three elements referenced above. Plaintiff has failed to demonstrate that it can satisfy any of them. For this reason, Plaintiff's lawsuit must be dismissed.

III. PLAINTIFF CANNOT SHOW THAT THE ECCPL LACKS A "RATIONAL BASIS," AND FOR THAT REASON, ITS DUE PROCESS AND EQUAL PROTECTION CLAIMS MUST BE DISMISSED.

Plaintiff's constitutional attack on the ECCPL is based on both "due process" and "equal protection" grounds. Plaintiff's due process claim is based on its allegation that the ECCPL is protectionist legislation that does not further any valid public health or safety purpose. In this regard, the claim is presumably a "substantive due process" claim.[3] Plaintiff's equal protection claim is based on two imagined "classifications" of physicians that Plaintiff posits are created by the ECCPL:

- between (1) ophthalmologists who write corrective-lens prescriptions based on an in-person refractive examination and (2) ophthalmologists who write corrective-lens prescriptions based on Opternative's Exam;

- Between (1) ophthalmologists who are not allowed to use their medical judgment to use online tools like Opternative to provide medical services that otherwise meet the general standard of care, and (2) other kinds of medical doctors who are allowed to use their medical judgment to use online tools like Opternative to provide medical services that otherwise meet the general standard of care.

(Plaintiff's Complaint, ¶¶ 92-96).

However, each of these arguments fails because the ECCPL is supported by a "rational basis."

[3] Plaintiff's Complaint contains no discernable allegations that it has been denied "procedural" due process. Plaintiff bases its due process claim on its allegations that the ECCPL is protectionist legislation that deprives it of its "right to pursue an honest living." (Plaintiff's Complaint, ¶¶ 88-90).

A. **Due Process.**

In order to show that the ECCPL violates Plaintiff's substantive due process rights, Plaintiff must show that it was arbitrarily and capriciously deprived of a cognizable property interest rooted in state law. *Sunset Cay, LLC v. City of Folly Beach,* 357 S.C. 414, 430, 593 S.E.2d 462, 470 (2004). The standard for reviewing all substantive due process challenges to state statutes or municipal ordinances, including economic and social welfare legislation, is whether the statute or ordinance bears a reasonable relationship to any legitimate interest of government. *Id.* at 430, 593 S.E.2d at 470; *Denene, Inc. v. City of Charleston*, 359 S.C. 85, 96, 596 S.E.2d 917, 923 (2004).

"No one has an unfettered right to pursue a business detrimental to the public health, safety, and welfare." *Denene, Inc.*, 359 S.C. at 97, 596 S.E.2d at 923 (citing *Greenville County v. Kenwood Enterprises, Inc.,* 353 S.C. 157, 170-71, 577 S.E.2d 428, 435 (2003) (county ordinance requiring a 1,500-foot setback for sexually oriented businesses based on the rationale of combating secondary effects of those businesses was constitutional)); *Curtis v. State,* 345 S.C. 557, 573, 549 S.E.2d 591, 599 (2001) (statute making it unlawful to defraud a drug test furthers the public purpose of ensuring a drug-free workplace, which is a legitimate exercise of the State's police powers in regulating public safety and welfare, and outweighs any legitimate interest of the business).

As set forth above, Defendant-Intervenor SCOPA noted that the ECCPL "protects patients of ophthalmologists and optometrists from unwittingly putting their eye health at risk by obtaining a prescription for corrective lenses without a comprehensive eye examination. Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person

comprehensive eye examination." (Answer of SCOPA to Plaintiff's First Set of Interrogatories, p. 2). SCOPA further asserts that this assertion derives from the collective training and clinical experience of SCOPA's members. (Answer of SCOPA to Plaintiff's First Set of Interrogatories, p. 3).

In light of the standards applicable to Plaintiff's due process claim, it appears uncontested that (1) undiagnosed diseases of the eye are a legitimate health concern of the state, and (2) requiring an in-person comprehensive eye examination may increase the chance of detecting these diseases. Therefore, the statute in question bears a reasonable relationship to a legitimate interest of government.[4]

For these reasons, Plaintiff's due process claim must fail.

B. Equal Protection.

In ruling on an equal protection challenge to a statute, if a classification does not implicate a suspect class[5] or abridge a fundamental right,[6] courts employ the "rational basis" test. *Denene, Inc.*, 359 S.C. at 91, 596 S.E.2d at 920. In such a case, Plaintiff bears the burden "to

---

[4] Furthermore, as set forth above, nothing prevents South Carolina-licensed ophthalmologists from deciding for themselves whether to use – or not use – Opternative's on-line technology to assist them in their provision of lawful corrective-lens prescriptions to their patients. That decision does not rest with the Board or with LLR.

[5] A suspect class, as defined by numerous court opinions, is a discrete and insular minority that is unable to shake or rise above the bonds and stigma of its minority status. Courts have been unwilling to extend suspect class status to any classification other than race, alienage and national origin. *Eldridge v. Bouchard*, 645 F. Supp. 749, 752 (W.D. Va. 1986), *aff'd*, 823 F.2d 546 (4th Cir. 1987). Plaintiff does not appear to argue that "ophthalmologists" are a suspect class.

[6] There is also no fundamental right for a physician to use Opternative's technology in violation of the ECCPL. *In re Evans*, 413 B.R. 315, 322 (Bankr. E.D. Va. 2009) (no "fundamental right" under the equal protection clause to pursue a calling as a bankruptcy petition preparer).

negate every conceivable basis which might support" the legislation. *Lehnhausen v. Lake Shore Auto Parts Co.,* 410 U.S. 356, 364, 93 S.Ct. 1001, 35 L.Ed.2d 351 (1973); *Mitchell v. Comm'r of the Soc. Sec. Admin.,* 182 F.3d 272, 274 (4th Cir. 1999). To be irrational in the Constitutional sense, "the relationship of the classification to its goal" must be "so attenuated as to render the distinction arbitrary." *Nordlinger v. Hahn,* 505 U.S. 1, 11, 112 S.Ct. 2326, 120 L.Ed.2d 1 (1992); *Johnson v. Hall*, 2011 WL 4501323, at *8 (D.S.C. Aug. 9, 2011), *report and recommendation adopted*, 2011 WL 4483642 (D.S.C. Sept. 28, 2011), *aff'd sub nom. Johnson v. Bryant*, 474 F. App'x 105 (4th Cir. 2012). Indeed, when social or economic legislation is at issue, the Equal Protection Clause allows the States wide latitude, and the Constitution presumes that even improvident decisions will eventually be rectified by the democratic processes.[7] *City of Cleburne, Tex. v. Cleburne Living Ctr.*, 473 U.S. 432, 440, 105 S. Ct. 3249, 3254, 87 L. Ed. 2d 313 (1985) (citations omitted).

Whatever Opternative's substantive objection to the ECCPL, and however it may disagree with the underlying reason articulated by SCOPA, it cannot dispute that the state has a legitimate interest in supporting good eye health, that undiagnosed diseases of the eye are a legitimate public health concern, and that legislation requiring an in-person comprehensive eye examination in order to increase the chance of detecting these diseases is reasonably related to a sound legislation.

For these reasons alone, Opternative's equal protection argument must fail.

[7] Indeed, the ECCPL only became law after the General Assembly overrode the Governor's veto.

CONCLUSION

As set forth above, Plaintiff has failed to raise a genuine issue of material fact sufficient to satisfy the exacting standard that a statute will not be declared unconstitutional unless its invalidity appears so clearly as to leave no doubt that it violates some provision of the Constitution. Further, Plaintiff has failed to demonstrate that it has standing to bring this claim.

For these reasons, the Board and LLR respectfully request that this lawsuit be dismissed, and that the Court grant any other such relief as it deems just and proper.

Dated this the 10th day of July, 2017.

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STATE OF SOUTH CAROLINA COUNTY OF RICHLAND	IN THE COURT OF COMMON PLEAS FIFTH JUDICIAL CIRCUIT
Opternative, Inc., Plaintiff, vs. South Carolina Board of Medical Examiners, and South Carolina Department of Labor, Licensing, and Regulation, Defendants, South Carolina Optometric Physicians Association, Defendant-Intervenor.	Civil Action No. 2016-CP-40-06276 **PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

This case concerns an attempt by one group of medical professionals to use the power of government to prevent another group of medical professionals from exercising their medical judgment to rely on innovative technology that expands access to care. Plaintiff Opternative, Inc., ("Opternative") has developed an online refractive test and software ("Technology") that allows customers to renew or update their corrective-lens prescriptions from the comfort of their own homes using a smartphone and a computer. South Carolina-licensed ophthalmologists were actively using that Technology to write prescriptions for patients who needed them. But last year, the South Carolina Optometric Physicians Association (SCOPA)—a group of licensed optometrists whose brick-and-mortar business model depends on selling patients expensive eyeglass frames in their offices—launched an aggressive lobbying campaign to pass legislation specifically designed to prevent licensed ophthalmologists from using Opternative's Technology.

Although SCOPA publicly claimed the legislation would protect patient health, internal communications reveal that the law was actually designed to achieve one thing only: economic protectionism. And SCOPA succeeded: The Eye Care Consumer Protection Law (ECCPL) prohibited Opternative's ongoing business activities, caused South Carolina-licensed ophthalmologists to refuse to continue working with Opternative, and forced the business to shut down operations in South Carolina—all while doing literally nothing to protect the public health or safety.

The question for this Court to resolve is whether that sort of naked economic protectionism is a legitimate use of the state's police power. Under binding South Carolina precedent, it is not: The South Carolina Constitution forbids protectionist legislation and requires that laws restricting constitutionally protected rights bear a real and substantial

relationship to a legitimate government end. Because the evidence in this case clearly establishes that the ECCPL bears no such relationship to anything other than the anti-competitive, economic interests of SCOPA's members, summary judgment should be entered on behalf of Plaintiff.

STATEMENT OF FACTS

I. Opternative's Automated Technology Disrupts Optometrists' Brick-And-Mortar Business Model.

A. Optometrists' brick-and-mortar business model.

Vision care is a lucrative business. In 2014, the total market generated over $35 billion in revenue, $23 billion of which came from the sale of eyeglasses and contact lenses alone.[1] Optometrists—limited eye-health professionals who specialize in corrective-vision and certain ocular-pathological care—have a major stake in that market.[2] And a significant portion of that stake comes from their ability to bring patients into brick-and-mortar offices so the patients can be induced to purchase expensive frames from the optometrist after receiving their prescription.

Most optometrists rely heavily on patients seeking corrective-lens prescriptions for a consistent source of daily appointments.[3] That is because, traditionally, it has only been possible to determine an appropriate prescription through an in-person examination: To generate an appropriate prescription, the optometrist instructs the patient to sit in a chair and view certain projected images through a lens-switching device called a phoropter.[4] The optometrist then asks

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[1] *See* Windham Aff., Ex. 2 at 153, 177.

[2] *See id.*, Ex. 1 at 9:2–9:18.

[3] *See id.* at 9:25–11:3 (South Carolina-licensed optometrist Michael Zolman admitting that half of his daily appointments come from patients seeking corrective-lens prescriptions and that his practice model is "fairly typical").

[4] SCOPA Ans. ¶ 14; *see also* Windham Aff., Ex. 1 at 35:25–36:9, 36:13–37:7, 37:12–38:7 (Zolman explaining how optometrists use a phoropter to generate a patient's corrective-lens prescription).

the patient to self-report subjective responses to what they see as the optometrist physically cycles through various lenses in an effort to measure what is called the eye's refractive error.[5] Finally, the optometrist manually records the patient's responses and uses that refractive data to write an appropriate corrective-lens prescription.[6]

At the conclusion of each appointment, it is common practice for optometrists (or office staff) to lead patients to a display room and attempt to sell them expensive eyeglass frames.[7] For many optometrists, such in-person sales constitute a majority of their overall revenue stream.[8] In this way, optometrists have traditionally enjoyed a dual status as both the gatekeepers (prescription-writers) and first vendors (eyeglass-sellers) patients encounter as they enter the broader eye-care market.

B. Opternative's Technology.

Opternative is a healthcare-technology company founded in 2012 by optometrist Steven Lee out of a sincere belief that corrective-lens prescriptions should be accessible and affordable for everyone.[9] As a practicing optometrist who had conducted over 20,000 refractive tests, experience taught Steven that the traditional, brick-and-mortar model was needlessly

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[5] SCOPA Ans. ¶ 14; *see also* Windham Aff., Ex. 1 at 36:10–36:12, 36:13–36:23, 38:14–38:17 (Zolman explaining that optometrists rely on subjective refractive information based on patient's responses to projected images to generate a patient's corrective-lens prescription). "Refractive" in this context refers to how light bends in a person's eye. *See id.* at 34:21–35:3.

[6] *See id.* at 34:16–34:20, 39:23–40:6 (Zolman explaining how optometrists record the patient's refractive data in order to generate an appropriate corrective-lens prescription).

[7] *See id.* at 65:5–66:15 (Zolman admitting that optometrists attempt post-appointment eyeglass sales "most of the time").

[8] *Compare* SCOPA Ans. ¶ 20 (admitting on information and belief the allegations of Paragraph 48 of Plaintiff's Complaint) *with* Compl. ¶ 48 (alleging that "many professional optometrists make the majority of their revenue from selling expensive frames in their brick-and-mortar offices rather than from professional fees earned from conducting traditional in-person eye examinations"); *see* Windham Aff., Ex. 5 at 28:20–28:22 (SCOPA Executive Director Jackie Rivers admitting that "most South Carolina optometrists sell eyeglass frames").

[9] *See* Bodde Aff. at ¶¶ 3–4.

inconvenient and expensive for patients just looking to renew or update their previous prescriptions.[10] Steven knew there must be a way for patients to obtain that simple care without having to physically travel to an optometrist's office—or endure a sales pitch on the way out—every single year.[11]

Opternative was the solution. In essence, Opternative's Technology allows qualifying customers to obtain a corrective-lens prescription from their own homes by using a smartphone and a computer.[12] Opternative's Technology is not a replacement for a comprehensive eye-health exam, as both Opternative's Technology and website repeatedly inform users; instead, it is a tool that an ophthalmologist can use where appropriate to write or renew a corrective-lens prescription for someone not currently in need of a comprehensive in-person eye-health exam.[13]

Using Opternative's Technology is straightforward: Customers start by visiting the Opternative website and providing detailed information about their existing prescription and relevant medical history.[14] Opternative's Technology then prompts customers with a series of written and audio questions that guide them through a vision assessment.[15] Customers next view various individually calibrated images on a computer screen and use a smartphone to self-report subjective responses to what they perceive.[16] Opternative's Technology records those responses and sends all of the user's responses (to both the vision assessment and the personal- and medical-history questions) to a state-licensed ophthalmologist for review.[17]

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[10] *See id.* at ¶ 4.
[11] *See id.*
[12] *See id.* at ¶ 3.
[13] Bodde Aff. at ¶¶ 8–9.
[14] *See id.* at ¶ 6.
[15] *See id.*
[16] *See id.*
[17] *See id.*; Chaum Aff. at ¶ 2.

Opternative's users are *not* guaranteed a prescription. Ophthalmologists are medical doctors who specialize in total eye care, which includes not only corrective-vision and ocular-pathological care, but also overall eye-health assessments and surgeries.[18] Accordingly, participating ophthalmologists review the information generated by the Technology and only write prescriptions where, in their *medical judgment*, it is appropriate to do so.[19] In addition, Opternative imposes front-end screening requirements to filter out people for whom ophthalmologists will not write prescriptions based on the Technology: Only otherwise-healthy customers between the ages of 18 and 50 are eligible for a prescription, and customers are prohibited from using Opternative's Technology four years in a row without first certifying that they have received a comprehensive eye-health examination.[20]

C. Opternative's Technology disrupts optometrists' business model.

Opternative's Technology expands access to care: There is real patient demand for more convenient and affordable access to renewed or updated corrective-lens prescriptions,[21] and, prior to the enactment of the ECCPL, South Carolina-licensed ophthalmologists successfully used Opternative's Technology to write or renew prescriptions.[22] But this expanded access to care is also a threat to optometrists' profits, because their bottom line depends on frequent office visits from patients seeking corrective-lens prescriptions.[23]

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[18] SCOPA Ans. ¶¶ 9, 11; Bodde Aff. at ¶ 7.

[19] *See id.* at ¶ 7.

[20] *See id.* at ¶¶ 8–9.

[21] *See id.* at ¶ 10; Chaum Aff. at ¶ 4; Windham Aff., Ex. 2 at 153 (Zolman asking rhetorically "how many patients do we see daily who really come in just wanting a new prescription for glasses and/or contacts?" and remarking that online refractive technology would "allow them to get what they want").

[22] *See* Chaum Aff. at ¶ 2; Bodde Aff. at ¶ 11.

[23] SCOPA Ans. ¶ 20; *see* Windham Aff., Ex. 1 at 66:16–67:9 (Zolman admitting that his revenue from eyeglass sales "would go down" if online refractive tests like Opternative's Technology ever became commercially popular).

II. Optometrists Drafted And Lobbied For The ECCPL To Protect Their Brick-And-Mortar Business Model From Competition By Opternative's Automated Technology.

A. The American Optometric Association drafted model legislation as part of a national campaign to shut Opternative down.

The threat Opternative's Technology poses to the commercial viability of brick-and-mortar optometry shops has not gone unnoticed. Since Opternative's Technology entered the market, the American Optometric Association ("AOA")—a national association of optometrists devoted to the promotion of the optometric profession[24]—has devoted significant time and attention to combatting what it calls "the Opternative issue."[25]

As relevant here, that time and attention has come through the AOA's State Government Relations Committee, which works with state affiliates to pursue legislation.[26] In 2014, the AOA informed affiliates of a special campaign to shut Opternative down in states across the country.[27] Months later, the AOA produced a model bill: the Consumer Protection in Eye Care Act.[28] In 2015, the AOA's State Government Relations Committee formally presented that bill to state affiliates in a webinar titled "Online Vision Screening, Self-adjusting Glasses and Kiosks and What ODs Need to Know."[29] That webinar had three principal agenda items: (1) survey the most recent innovations and technologies in vision care and how those stood to impact the

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[24] *See id.*, Ex. 1 at 11:15–13:7.

[25] *See id.*, Ex. 7 at 501 (AOA providing state affiliates an "update on AOA actions on the Opternative issue").

[26] *See id.*, Ex. 1 at 15:3–15:19 (Zolman admitting that the State Government Relations Committee works with state affiliates—including SCOPA—to pursue legislation).

[27] *See id.*, Ex. 7 at 501 (AOA informing state affiliates of an upcoming legal review of Opternative's Technology and promising to "make recommendations to state affiliates about suggested strategies to stop this from operating in your state").

[28] *See id.*, Ex. 2 at 181–93.

[29] *See id.* at 155 (AOA webinar slides introducing the Consumer Protection in Eye Care Act to state affiliates).

business side of optometry; (2) recommend actions for state affiliates; and (3) explain the AOA's model bill.[30]

The webinar began with a "Background on The Issue."[31] According to the AOA, recent technological innovations have made self-refracting kiosks available through companies like CVS and Rite Aid, direct-to-consumer vision care available through companies like Warby Parker and 1-800 Contacts, and online refractive tests available through companies like Opternative—who received far more attention throughout the presentation than any other market entity.[32] The webinar was frank about the source of the AOA's interest in these innovations: A screen titled "Why are We Discussing Any of This???" explained that a majority of the revenue generated in the vision-care market comes not from medical treatment like eye examinations, but from the combined sales of eyeglasses and contact lenses.[33]

The webinar proceeded by asking, "Can We Fight This and Protect Our Patients?"[34] That question was answered below an image of two soldiers on horseback with an enthusiastic "YES!!!," followed by a slide recommending that affiliates "Pass the 'Consumer Protection in Eye Care Act.'"[35] As explained more fully below, the AOA's model bill formed the basis of the law challenged in this action.[36]

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[30] *See id.*, Ex. 2 at 158.

[31] *See id.* at 158, 160.

[32] *See id.* at 161–76.

[33] *See id.* at 177.

[34] *See id.* at 178.

[35] *See id.* at 178–79.

[36] *See id.*, Ex. 5 at 34:17–35:2 (Rivers explaining that "[t]he original draft language [for the ECCPL] came from the American Optometric Association" and admitting that "SCOPA . . . generate[d] a draft based on that language").

B. SCOPA adapted the AOA's model legislation to shut Opternative down in South Carolina.

One of the attendees at the AOA's 2015 webinar was then-Legislative Co-Chair of the South Carolina Optometric Physicians Association, Michael Zolman.[37] SCOPA—Defendant-Intervenor in this case—is an AOA state affiliate devoted to the promotion of the optometric profession in South Carolina through a combination of public, legislative, and other advocacy.[38]

After viewing the webinar, Zolman shared the AOA's concerns about how the innovations and technologies presented might impact the business side of optometry.[39] Indeed, Zolman was so concerned by what he learned from the webinar that he immediately e-mailed the SCOPA Board to explain how "kiosks and online eye exams" posed "a huge threat to our profession"—and what could be done about it.[40] Echoing the AOA webinar, Zolman was frank about the economic interests at stake, noting that "total eye care [is] a 35 BILLION DOLLAR industry, 23 BILLION coming from glasses and [contact-lens] sales," and that this amount of revenue would give competing retailers an incentive to cut optometrists out of the process.[41]

With Opternative in mind, Zolman explained that "kiosks and online eye exams" would be cheaper, more convenient, and would generate more revenue because there was real patient demand for such options.[42] He warned that "[i]t would only take one sellout OD or

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[37] *See id.*, Ex. 1 at 48:21–48:25, 51:3–51:5 (Zolman acknowledging having attended the webinar); *id.*, Ex. 2 at 153–54 (same).

[38] *See id.*, Ex. 1 at 16:4–16:21, 22:15–22:21.

[39] *See id.* at 51:25–52:9, 53:23–54:1 (Zolman admitting that he was concerned with how new vision-care technologies presented in the webinar might impact the "business side" of the optometric profession).

[40] *See id.*, Ex. 2 at 153–54 (Zolman's post-webinar e-mail to the SCOPA Board); *id.*, Ex. 1 at 51:3–51:5 (Zolman confirming that his e-mail was prompted by the webinar).

[41] *See id.*, Ex. 2 at 153.

[42] *See id.*; *id.*, Ex. 1 at 54:2–54:12 (Zolman admitting that he "had Opternative in mind" when he wrote the e-mail).

ophthalmologist to approve of countless prescriptions generated from self-refracting kiosks and forego the exam altogether."[43] Zolman recommended that SCOPA "address [the issue] quickly and attack aggressively," explaining that "the AOA is on the ball and recently drafted a bill that can be modified on a state-by-state basis to prevent this . . . [which is] something we definitely want to do."[44]

To be fair to Zolman, one line of his eleven-paragraph e-mail actually does discuss patient safety, instead of just the economic impact of new technology on optometrists: "Think of all the glaucoma, ARMD, Diabetic retinopathy, Cataracts, amblyopia, (the list goes on and on) that would be missed."[45] But Zolman does not discuss how the AOA's proposed legislation would actually protect the public from these diseases. And as explained below, while the legislation eventually adopted in South Carolina would do nothing to address the public-health concern briefly identified in Zolman's e-mail, it would do quite a lot to address his economic-competition concerns.

In any event, the SCOPA Board took Zolman's advice.[46] In the months that followed, SCOPA engaged in a vigorous, AOA-assisted and Department of Labor, Licensing, and Regulation (LLR)-backed lobbying campaign to get their version of the AOA's model bill passed in South Carolina.

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[43] *See id.*, Ex. 2 at 153.

[44] *See id.*

[45] *See id.*

[46] *See id.* at 152 (Wayne Cannon notifying SCOPA's lobbyists that "[t]he SCOPA board voted to evaluate the passing of a consumer protection leg. The AOA suggested bill is attached for your review. We will need to meet soon to evaluate our strategy."); *id.*, Ex. 5 at 26:16–26:19 (explaining that Wayne Cannon was the President of the SCOPA Board).

C. SCOPA engaged in a vigorous lobbying campaign—assisted by the AOA and LLR—to ensure the passage of a law banning Opternative's Technology.

Both government employees and SCOPA officials agree that the ECCPL was passed at SCOPA's behest and as the result of SCOPA's lobbying campaign.[47] And SCOPA consistently viewed the purpose of the ECCPL as to prevent anyone from employing technology like Opternative's to compete with brick-and-mortar optometry shops: Indeed, when someone suggested amending the ECCPL to regulate optometrists only, SCOPA took the position that removing ophthalmologists from the ECCPL would render the entire legislation "moot."[48] The point of the law, in other words, was not to simply regulate the conduct of optometrists, but to limit the medical discretion of medical doctors in an effort to prevent them from undercutting optometrists' profits.

To be sure, SCOPA carefully managed its talking points (with help from the national AOA), with internal e-mails stressing the importance of avoiding any discussion of telemedicine

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[47] *See id.* at 23:13–23:15 (Rivers admitting that "the ECCPL is a bill that SCOPA passed"), 46:22–47:2 (Rivers admitting that "the bill that eventually became the ECCPL was primarily pushed by the optometrists"); *id.*, Ex. 3 at 129 (Zolman boasting that the passage of the ECCPL "is what organized Optometry looks like at it's [sic] best!" and that "[i]t took the grassroots efforts of all of you contacting your legislators to make this happen as well as the tireless efforts of your SCOPA Board of Directors working in conjunction with AOA to make this possible"); *id.*, Ex. 15 at 455, 573–74, 721 (Holly Beeson confirming that the ECCPL "was largely pushed by the optometrist community"); *id.*, Ex. 11 at 6:13–7:1, 40:18–41:5 (LLR 30(b)(6) designee Darra Coleman explaining that Holly Beeson is an attorney "responsible for the supervision of [LLR's] Office of Communications, which includes [LLR's] legislative affairs").

[48] *See id.*, Ex. 8 at 469 (Rivers forwarding AOA feedback on Opternative's proposed edit to the bill that would have removed ophthalmologists: "Removing MDs basically makes the bill moot."); *id.*, Ex. 5 at 52:1–52:8 (Rivers explaining that removing ophthalmologists would have made the bill moot "[b]ecause it would still create an avenue potentially for someone to give themselves a refraction utilizing technology that removes them out of the doctor's office"), 55:16–55:22 (Rivers admitting that SCOPA's "effort to pass the ECCPL [was] prompted by the existence of businesses offering online eye exams").

or kiosks and instead casting the ECCPL as a consumer protection law.[49] But these talking points were ultimately unpersuasive to then-Governor Nikki Haley, who vetoed the ECCPL on May 16, 2016. Her explanation of the veto read, in full:

> **I am vetoing this bill because it uses health practice mandates to stifle competition for the benefit of a single industry**, effectively banning eye care kiosks statewide.
>
> During my administration, South Carolina has expanded access to health care, including mental health services, to rural and underserved regions of our state using telemedicine. Unfortunately, a small group of eyecare professionals is seeking to block new technologies that expand low-cost access to vision correction services, using two basic arguments.
>
> First, advocates state that kiosks pose a public health risk, which is simply untrue. Individuals can, and should, continue to see their doctor for comprehensive medical exams, and these kiosks do not offer medical evaluations or advice. Second, optometrists argue that kiosks create an uneven playing field because licensed practitioners cannot take advantage of this technology and charge patients for its use in a medical practice. The answer to this problem is not to ban a new technology, but rather to expand its use. **Send a bill to my desk that allows for the expanded use of automated vision evaluations in all medical settings, and I will sign it.**
>
> If [the ECCPL were] allowed to become law, South Carolina would become the eighth state to impose such a ban, putting us on the leading edge of protectionism, not innovation. This is the wrong message to send to the business community. **I urge you to continue promoting South Carolina's use of innovative technologies to expand access to medical care and sustain this veto.**[50]

SCOPA's lobbying efforts continued after the veto, as did its internal insistence on message discipline: "We do NOT want to make this an anti-Opternative arguement [sic],"

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[49] *See id.*, Ex. 13 at 1257–58 (Zolman response to SCOPA membership e-mail with subject line "Fw: Governor Haley's Decision on The Consumer Eye Care Protection Bill"); *id.*, Ex. 8 at 469 (Rivers forwarding e-mail from AOA with subject line "RE: Meeting Monday"); *id.*, Ex. 6 at 667 (Rivers forwarding e-mail from SCOPA Board Member Michael Campbell with subject line "SCOPA's Bill – How to Reference").

[50] *See id.*, Ex. 16 (emphases in original).

Zolman explained in one e-mail, "as Legislators frown upon legislation that singles out and restricts a specific business."[51] Instead, SCOPA "must maintain the argument that this bill protects the consumer from false and misleading claims to what an eye exam is as well as that it protects our citizens from unproven technology and that anything less jeopardizes consumers [sic] health care."[52]

SCOPA was not alone in resisting the veto; it had help from the South Carolina Board of Examiners in Optometry ("Optometry Board"), which is part of Defendant LLR. *See* S.C. Code Ann. § 1-30-65. While LLR and its agencies are prohibited from engaging in lobbying and can generally provide input on legislation "[w]hen asked by . . . legislative staff or individual legislators,"[53] the Optometry Board appears to have been unusually excited about the ECCPL, engaging in atypical and apparently uninvited lobbying efforts of its own: On May 16, 2016, the Optometry Board's then-President—and SCOPA member—Peter Candela sent a letter on behalf of the Board to the Governor's office "in support of her hopeful signature," and asking his colleagues at LLR that, "if someone has a direct contact to the Gov, please pass a long [sic] that we strongly support this bill and hope that she signs it in to [sic] law."[54] The following day, Candela sent Senator John Scott a letter emphasizing the Optometry Board's support for the ECCPL and asking Scott to "continue to encourage your colleagues in the House and Senate to override the Governors [sic] veto."[55]

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[51] *See id.*, Ex. 13 at 1258.

[52] *See id.*

[53] *See* Windham Aff., Ex. 11 at 37:9–38:9.

[54] *See id.*, Ex. 12 at 2621; *id.*, Ex. Windham Aff., Ex. 11 at 46:18–47:22 (Coleman explaining that Candela is "an optometrist licensed in South Carolina" and that "in 2016, he would have been president of the Board of Examiners of Optometry"); *id.*, Ex. 5 at 20:15–20:18 (Rivers explaining that Candela is a SCOPA member).

[55] *See id.*, Ex. 14 at 86–87.

The post-veto lobbying efforts were successful, and the legislature overrode Governor Haley's veto on May 19, 2016.[56] Once the law's passage was final, though, SCOPA and its officials seemed to lose some of the message discipline that had characterized their lobbying efforts. Indeed, SCOPA's uncensored internal reaction to the veto override was markedly different from the organization's careful public statements: In public, SCOPA hewed to the AOA's advice to "[c]ontinue talking about public safety" to make it seem like the law was not protectionist legislation designed to restrict a single business—namely, Opternative.[57] But in private, as the Senate voted to override Governor Haley's veto, SCOPA Executive Director Jackie Rivers sent an e-mail to AOA officials, exclaiming: "[T]ake that Opternative!!!!!!"[58] Zolman followed almost immediately by describing the law's effect in a message to SCOPA's membership: "It's with the utmost pleasure to announce that today, Opternative and 'eye exam' kiosks are now **PROHIBITED BY LAW** in the great state of SC!"[59] He closed with a final message summing up what SCOPA had achieved: "Good-bye Opternative!"[60]

Months later, when the AOA asked SCOPA to present for its other state affiliates on their success adapting and passing the AOA's model legislation in South Carolina, SCOPA used that

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[56] *See id.*, Ex. 3 at 129 (Zolman e-mail to SCOPA's membership with subject line "It's a GREAT day in SC" announcing that "[b]oth the SC House and Senate voted to override Governor Haley's veto of our bill S1016").

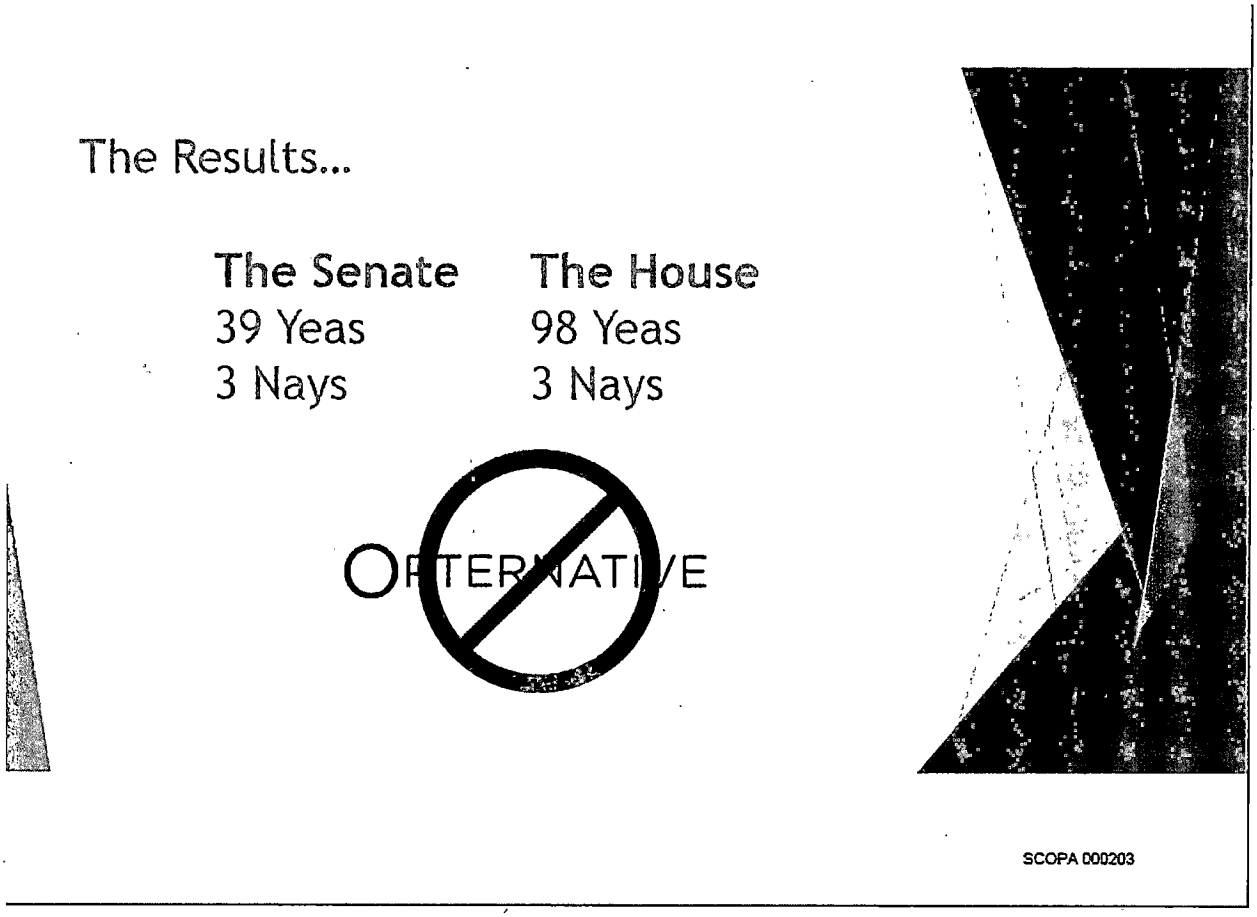
[57] *Compare id.*, Ex. 8 at 469 (Rivers forwarding AOA admonition to "continue talking about patient safety"), *with id.*, Ex. 5 at 55:16–55:22, 56:6–56:11 (Rivers admitting that the ECCPL was "prompted by the existence of online eye exams" but that there were "internal discussions at SCOPA about the importance of discussing the ECCPL as if it were not an effort to ban Opternative").

[58] *See id.*, Ex. 9 at 116.

[59] *See id.*, Ex. 3 at 129.

[60] *See id.*

presentation as an opportunity to boast without restraint about what the ECCPL had really accomplished[61]:



In sum, SCOPA and its officers treated the passage of the ECCPL as what it really was: The culmination of a successful effort to ban Opternative and its Technology.[62]

Understandably, South Carolina-licensed ophthalmologists seem to have had the same understanding of what the ECCPL does. Before the ECCPL, Opternative had no problem operating in South Carolina, and many South Carolinians actually received corrective-lens prescriptions after a South Carolina-licensed ophthalmologist used his medical judgment to write

[61] *See id.*, Ex. 10 at 203.

[62] *See id.*, Ex. 5 at 59:5–60:6.

a prescription based on information generated by the Technology.[63] But after the ECCPL passed, no ophthalmologist was willing to use Opternative's Technology.[64] And rightly so: As explained below, the ECCPL clearly prohibits the use of Opternative's Technology because it requires corrective-lens prescriptions to be based in part on an examination by a human being (though not necessarily by the prescribing ophthalmologist).

South Carolina-licensed ophthalmologists have good reason not to test the boundaries of South Carolina law. *See* S.C. Code Ann. §§ 40-1-80, 40-47-80, 40-47-110. If the South Carolina Board of Medical Examiners receives a complaint that a licensed ophthalmologist has violated the law, that complaint triggers an investigatory process that lasts at least a year—indeed, the Board's 30(b)(6) designee testified that it was not even theoretically possible for the process to conclude in *less* than a year.[65] And while the Board has some discretion over the degree of punishment to mete out, it has no discretion at all to refrain from enforcing the law: If an ophthalmologist violates the ECCPL by writing a prescription based solely on automatically collected information (using Opternative or any other computerized technology), that ophthalmologist would face a lengthy investigation followed by an enforcement action.[66]

Unable to find ophthalmologists willing to risk burdensome investigations and ruinous penalties, Opternative was forced to cease its operations in South Carolina—though it is currently in contact with South Carolina-licensed ophthalmologists who would continue using

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[63] *See* Bodde Aff. at ¶ 11; Chaum Aff. ¶ 2.

[64] *See* Bodde Aff. at ¶ 12–13; Chaum Aff. at ¶ 3.

[65] *See* Windham Aff., Ex. 11 at 19:17–19:23 (Coleman responding "No, I would not say so" and "I would not say that that would be a realistic expectation" in response to question about whether case-investigation process could theoretically conclude in less than a year).

[66] *See id.* at 10:13–15:17 (Coleman explaining procedures of lengthy case-investigation process), 69:5–69:10 (Coleman explaining that LLR "[doesn't] have the luxury of not enforcing law").

the Technology to write corrective-lens prescriptions (where medically appropriate) if the barrier of the ECCPL were removed.[67]

III. The ECCPL Bans Opternative's Technology—And That Is All It Does.

The ECCPL was intended as a ban on Opternative's Technology, rather than as a requirement that patients receive a comprehensive eye-health examination before updating or renewing their corrective-lens prescriptions. Unsurprisingly, then, the ECCPL does a very good job of banning Opternative but almost nothing at all to ensure that patients receive comprehensive eye-health exams.

The ECCPL is codified at S.C. Code Ann. sections 40-24-10 and 40-24-20. The law lays out two requirements for a corrective-lens prescription:

> **To be valid, a prescription must contain an expiration date on spectacles or contact lenses of one year from the date of examination by the provider** or a statement of the reasons why a shorter time is appropriate based on the medical needs of the patient. **The prescription must take into consideration medical findings made and refractive error discovered during the eye examination.** If a provider determines a patient is a suitable candidate for a prescription for contact lenses or spectacles, a provider may not thereafter refuse to issue a prescription for spectacles or contact lenses to a patient.

Id. § 40-24-20(B) (emphasis added). It also provides that "[a] prescription for spectacles or contact lenses may not be based solely on the refractive eye error of the human eye or be generated by a kiosk." *Id.* § 40-24-20(C). Both the term "eye examination" and the term "kiosk" are further defined: To be valid, an eye examination "must not be based solely on objective refractive data or information gathered by an automated testing device." *Id.* §§ 40-24-10(3) and 40-24-10(9). Similarly, "kiosk" is broadly defined to include any "automated application, which

[67] *See* Bodde Aff. at ¶¶ 13–14; Chaum Aff. at ¶¶ 3–4.

is designed to be used on a phone, computer, or Internet-based device . . . to provide refractive data or information." *Id.* § 40-24-10(4).

In other words, the ECCPL requires that corrective-lens prescriptions must expire annually, and they must be based at least in part on information collected by a human being.

Tellingly, and as confirmed by the Defendants' 30(b)(6) designee at deposition, these are the only constraints the ECCPL places on an ophthalmologist's medical judgment.[68] The ECCPL does not specify what findings an ophthalmologist must make before prescribing corrective lenses.[69] It does not require an ophthalmologist to conduct or not conduct any particular tests.[70] It only requires that some part (however small) of the medical information on which an ophthalmologist bases his corrective-lens prescription must have been collected by a human being instead of by a computerized device.[71]

And that human being *does not even need to be the prescribing ophthalmologist.* Ophthalmologists, like other South Carolina-licensed doctors, can and do delegate some or all of their examinations to assistants, either licensed assistants like nurses or totally unlicensed assistants, in their sole discretion.[72] The ECCPL does nothing to change this. In other words, the only requirement actually imposed by the ECCPL before an ophthalmologist writes a

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[68] *See* Windham Aff., Ex. 11 at 65:17–65:23 (Coleman admitting that "the ECCPL leaves it to an ophthalmologist's professional judgment exactly what diagnostic methodologies and exactly what medical information he needs before writing a prescription").

[69] *See id.* at 65:4–65:16 (Coleman admitting that the ECCPL "doesn't identify diagnostic methodologies that have to be employed in order to develop the medical findings" or even "specify what those medical findings must be").

[70] *See id.* at 64:16–65:2 (Coleman explaining that the ECCPL has "no explicit requirement" regarding tests that must be performed before writing a corrective-lens prescription).

[71] *See id.* at 67:14–67:18 (Coleman explaining that the ECCPL imposes "some expectation that there will be some type of human involvement").

[72] *See id.* at 65:17–65:23, 67:14–68:10 (Coleman explaining it is generally within the physician's discretion to use any number of "physician extenders" and that such extenders can even include "unlicensed professionals, such as a medical assistant or a certified nurse assistant").

prescription is that a human—any human—obtain some information—any information—from the person seeking the prescription.

This very effectively bans Opternative, whose Technology uses a computer program to automatically collect and send information over the Internet for a doctor's review. But it does nothing to require that an ophthalmologist conduct a comprehensive eye-health examination every single time he writes a corrective-lens prescription. Nor should we expect an ophthalmologist to do so: While periodic comprehensive eye-health examinations are important, the American Academy of Ophthalmology does not recommend that most people receive such exams annually. Instead, the American Academy of Ophthalmology recommends that otherwise-healthy people obtain at least ***one*** such examination by the time they reach 40 years old, and that otherwise-healthy people between the ages of 40 and 54 obtain one every 2–4 years.[73]

To be sure, the ophthalmologists' professional recommendations recognize that comprehensive eye-health exams are important, but they also recognize that for most people—people without sudden changes in their vision or other symptoms of eye disease—more regular exams are simply unnecessary. That group—the people who need new glasses occasionally but whose doctors believe they do not need annual eye-health checkups—is exactly the group that was using and benefitting from Opternative prior to the ECCPL.

The ECCPL's expiration period is further evidence that it has no relationship to public health or safety. While the one-year expiration requirement has no footing whatsoever in—and

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[73] *See id.*, Ex. 4 at1–2 ("Adults with no signs or risk factors for eye disease should receive a baseline comprehensive eye evaluation at age 40. Individuals without risk factors aged 40 to 54 should be examined by an ophthalmologist every 2 to 4 years."); *id.*, Ex., 1 at 47:24–48:3 (Zolman admitting that he has no reason to doubt that the American Academy of Ophthalmology's statement conveys the ophthalmological standard of care because "I'm not an ophthalmologist"); *see also* SCOPA Ans. ¶ 16.

indeed, is radically different from—ophthalmologists' actual recommendations for comprehensive eye-health examinations, it bears an obvious relationship to optometrists' interest in selling expensive eyeglass frames to their customers on a regular basis.

In short, the ECCPL does not require ophthalmologists to conduct comprehensive eye-health examinations; instead, it requires in-person exams by someone (who can be anyone) who is looking for something (which can be anything). And it requires these in-person exams far more frequently than practicing doctors believe comprehensive eye-health examinations are necessary for the vast majority of the population. These requirements bear strikingly little relationship to a concern about the detection of eye disease in the general public, but they bear an undeniable relationship to the economic interests of practicing optometrists—the very group that everyone agrees drafted and lobbied for the law in the first place. The question before the Court, as discussed below, is whether this kind of pure economic protectionism is a valid use of government power under the South Carolina Constitution.

STANDARD OF REVIEW

"Summary judgment is appropriate where the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." *Lawing v. Univar, USA, Inc.*, 415 S.C. 209, 220, 781 S.E.2d 548, 554 (2015); *accord Joseph v. S.C. Dep't of Labor, Licensing & Regulation*, 417 S.C. 436, 448, 790 S.E.2d 763, 769 (2016) (plurality). Material facts cannot be disputed based upon mere denials or averments of ignorance as to the factual basis for allegations set forth in the pleadings. *Bankers Tr. of S.C. v. Benson*, 267 S.C. 152, 154–55, 226 S.E.2d 703, 704 (1976). Nor will contrary allegations suffice. *City of Columbia v. Town of Irmo*, 316 S.C. 193, 195, 447 S.E.2d 855, 857 (1994). Instead, the non-

moving party must proffer actual evidence of a specific factual dispute. *Coker v. Cummings*, 381 S.C. 45, 54–55, 671 S.E.2d 383, 388 (Ct. App. 2008). If the non-moving party fails to meet that burden, the trial court must enter summary judgment. *Id.* at 55, 671 S.E.2d at 388.

ARGUMENT

Summary judgment is appropriate in this case because the undisputed evidence reveals the ECCPL to be nothing more than a protectionist law designed to ban Opternative's Technology in order to protect South Carolina optometrists' outdated business model from competition, and protectionism is not a legitimate use of the state's police power. Moreover, this case is brought under the South Carolina Constitution, which demands a far more searching version of rational-basis review than is sometimes applied by federal courts. Not only have South Carolina courts squarely rejected the sort of naked economic protectionism embodied by the ECCPL, but South Carolina's due-process and equal-protection jurisprudence demand that economic regulations like the ECCPL bear a real and substantial relationship to some legitimate, non-protectionist end of government—a standard the ECCPL cannot hope to meet.

I. The South Carolina Rational-Basis Test Controls.

Plaintiff challenges the ECCPL under Article I, Section 3 of the South Carolina Constitution—and only that provision. Because this case involves no suspect class or fundamental right, the rational-basis test applies. *Denene, Inc. v. City of Charleston*, 359 S.C. 85, 91, 596 S.E.2d 917, 920 (2004). But this Court is bound to apply the version of that test articulated and applied by South Carolina courts—and that test (unlike some articulations of the federal rational-basis test) requires an inquiry into the true purpose of a statute and whether the record evidence suggests that the statute actually serves that purpose. As explained more fully below, under *that* test, the ECCPL cannot hope to survive. *See infra* 23–35.

This difference between state and federal law matters because the facts of this case bear a striking resemblance to those considered by the United States Supreme Court over a half-century ago in *Williamson v. Lee Optical of Oklahoma, Inc.* *See* 348 U.S. 483 (1955). There, an Oklahoma statute made it illegal for opticians to fit already-prescribed lenses into new eyeglass frames, or to replace those lenses when they broke, unless customers obtained an additional prescription from a state-licensed optometrist or ophthalmologist. *Id.* at 485. A review of the record led the District Court to conclude that while some patient-health interest was at stake, banning opticians from "tak[ing] old lenses and plac[ing] them in new frames and then fit[ting] the completed spectacles to the face of the eyeglass wearer" failed to further that interest by means "reasonably necessary []or reasonably related to the end sought to be achieved." *Lee Optical of Okla., Inc. v. Williamson*, 120 F. Supp. 128, 135, 137 (W.D. Okla. 1954).

But the Supreme Court reversed. Rather than weigh record evidence to determine whether the law actually protected patient health, the Court suggested that no such facts were necessary to dispose of the challenge: "[T]he law need not be in every respect logically consistent with its aims to be constitutional. It is enough that there is an evil at hand for correction, and that it might be thought that the particular legislative measure was a rational way to correct it." *Lee Optical*, 348 U.S. at 487–88. The Court suggested that "the legislature may have concluded that eye examinations were so critical, not only for correction of vision but also for detection of latent ailments or disease, that every change in frames and every duplication of a lens should be accompanied by a prescription from a medical expert." *Id.* at 487.

Defendants will undoubtedly invoke *Lee Optical* here, arguing that the ECCPL makes it harder to get corrective-lens prescriptions without going to an optometrist or ophthalmologist's office, and that simply being in such an office makes it more likely that certain eye diseases will

be detected. But *Lee Optical* does not control the outcome of this case. Indeed, *Lee Optical* does not even describe the rational-basis test as actually applied by modern federal courts: Modern federal courts have repeatedly rejected regulations that, like the regulation at issue here, are justified by purported "health and safety" concerns that the government has declined to regulate more directly. *See, e.g.*, *St. Joseph Abbey v. Castille*, 712 F.3d 215 (5th Cir. 2013); *Craigmiles v. Giles*, 312 F.3d 220 (6th Cir. 2002).

Moreover, the South Carolina Supreme Court has never adopted *Lee Optical*. Quite the contrary: The case has been cited all of twice in South Carolina history, most recently in a two-Justice plurality opinion—which cites it in dicta, in a footnote noting that the plaintiff had failed to make arguments "sufficient to invoke the rational basis test." *State v. Dykes*, 398 S.C. 351, 369, 728 S.E.2d 455, 464 n.8 (2012), *superseded by State v. Dykes*, 403 S.C. 499, 744 S.E.2d 505 (2013); *see also Dantzler v. Callison*, 230 S.C. 75, 94 S.E.2d 177 (1956) (weighing challenge under Article 3, Section 17 of the South Carolina Constitution and citing *Lee Optical* in dicta as illustration of police power). And South Carolina courts have flatly disclaimed acquiescence to the federal judiciary on questions of state-constitutional interpretation. *State v. Forrester*, 343 S.C. 637, 643, 541 S.E.2d 837, 840 (2001) ("[T]he federal Constitution sets the floor for individual rights . . . the state constitution establishes the ceiling."); *State v. Austin*, 306 S.C. 9, 16, 409 S.E.2d 811, 815 (Ct. App. 1991) ("It is firmly established that state courts may interpret their own constitutions in such a way as to expand rights conferred by the Federal Constitution.").

Most significantly for purposes of this case, South Carolina's courts have read the South Carolina Constitution to provide far more robust protection for individual rights against economic regulations than the sort of deference embodied by *Lee Optical*. Indeed, twice in the

past year alone, pluralities of the South Carolina Supreme Court have used the specific guarantees of the South Carolina Constitution to reject economic regulations subject to so-called "rational-basis review." *See Retail Servs. & Sys., Inc. v. S.C. Dep't of Revenue*, 419 S.C. 469, 474, 799 S.E.2d 665, 667 (2017) (plurality) (rejecting law restricting liquor-license ownership); *accord Joseph v. S.C. Dep't of Labor, Licensing & Regulation*, 417 S.C. 436, 453, 790 S.E.2d 763, 772 (2016) (plurality) ("It is the duty of this Court, not the legislature, to determine the constitutionality of a statute.").

South Carolina's robust review of economic regulation is not an anomaly; it is a natural outgrowth of South Carolina's independent constitutional language. Neither is South Carolina alone here: Other states with similar constitutions to South Carolina's have similarly rejected *Lee Optical*-style deference in favor of more meaningful review of economic regulations. For example, Texas, like South Carolina, has a state constitution whose individual-rights protections that are phrased differently than those of the United States Constitution and which state courts have applied differently.[74] As in South Carolina, the relevant language of Texas's Constitution was adopted in the second half of the 19th century, "after the United States Supreme Court decision in the *Slaughter-House Cases* by which the Court put the responsibility for protecting a large segment of individual rights directly on the states." *Patel v. Tex. Dep't of Licensing & Regulation*, 469 S.W.3d 69, 87 (Tex. 2015).[75] And as in South Carolina, Texas courts have held

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[74] Article I, Section 3 of the South Carolina Constitution, the provision raised in this action, reads: "The privileges and immunities of citizens of this State and of the United States under this Constitution shall not be abridged, nor shall any person be deprived of life, liberty, or property without due process of law, nor shall any person be denied the equal protection of the laws." Article I, Section 19 of the Texas Constitution similarly provides: "No citizen of this State shall be deprived of life, liberty, property, privileges or immunities, or in any manner disfranchised, except by the due course of the law of the land."

[75] The relevant provision of Texas's Constitution was adopted in 1875. *Id.* at 86–87. The relevant provision of the South Carolina Constitution was adopted in 1895. *See State v. Duncan*,

that their independent Constitution was meant to take this responsibility seriously and have interpreted it to provide more robust protection for individual rights than is provided in some instances by the U.S. Constitution. *Id.*

Specifically, Texas courts interpret their Constitution to require a real examination of record evidence to determine whether a challenged "statute's purpose could not arguably be rationally related to a legitimate governmental interest" or "when considered as a whole, the statute's actual, real-world effect as applied to the challenging party could not arguably be rationally related to, or is so burdensome as to be oppressive in light of, the governmental interest." *Id.* In other words, in interpreting Texas's parallel constitutional provision, Texas courts look both to the arguable legislative motive and to the evidence of the effect a challenged law would have in the real world. The Texas Supreme Court in *Patel* used this test in 2015 to reject a cosmetology regulation that, while nominally related to public health and safety, did not actually achieve public-safety goals commensurate with the restrictions it imposed on individuals. *See id.* at 87–90.

As discussed more fully below, the South Carolina Supreme Court has interpreted its own independent Constitution to require review just as robust as that of Texas (if not more so). South Carolina courts are *also* charged to examine whether a law's actual purpose is a legitimate one and are *also* charged to examine record evidence to determine whether, in the real world, a law actually serves that legitimate purpose (instead of another, illegitimate purpose). As explained below, the ECCPL fails on both scores, and summary judgment should therefore be granted in favor of Plaintiff.

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269 S.C. 510, 512, 238 S.E.2d 205, 206 n.2 (1977); *Standard Oil Co. v. City of Spartanburg*, 66 S.C. 37, 44 S.E. 377, 377 (1903).

II. The ECCPL Is A Purely Protectionist Law, And Protectionism Is Not A Legitimate Government End.

Article I, Section 3 of the South Carolina Constitution secures individual rights against encroachment by government power: "The privileges and immunities of citizens of this State and of the United States under this Constitution shall not be abridged, nor shall any person be deprived of life, liberty, or property without due process of law, nor shall any person be denied the equal protection of the laws." S.C. Const. art I, § 3. Under any provision of Article I, Section 3, whether styled as a due process or equal protection guarantee, the fundamental requirement is that all exercises of the police power further a *legitimate* government end, such as the protection of the public health or safety. *See Denene, Inc.*, 359 S.C. at 93, 596 S.E.2d at 921; *R.L. Jordan Co. v. Boardman Petroleum, Inc.*, 338 S.C. 475, 478, 527 S.E.2d 763, 765 (2000) (per curiam).

While the police power is broad, South Carolina has a proud tradition of consistently rejecting naked economic protectionism. *See, e.g., Retail Servs. & Sys., Inc. v. S.C. Dep't of Revenue*, 419 S.C. 469, 474, 799 S.E.2d 665, 667 (2017) (plurality) (rejecting law limiting owner to three retail liquor licenses because economic protectionism for a certain class of retailers is not a constitutionally sound basis for regulating liquor sales); *Joseph*, 417 S.C. at 452–53, 790 S.E.2d at 771–72 (plurality) (striking down arbitrary employment and referral restriction on physical therapists and surgeons as merely anti-competitive regulation intended to protect therapists' personal financial interests rather than those of patients); *Kirven v. Cent. States Health & Life Co.*, 409 S.C. 30, 42–43, 760 S.E.2d 794, 801 (2014) (rejecting retroactive application of statutory definition to existing insurance contracts because it appeared that insurance industry had merely convinced General Assembly to contract for them by fiat); *ATC S., Inc. v. Charleston Cty.*, 380 S.C. 191, 198, 669 S.E.2d 337, 340 (2008) (denying standing to

cell-phone-tower company seeking to use zoning system to prevent competitor from building tower on nearby land because increased business competition is not a cognizable injury); *G-H Ins. Agency, Inc. v. Cont'l Ins. Co.*, 278 S.C. 241, 248–49, 294 S.E.2d 336, 340–41 (1982) (striking down law forbidding auto-insurance providers from terminating agents where it appeared that predominant purpose was merely to protect private profits of insurance agents rather than any broader social interest); *Painter v. Town of Forest Acres*, 231 S.C. 56, 61, 97 S.E.2d 71, 73 (1957) (rejecting ordinance requiring all businesses to close at midnight where ordinance would have destroyed lawful enterprises and appeared directed at respondent with that purpose in mind); *McCoy v. Town of York*, 193 S.C. 390, 8 S.E.2d 905, 907–09 (1940) (striking down petroleum-vehicle restrictions so specific as to apply to only one filling station because restrictions appeared designed to discriminate against that station to benefit of all other local stations); *City of Orangeburg v. Farmer*, 181 S.C. 143, 186 S.E. 783, 785 (1936) (rejecting ordinance declaring door-to-door solicitation a nuisance where no public-health justification appeared and ordinance was passed not due to complaints by homeowners but at request of city's Retail Merchants Association).

Thus, where a challenged law appears designed to further merely private interests rather than some broader social purpose, or its asserted justification appears spurious, courts in this state will not hesitate to recognize economic protectionism as the true motivation behind that law and strike it down.

This approach is perhaps best illustrated by the South Carolina Supreme Court's recent plurality opinion in *Joseph*. *See* 417 S.C. at 442, 790 S.E.2d at 766.[76] There, a physical therapist

[76] While the lead opinion in *Joseph* commanded only two votes, two Justices dissented on the grounds that the appellants lacked standing while calling the lead opinion otherwise "laudable." 417 S.C. at 466, 790 S.E.2d at 799 (Beatty, J., dissenting).

and two orthopedic surgeons challenged certain South Carolina Board of Physical Therapy position statements and judicial precedent interpreting a law that allowed physicians to employ and refer patients to healthcare professionals according to their judgment—*except* physical therapists, who could only be employed by and refer patients to one another. *Id.* at 446, 790 S.E.2d at 768. The government claimed the distinction was intended to protect patients and state-sponsored programs from conflicts of interest, but the Court did not hesitate to pull back the veil to identify the true motivation at work: "[This law] appears merely to be anti-competitive protectionist legislation intended to protect personal financial interests, which is driven by reimbursement purposes, rather than actual benefits to patients." *Id.* at 452–53, 790 S.E.2d at 771–72. The interpretation was declared unconstitutional. *Id.* at 453, 790 S.E.2d at 771–72.

Similarly here, the overwhelming evidence indicates that the ECCPL was intended to protect the personal financial interests of optometrists rather than to serve patient health. While the Court in *Joseph* made an inference about the corrupt purpose of the challenged law based on the lack of any plausible connection to a legitimate justification, here there is actually *direct evidence* that the ECCPL was designed by the very group that stands to benefit economically from its enforcement.[77] Moreover, just as the interpretation in *Joseph* appeared arbitrary absent any evidence that it protected patients, so the ECCPL—which does nothing to require a

[77] *See* Windham Aff., Ex. 7 at 501 (AOA e-mail to state affiliate on "the Opternative issue" and forecasting plan to "stop this from operating in your state"); *id.*, Ex. 2 at 152–53 (Zolman post-webinar e-mail to SCOPA Board stressing that "kiosks and online eye exams" posed "a huge threat to our profession" and recommending that SCOPA adapt the AOA's model legislation for a legislative campaign); *id.* at 152 (Cannon e-mail informing SCOPA's lobbyists that the Board had voted to pursue Zolman's recommendation); *id.*, Ex. 5 at 23:13–23:15, 34:17–34:20, 38:6–38:14 (Rivers taking complete responsibility for the ECCPL on SCOPA's behalf); *id.*, Ex. 3 at 129 (Zolman boasting to SCOPA's membership after veto override about SCOPA's efforts to get the ECCPL passed and exclaiming that "Opternative and 'eye exam' kiosks are now **PROHIBITED BY LAW** in the great state of SC!"); *id.*, Ex. 10 at 203 (SCOPA presentation slide portraying "The Results…" of SCOPA's efforts to get the ECCPL passed and prominently displaying the word "Opternative" with a red circle and strikethrough).

comprehensive eye-health examination—is arbitrary if viewed as anything *other* than economic protectionism: Indeed, the only justification in the record is that requiring an examination by a human being *might* result in ophthalmologists' choosing to conduct comprehensive eye-health exams more frequently than they otherwise would.[78] But again, Defendants admit they have no evidence for this justification, and the ophthalmological standard of care does not even recommend annual comprehensive eye-health examinations for the vast majority of the population.[79]

Accordingly, the ECCPL is nothing more than "anti-competitive protectionist legislation" of the sort expressly rejected in *Joseph*, and is beyond the legitimate bounds of the state's police power. The ECCPL therefore violates the South Carolina Constitution, and summary judgment should be granted in Plaintiff's favor.

III. The ECCPL Lacks A Rational Relationship To Patient Health And Thereby Violates Both Due Process And Equal Protection.

The best either Defendants or Defendant-Intervenor can muster in defense of the ECCPL is to say that comprehensive eye-health examinations are good, and that certain diseases of the eye can be detected in the course of such examinations. But that rationale simply has no connection to the ECCPL, which: (1) requires prescriptions to be renewed annually (even though the relevant ophthalmological guidelines do not call for comprehensive eye-health exams on an annual basis); and (2) in any event, does not require ophthalmologists to conduct in-person examinations at all—only that some information (any information) be collected by a human (any

[78] *See id.*, Ex. 17 at ¶ 1 (SCOPA interrogatory response asserting that "[c]ertain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination").

[79] *See id.*, Ex. 11 at 54:22–55:7, 55:9–56:1 (Coleman admitting that Defendants have no evidence that the ECCPL actually protects the public health or safety); *id.*, Ex. 4 at 2 (American Academy of Ophthalmology policy statement); *see also* Chaum Aff. at ¶ 4.

human) who then reports that information to the ophthalmologist. This falls far short of the kind of genuine relationship to public health and safety that South Carolina courts consistently demand under the South Carolina Constitution's due-process and equal-protection guarantees.

A. The ECCPL lacks a reasonable relationship to patient health and thereby violates due process.

The South Carolina Supreme Court has recently clarified that the standard for reviewing all substantive-due-process challenges to state statutes is: "Whether it bears a reasonable relationship to any legitimate interest of government." *Boardman*, 338 S.C. at 478, 527 S.E.2d at 765. This makes sense, because the whole point of substantive due process is to protect against arbitrary deprivations of life, liberty, and property. *Worsley Cos. v. Town of Mount Pleasant*, 339 S.C. 51, 56, 528 S.E.2d 657, 660 (2000). While the threshold is not high in rational-basis cases, it nonetheless demands a genuine inquiry into how a law actually operates: Unlike federal courts, which sometimes reach for any *conceivable* justification, South Carolina courts consistently look to see whether laws have *plausible* justifications. *Joseph*, 417 S.C. at 452, 790 S.E.2d at 771 (plurality opinion); *see also Lurey v. City of Laurens*, 265 S.C. 217, 222, 217 S.E.2d 226, 228 (1975) (principle of avoiding judicial lawmaking "does not suggest that this Court should abdicate its obligation to closely scrutinize legitimate constitutional questions").

In practice, this means requiring that the relationship between a law and its purported end have at least some basis in fact, and rejecting mere speculation as a substitute for that relationship. *See, e.g.*, *Retail Servs.*, 419 S.C. at 475–76, 799 S.E.2d at 668 (plurality opinion) (striking down law limiting owner to three retail liquor licenses absent record evidence of alleged safety concerns); *Joseph*, 417 S.C. at 452–53, 790 S.E.2d at 771–72 (rejecting employment and referral restriction on physical therapists and surgeons because appellants failed to articulate basis for law rooted in actual benefits to patients); *Kirven*, 409 S.C. at 43, 760 S.E.2d at 801

(striking down retroactive application of statutory definition to existing insurance contracts absent showing that actual language of definition addressed some important societal problem); *G-H Ins. Agency*, 278 S.C. at 248–49, 294 S.E.2d at 340 (rejecting law forbidding auto-insurance providers from terminating agents where experience revealed that provision lacked tailoring that should have been obvious given purpose of law); *McCoy*, 193 S.C. 390, 8 S.E.2d at 907–09 (striking down petroleum-vehicle restrictions for lack of real connection to actual dangers involved in handling petroleum despite recitation of protective purpose in preamble); *Orangeburg*, 181 S.C. 143, 186 S.E. at 785 (rejecting ordinance banning door-to-door solicitation where appellant offered testimony to effect that solicitation was harmless and ordinance lacked tailoring to valid public health concern despite numerous less-restrictive alternatives).

The thrust is that under the South Carolina Constitution, where the evidence reveals no tendency in a law to serve its purported purpose, and there appear to be obvious means by which it might have done so, that law is arbitrary and cannot survive even rational-basis review.

Joseph is again illustrative. There, the question was whether a statutory interpretation that banned physicians from employing and referring patients to physical therapists was rationally related to the goal of protecting patients and state-sponsored programs from conflicts of interest. *Joseph*, 417 S.C. at 443–46, 790 S.E.2d at 766–68. The Court observed that if the statute were actually intended to do that, it would have prevented referral-for-pay situations. *Id.* at 452, 790 S.E.2d at 771. Instead, all it did was "deprive[] physicians of their right to practice medicine in the best interests of their patients." *Id.*, 790 S.E.2d at 771. The Court found the interpretation arbitrary and, therefore, unconstitutional. *Id.* at 453, 790 S.E.2d at 771–72. Similarly, in *Retail Services*, the Court was not persuaded by the fact that (as the dissent noted)

the challenged statute's protectionist justifications were "listed *after* several non-protectionist motives, such as promoting temperance by discouraging business practices that promote alcohol consumption." *Retail Servs.*, 419 S.C. at 480, 799 S.E.2d at 670 (dissenting opinion). These notional rationales, the plurality noted, were simply "not supported by the record below." 419 S.C. at 475, 799 S.E.2d at 668.

Similarly, here, the challenged law can be supported only by hypothetical rationales, not by record evidence of how it actually addresses patient safety. Just like the statutory interpretation in *Joseph*, which deprived physicians of the right to practice in the best interests of their patients, the ECCPL deprives South Carolina-licensed ophthalmologists from using their medical judgment to write corrective-lens prescriptions for patients who need them.[80] Defendant-Intervenor admits that there is real patient demand for more convenient and affordable access to updated corrective-lens prescriptions, and that Opternative's Technology would help meet this demand.[81] Even Michael Zolman, who led SCOPA's efforts to pass the ECCPL, concedes that in some circumstances updating a corrective-lens prescription without first conducting a comprehensive eye-health examination neither violates the standard of care nor endangers patient health, but instead can actually *improve* patients' quality of life.[82] And the South Carolina-licensed ophthalmologists who have exercised their medical judgment to use Opternative's Technology in appropriate cases obviously agree.[83]

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[80] *See* Chaum Aff. at ¶ 3.

[81] *See* Windham Aff., Ex. 2 at 153 (Zolman asking rhetorically "how many patients do we see daily who really come in just wanting a new prescription for glasses and/or contacts?" and remarking that online refractive technology would "allow them to get what they want"); *see also, e.g.*, Bodde Aff. at ¶ 10; Chaum Aff. at ¶ 4.

[82] *See* Windham Aff., Ex. 1 at 32:8–33:14, 47:5–48:3.

[83] *See* Chaum Aff. at ¶¶ 2, 4.

Moreover, just as there was an obvious means by which the statute in *Joseph* could have addressed the government's purported concern, there are numerous simple ways that the ECCPL could have addressed the "diseases-might-be-missed" issue if that were truly the law's motivating concern (which it was not). As explained above, the ECCPL requires valid corrective-lens prescriptions to: (1) expire annually; and (2) be based on an eye examination that includes (a) a written or electronic medical history, (b) an assessment of the patient's visual acuity (including refractive error), *plus* (c) some additional "medical findings." *See generally* S.C. Code Ann. §§ 40-24-10 and 40-24-20.

But the ECCPL fails to specify *which* medical findings must be made, *how*, or even *by whom*. The law could have required that they be made during an in-person, comprehensive eye-health exam—it does not.[84] It could have required ophthalmologists to physically examine patients for certain ocular-pathological risk factors before writing prescriptions—it does not.[85] It could have even required ophthalmologists to take particular medical facts into account before writing prescriptions—it does not.[86] It does not require these things because for most people, annual comprehensive eye-health exams are unnecessary, and South Carolina law relies on ophthalmologists (like other doctors) to exercise their medical judgment on a case-by-case basis—*unless* the ophthalmologist is using computerized technology.

Instead of requiring that a doctor conduct a particular test or search for particular diseases, all the ECCPL requires is that a doctor writing a corrective-lens prescription rely on

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[84] *See* Windham Aff., Ex. 11 at 65:17–65:23 (Coleman admitting that "the ECCPL leaves it to an ophthalmologist's professional judgment exactly what diagnostic methodologies and exactly what medical information he needs before writing a prescription").

[85] *See id.* at 64:16–65:2 (Coleman explaining that the ECCPL has "no explicit requirement" regarding tests that must be performed before writing a corrective-lens prescription).

[86] *See id.* at 65:4–65:16 (Coleman admitting that the ECCPL "doesn't identify diagnostic methodologies that have to be employed in order to develop the medical findings" or even "specify what those medical findings must be").

information collected by a human being instead of an automated device.[87] Unsurprisingly, Defendant-Intervenor has failed to produce any evidence that restricting ophthalmologists' medical judgment in this way—and *only* in this way—actually protects patient health, and Defendants outright admit they have none.[88] By contrast, the impact on SCOPA's members' economic well-being is obvious: Opternative's Technology is automated, and it is therefore banned.[89]

In short, just like in *Joseph* and the numerous other cases cited above, there is no evidence here that the ECCPL furthers a public health or safety purpose. The law hinders patient health by preventing ophthalmologists from using innovative technology to write corrective-lens prescriptions—prescriptions their patients want—when their medical judgment indicates that such prescriptions are appropriate and within the ophthalmological standard of care. And it lacks any of the obvious tailoring that would be expected of a law actually designed to address the "diseases-might-be-missed" justification. Accordingly, the ECCPL is arbitrary, does not bear a reasonable relationship to patient health, and cannot stand under the Article I, Section 3's guarantee of due process.

B. The ECCPL lacks a fair and substantial relationship to patient health and thereby violates equal protection.

The basic mandate of equal protection is that government classifications must be "reasonable, not arbitrary, and must rest upon some ground of difference having a fair and substantial relation to the object of the legislation, so that all persons similarly circumstanced shall be treated alike." *Harbit v. City of Charleston*, 382 S.C. 383, 396, 675 S.E.2d 776, 783 (Ct.

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[87] *See id.* at 67:14–67:18 (Coleman explaining that the ECCPL imposes "some expectation that there will be some type of human involvement").

[88] *See id.*, Ex. 11 at 54:22–55:7, 55:9–56:1 (Coleman admitting that Defendants have no evidence that the ECCPL actually protects the public health or safety)

[89] *See* Bodde Aff. at ¶¶ 6, 12–13; Chaum Aff. at ¶¶ 2–3.

App. 2009) (citation omitted). Should the Court decide to credit SCOPA's spurious "diseases-might-be-missed" justification, therefore, equal protection still demands that any classifications drawn by the ECCPL bear a fair and substantial relationship to that end. As in the substantive-due-process context, while this is not a heavy burden, it does still require that classifications find their basis in *facts*, not fancy. *Daniel v. Cruz*, 268 S.C. 11, 14, 231 S.E.2d 293, 294 (1977) ("If there is no *real* difference between localities, persons, occupations, or property, the State cannot make one." (emphasis added) (citation omitted)).

Indeed, it is only when such facts support the classification as a reasonable means of achieving the asserted end that the relationship between the two can be called "fair and substantial," and courts in this state have no trouble recognizing when no such relationship exists. *See, e.g.*, *Joseph*, 417 S.C. at 452, 790 S.E.2d at 771 (plurality opinion) (law prohibiting physicians from employing physical therapists and referring patients to them was not calculated to further asserted end); *Hanvey v. Oconee Mem'l Hosp.*, 308 S.C. 1, 5, 416 S.E.2d 623, 626 (1992) (law lacked rational basis for distinguishing between charitable hospitals and other medical providers for purposes of limiting liability); *Broome v. Truluck*, 270 S.C. 227, 230–31, 241 S.E.2d 739, 740 (1978) (law lacked rational basis for drawing statute-of-limitations distinctions for recovery against various professionals whose work involved designing improvements to real estate); *Daniel*, 268 S.C. at 14, 231 S.E.2d at 294 (law prohibiting practice of fortunetelling in some counties but not others was not based on any real difference between fortunetellers); *Gasque, Inc. v. Nates*, 191 S.C. 271, 2 S.E.2d 36, 44 (1939) (law imposing maximum-hours caps on certain manufacturing and mercantile establishments but not others was not based on any material differences between such establishments).

The ECCPL draws two clear classifications. First, the law penalizes South Carolina-licensed ophthalmologists who use their medical judgment to write corrective-lens prescriptions based on "medical findings" generated automatically, but does not penalize ophthalmologists who base prescriptions on precisely the same information, *some* of which was collected manually by a human being. *See generally* S.C. Code Ann. §§ 40-24-10 and 40-24-20. Second, the law forbids South Carolina-licensed ophthalmologists from using telehealth technologies to provide services according to their medical judgment and within the relevant standard of care, while all other South Carolina-licensed physicians are statutorily permitted to do just that. *See* S.C. Code Ann. § 40-47-37. The question for both is whether the classification bears a fair and substantial relationship to the "diseases-might-be-missed" justification.

As for the first, *Daniel* is instructive. There, a statute prohibiting licensed fortunetellers from practicing in one county while allowing them to practice in the other state counties was challenged under Article I, Section 3. *Daniel*, 268 S.C. at 13–14, 231 S.E.2d at 294. Relying on the principle that "[i]f there is no real difference between localities, persons, occupations, or property, the State cannot make one," the South Carolina Supreme Court found no rational basis for the classification and struck it down as an equal-protection violation. *Id.*, 231 S.E.2d at 294 (citation omitted).

Similarly here, there is no "real difference" between information collected manually by a human being and the *same* information when collected automatically. The ECCPL would allow South Carolina-licensed ophthalmologists to use Opternative's Technology to write corrective-lens prescriptions based on information collected by a physical person who manually recorded

patients' responses using, say, a clipboard.[90] But the same prescription based on the same information would be banned if the ophthalmologist received that information directly from Opternative's Technology, over the Internet.[91] Information does not become tainted simply because it was generated automatically, and there is no valid health or safety reason to pretend that it does.

As for the second classification, *Joseph* is again instructive. There, a statute was interpreted to prohibit physicians from employing and referring patients to physical therapists, despite the fact that physicians were generally allowed to do so for all other types of healthcare professionals. *Joseph*, 417 S.C. at 442–43, 790 S.E.2d at 766–67. The government claimed the classification was intended to protect patients and government-sponsored programs from conflicts of interest, but the Court observed that "the PTs stand alone in South Carolina," *id.* at 442–43, 790 S.E.2d at 767, and found the distinction "arbitrary and not calculated to avoid the legislative purpose," *id.* at 452, 790 S.E.2d at 771. That classification violated equal protection, too. *Id.*, 790 S.E.2d at 771.

Just like the physical therapists in *Joseph*, ophthalmologists "stand alone" in South Carolina as the *only* physicians forbidden from using telehealth technologies to provide services according to their medical judgment and within the relevant standard of care. *See generally* S.C. Code Ann. §§ 40-24-10 and 40-24-20. All other South Carolina-licensed physicians are statutorily permitted to do so without running afoul of the "diseases-might-be-missed" concern in their respective practice areas. *See id.* § 40-47-37. And neither Defendants nor Defendant-

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[90] *See* Defs.' Mot. Summ. J. 9 ("[A] South Carolina-licensed ophthalmologist may still use Opternative's technology to assist him or her in making a determination to write a prescription for spectacles or contact lenses. He or she simply cannot solely base the prescription on the refractive eye error of the human eye or be generated [sic] by a kiosk.").

[91] *See* Windham Aff., Ex. 11 at 67:14–67:18 (Coleman explaining that the ECCPL imposes "some expectation that there will be some type of human involvement").

Intervenor have produced any evidence of the sort of "real difference" between ophthalmologists and all other physicians that would warrant singling the former out for disparate treatment.

In sum, SCOPA contends that the ECCPL is designed to prevent certain diseases of the eye from going undetected. But the record is utterly devoid of evidence that would help to explain how either of the two distinctions discussed above alleviate that concern. The argument for the ECCPL seems to boil down to: "If Opternative is banned, then patients will need to see their optometrists more frequently—where, perhaps, they will receive comprehensive eye-health exams." While that sort of purely speculative argument may have carried the day in *Lee Optical*, it is not the stuff of which "fair and substantial" relationships are made. The South Carolina Constitution, equal protection, and common sense demand more.

CONCLUSION

The ECCPL is a purely protectionist law that bears no rational relationship to patient health or safety, which violates both the due-process and equal-protection guarantees of the South Carolina Constitution. Plaintiff therefore respectfully requests this Court to issue an Order granting summary judgment for Plaintiff on both claims, declaring the ECCPL unconstitutional, and permanently enjoining Defendants from enforcing that law.

[*SIGNATURE PAGE ATTACHED*]

Respectfully submitted,

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September 6, 2017.

Opternative, Inc. v. S.C. Board of Medical Examiners et al.
(Civil Action No. 2016-CP-40-06276)

Affidavit of Daniel Bodde in Support of Opternative, Inc.'s Motion for Summary Judgment

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND	IN THE COURT OF COMMON PLEAS FIFTH JUDICIAL CIRCUIT
Opternative, Inc., Plaintiff, vs. South Carolina Board of Medical Examiners, and South Carolina Department of Labor, Licensing, and Regulation, Defendants, and South Carolina Optometric Physicians Association, Defendant-Intervenors.	Civil Action No. 2016-CP-40-06276 **AFFIDAVIT OF DANIEL BODDE**

RICHLAND CO.
FILED
2017 SEP -6 PM 4:03
JEANNETTE W. McBRIDE
C.C.P. & G.S.

I, Daniel Bodde, having been duly sworn, depose and say:

1. My name is Daniel Bodde. I am over eighteen years of age, and I am competent to testify as to the matters contained herein. The information below is based on my own personal knowledge and experience.

2. I am (and at all times relevant to this affidavit have been) the Chief Marketing Officer for Plaintiff Opternative, Inc. ("Opternative"), and in that capacity I have personal knowledge of Opternative's history, its operations, and its Technology. Throughout this

affidavit, references to Opternative's Technology are references to the Technology as it existed when this case was filed on October 24, 2016.

3. Opternative is a healthcare-technology company that offers qualifying customers the ability to obtain a corrective-lens prescription from the comfort of their own homes using a smart phone and a computer. Specifically, Opternative allows customers to obtain a first-time prescription for eyeglasses, to renew or update their previous prescription for eyeglasses, or to renew or update their previous prescription for contact lenses.

4. Opternative was founded in 2012 out of the sincere belief that corrective-lens prescriptions should be affordable and accessible for everyone. The company was founded by Steven Lee, a practicing optometrist who had conducted over 20,000 refractive tests. Steven's experience was that the traditional, brick-and-mortar model for obtaining corrective-lens prescriptions was needlessly inconvenient and expensive for patients—especially those just looking to renew or update their previous prescriptions. The company knew there must be a way for patients to obtain that simple care without having to physically travel to an optometrist's office every single time they wanted a new prescription.

5. Traditional, brick-and-mortar refractive tests rely on patient-self reporting: An individual sits in a chair and reports to the administering optometrist or ophthalmologist what they perceive as they are shown a series of images using a phoropter (a mechanical device that switches multiple lenses in front of a patient's eyes). Traditional refractive tests are subjective, in that they rely on the patient's self-reporting what they see, as distinct from objective tests that physically measure the patient's eyes.

6. Opternative's Technology relies on the same subjective, self-reporting principle as traditional refractive tests. The way our Technology works is that customers start by visiting the Opternative website and providing detailed information about their existing prescription and relevant medical history. The Technology then prompts customers with a series of written and audio questions that guide them through a vision assessment. Customers next view various individually-calibrated images on a computer screen and use a smartphone to self-report subjective responses to what they perceive. The Technology then automatically records those responses and compiles refractive data which, together with the customer's previous-prescription and medical-history information, the Technology electronically sends to a state-licensed ophthalmologist.

7. Importantly, Opternative's users are *not* guaranteed a prescription: Ophthalmologists are medical doctors who specialize in total eye care, which includes not only corrective-vision and ocular-pathological care, but also overall eye-health assessments and surgeries. Accordingly, the ophthalmologists who review the information generated by our Technology only write prescriptions where, in their *medical judgment*, it would be appropriate to do so.

8. Opternative also imposes front-end screening requirements to filter out people for whom ophthalmologists will not write prescriptions based on the Technology: Only otherwise-healthy customers between the ages of 18 and 50 are eligible for a prescription, and customers are prohibited from using Opternative's Technology four years in a row without first certifying that they have received a comprehensive eye-health examination. Both before and after customers use the Technology, they are made aware of the fact that it is not a comprehensive

eye-health examination: Messages to that effect, which also reinforce the importance of periodic comprehensive eye-health examinations, are included on Opternative's website, in the Terms and Conditions a customer must accept when using the Technology itself. If a participating ophthalmologist decides that, in his medical judgment, it would not be appropriate for him to write a prescription based on the information collected by Opternative's Technology, we also provide the non-qualifying customer with contact information for local eye care professionals who can conduct an in-person examination.

9. We also display the following notice on our website at www.opternative.com:

> Opternative **is not a replacement** for a comprehensive eye examination. Our licensed Ophthalmologists use Opternative's on-line technology to evaluate a patient's visual acuity and a portion of the ocular health profile, diagnose refractive error, and issue a prescription for corrective eyewear, where clinically appropriate. Our services are limited to patients between the ages of 18 and 50 who are in good health. All examinations are conducted and all prescriptions are issued based on the independent clinical judgment of an ophthalmologist. Because our services are not a replacement for an eye health examination, we encourage everyone to obtain a comprehensive eye health exam at least once every 2 years. We prohibit patients from taking an Opternative exam more than 4 consecutive years without certifying that they have received a comprehensive eye health exam first. If you need helping finding an eye care professional near you, please contact us at info@opternative.com.

10. Since our Technology officially went live in 2014, we have experienced a genuine demand for our services. Opternative now successfully operates in 39 states, has helped tens of thousands satisfied customers obtain corrective-lens prescriptions they needed, and would like to expand access to care in South Carolina, too.

11. In fact, prior to the passage of the "Eye Care Consumer Protection Law" (ECCPL) in May of 2016, Opternative *was* successfully operating in South Carolina, and many

South Carolinians actually *did* receive corrective-lens prescriptions from a South Carolina-licensed ophthalmologist who used his medical judgment to write a prescription based on information generated by our Technology.

12. But Opternative's understanding was (and still is) that the ECCPL forbids South Carolina-licensed ophthalmologists from writing corrective-lens prescriptions based solely on information electronically compiled by automated testing devices, including Opternative's Technology. Insofar as Opternative's Technology automatically records users' responses (rather than having those responses written down by a human being), our understanding (and the understanding of all the South Carolina-licensed ophthalmologists we were in contact with) was that the ECCPL barred the use of Opternative's Technology to write prescriptions.

13. Thus, immediately after the passage of the ECCPL, South Carolina-licensed ophthalmologists refused to write prescriptions based on Opternative's Technology, and Opternative was unable to find ophthalmologists willing to risk violating the law and potentially incurring penalties or even losing their license, as a result. Because ophthalmologists' willingness to use information generated by our Technology to write corrective-lens prescriptions is at the core of our business model, Opternative was forced to cease operations in South Carolina.

14. However, Opternative is currently in contact with South Carolina-licensed ophthalmologists who would continue using our Technology to write corrective-lens prescriptions (according to their medical judgment) if the barrier of the ECCPL were removed. The ECCPL is thus the only thing standing between Opternative and continued operations in

South Carolina. In the absence of the ECCPL—or should it be struck down in this case—Opternative would immediately continue operating in South Carolina.

FURTHER AFFIANT SAYETH NOT.

Daniel Bodde

SWORN to and subscribed before me

)

This 1 day of September, 2017

DIANE C SUM
NOTARY PUBLIC - MINNESOTA
My Commission Expires Jan. 31 2022

Notary Public for the State of Minnesota

My Commission Expires: 01/31/22

Opternative, Inc. v. S.C. Board of Medical Examiners et al.
(Civil Action No. 2016-CP-40-06276)

Affidavit of Edward Chaum, MD in Support of Opternative, Inc.'s Motion for Summary Judgment

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND	)	IN THE COURT OF COMMON PLEAS FIFTH JUDICIAL CIRCUIT
Opternative, Inc., Plaintiff, vs. South Carolina Board of Medical Examiners, and South Carolina Department of Labor, Licensing, and Regulation, Defendants.	)	Civil Action No. 2016-CP-40-06276 **AFFIDAVIT FOR EDWARD CHAUM, MD**

RICHLAND COUNTY FILED
2017 SEP -6 PM 4:04
JEANNETTE W. MCBRIDE C.C.P. & G.S.

I, Edward Chaum, MD, having been duly sworn, depose and say:

1. My name is Edward Chaum. I am over eighteen years of age, and I am competent to testify as to the matters contained herein. The below information is based on my own personal knowledge and experience.

2. I am a South Carolina-licensed ophthalmologist. Prior to May 2016, I used information electronically compiled by the online service "Opternative" to assist me in providing prescriptions for corrective lenses for multiple individual patients.

3. South Carolina's "Eye Care Consumer Protection Law" (ECCPL) went into effect in May of 2016. My understanding was and is that the ECCPL forbids South Carolina-licensed ophthalmologists from writing prescriptions for glasses and contact lenses based on information electronically compiled by services like Opternative. Once the ECCPL went into effect, I promptly stopped using Opternative's technology for this purpose and do not currently provide prescriptions for corrective lenses or contact lenses in South Carolina.

4. In my personal and professional opinion, Opternative's technology providing online subjective refractions has been validated in broad clinical use across the country and provides meaningful access to personalized refractive care for appropriately selected patients. The development, maturation, and validation of these types of new technologies for patient-centered access and care are actively supported in written opinions by my professional society, the American Academy of Ophthalmology Should the law in South Carolina change to permit their use for the benefit of patients in the state, I would support the reintroduction of this and other similar technologies to improve patient access for their refractive needs

FURTHER AFFIANT SAYETH NOT.

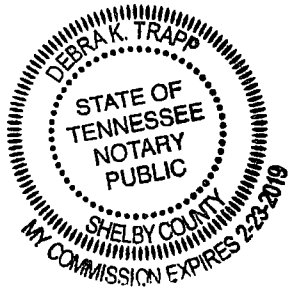
Edward Chaum, MD PhD

SWORN to and subscribed before me

This 31st day of ~~July~~ August, 2017

Notary Public for the State of Tennessee

My Commission Expires: 2/23/19



(First) Affidavit of Joshua Windham (and Exhibits)

Originally attached to Plaintiff's (First) Motion for Summary Judgment and can be found in the Record on Appeal at pages 676-935

(All exhibits that were attached to this Affidavit were also attached to the Affidavit submitted with Plaintiffs' Response to SCOPA's Motion for Summary Judgment, with the exception of the Haley Veto Statement, which can be found at https://tinyurl.com/a7w4kfdy)

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND	IN THE COURT OF COMMON PLEAS FIFTH JUDICIAL CIRCUIT
Opternative, Inc., Plaintiff, vs. South Carolina Board of Medical Examiners, and South Carolina Department of Labor, Licensing, and Regulation, Defendants, South Carolina Optometric Physicians Association, Defendant-Intervenor.	Civil Action No. 2016-CP-40-06276 **PLAINTIFF'S BRIEF IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

This case concerns an attempt by one group of medical professionals to use the power of government to prevent another group of medical professionals from exercising their medical judgment to rely on innovative technology that expands access to care. Plaintiff Opternative, Inc., ("Opternative") has developed an online refractive test and software ("Technology") that allows customers to renew or update their corrective-lens prescriptions from the comfort of their own homes using a smartphone and a computer. South Carolina-licensed ophthalmologists were actively using that Technology to write prescriptions for patients who needed them. But last year, the South Carolina Optometric Physicians Association (SCOPA)—a group of licensed optometrists whose brick-and-mortar business model depends on selling patients expensive eyeglass frames in their offices—launched an aggressive lobbying campaign to pass legislation specifically designed to prevent licensed ophthalmologists from using Opternative's Technology.

SCOPA succeeded: The Eye Care Consumer Protection Law (ECCPL) prohibited Opternative's ongoing business activities, caused South Carolina-licensed ophthalmologists to refuse to continue working with Opternative, and forced the business to shut down operations in South Carolina—all while doing literally nothing to protect the public health or safety. Plaintiff has challenged that law as a violation of its due-process and equal-protection rights under Article I, Section 3 of the South Carolina Constitution, and Defendants Department of Labor, Licensing, and Regulation (LLR) and Board of Medical Examiners (BME) have moved for summary judgment, arguing that that Plaintiff lacks standing and that the ECCPL is supported by a rational basis.[1]

[1] Plaintiff has also separately moved for summary judgment in its favor. *See generally See* Pl.'s Mot. Summ. J.

That motion should be denied because, as explained more fully below, Defendants are incorrect on both fronts. First, Plaintiff has standing because: (1) before the ECCPL passed, Plaintiff was operating in South Carolina and South Carolina-licensed ophthalmologists were using its Technology; (2) after the ECCPL passed, Plaintiff ceased operations in South Carolina because South Carolina-licensed ophthalmologists could no longer use its Technology; and (3) if this Court rules in favor of Plaintiff in this action, Plaintiff (and at least some South Carolina-licensed ophthalmologists) will resume their past business practices in South Carolina. Second, the summary-judgment record shows that the ECCPL fails constitutional scrutiny under the South Carolina Constitution because it is a purely protectionist law that is not reasonably related to protecting the public health or safety. For these reasons, Defendants' Motion for Summary Judgment should be denied, and Plaintiff's Motion for Summary Judgment should be granted.

STATEMENT OF FACTS[2]

The record in this case tells a simple, undisputed story: Opternative developed Technology that allowed patients to take an online vision test and connect remotely with an ophthalmologist, who would review the patient's medical information and write a prescription for corrective lenses if, in his medical judgment, it would be safe to do so. But South Carolina optometrists felt that their brick-and-mortar business model was threatened by that Technology, and pushed the Eye Care Consumer Protection Law to shut Opternative down. That law does nothing to promote the public health or safety, though, and does only what it was actually

[2] As noted above, Plaintiff has filed its own Motion for Summary Judgment with supporting evidence. In the interest of judicial economy, Plaintiff has not re-filed its supporting evidence along with this Motion; that evidence is hereby incorporated by reference. What follows is a brief summary of that evidence designed to provide context for discussion of Defendants' Motion while limiting repetition of the fuller discussion contained in Plaintiff's Motion for Summary Judgment. *See* Pl.'s Mot. for Summ. J. at 2–19.

designed to do: ban Opternative's Technology in order to protect brick-and-mortar optometrists' profits.

I. Opternative's Automated Technology Disrupts Optometrists' Brick-And-Mortar Business Model.

Optometrists are limited-practice eye-health professionals who specialize in corrective-vision and certain ocular-pathological care.[3] Most optometrists operate on a brick-and-mortar business model that depends heavily for appointments on patients seeking corrective-lenses.[4] Traditionally, that model has been successful because it has only been possible to determine an appropriate prescription through an in-person vision test: To generate an appropriate prescription, an optometrist instructs the patient to sit in a chair and view certain projected images through various lenses while they self-report their subjective responses—e.g., reporting whether a lens makes an image "better" or "worse."[5] The optometrist physically cycles through the lenses and records patients' responses in an effort to measure what is called the eye's refractive error, which the optometrist then uses to write an appropriate corrective-lens prescription.[6] At the conclusion of each appointment, it is common practice for optometrists (or

[3] *See* Affidavit of Joshua Windham in Support of Opternative, Inc.'s Motion for Summary Judgment (Windham Aff.), Ex. 1 at 9:2–9:18.

[4] *See id.* at 9:25–11:3 (South Carolina-licensed optometrist Michael Zolman admitting that half of his daily appointments come from patients seeking corrective-lens prescriptions and that his practice model is "fairly typical").

[5] SCOPA Ans. ¶ 14; *see also* Windham Aff., Ex. 1 at 35:25–36:9, 36:13–37:7, 37:12–38:7 (Zolman explaining how optometrists use a phoropter to generate a patient's corrective-lens prescription).

[6] SCOPA Ans. ¶ 14; *see also* Windham Aff., Ex. 1 at 36:10–36:12, 36:13–36:23, 38:14–38:17 (Zolman explaining that optometrists rely on subjective refractive information based on patient's responses to projected images to generate a patient's corrective-lens prescription). "Refractive" in this context refers to how light bends in a person's eye. *See id.* at 34:21–35:3.

office staff) to lead patients to a display room and attempt to sell them expensive eyeglass frames.[7]

Opternative's Technology disrupts that business model by allowing people to conduct the self-reporting part of the eye exam from the comfort of their own home.[8] Using Opternative's Technology is straightforward: Customers start by visiting the Opternative website and providing detailed information about their existing prescription and relevant medical history.[9] The Technology then prompts customers with a series of written and audio questions that guide them through a vision assessment.[10] Customers next view various individually calibrated images on a computer screen and use a smartphone to self-report subjective responses to what they perceive.[11] Opternative's Technology then records those responses and sends all of the collected information (from both the vision assessment and the personal- and medical-history questions) to a state-licensed ophthalmologist for review.[12]

Ophthalmologists are medical doctors who specialize in total eye care, including not just vision correction but overall eye health and surgical interventions.[13] Licensed ophthalmologists in states across the country (including, until last year, South Carolina) have successfully used

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[7] *See id.* at 65:5–66:15 (Zolman admitting that optometrists attempt post-appointment eyeglass sales "most of the time").

[8] *See* Affidavit of Daniel Bodde in Support of Opternative, Inc.'s Motion for Summary Judgment (Bodde Aff.) at ¶¶ 3–6; Windham Aff., Ex. 1 at 66:16–67:9 (Zolman admitting that his revenue from eyeglass sales "would go down" if online refractive tests like Opternative's Technology ever became commercially popular).

[9] *See* Bodde Aff. at ¶ 6.

[10] *See id.*

[11] *See id.*

[12] *See id.*; Affidavit of Edward Chaum, MD, in Support of Opternative, Inc.'s Motion for Summary Judgment (Chaum Aff.) at ¶ 2.

[13] SCOPA Ans. ¶¶ 9, 11; Bodde Aff. at ¶ 7.

information generated by Opternative's Technology to write prescriptions for patients when, in their medical judgment, such a prescription is appropriate.[14] But ophthalmologists have not always determined a prescription is appropriate, and Opternative users are never guaranteed a prescription.[15] Opternative's Technology is not a replacement for a comprehensive eye-health examination (a fact of which Opternative's users are repeatedly reminded), and ophthalmologists reviewing information generated by Opternative's Technology always have (and have frequently exercised) the option to refuse to write a prescription and instead refer a particular user to a local eye-health practitioner for a full in-person examination.[16] A reviewing ophthalmologist can refuse to write a prescription for any reason, including particular factors revealed in a patient's medical history, particular indications from a patient's responses to the eye exam, or simply the length of time since a patient last saw an ophthalmologist in person.[17] Indeed, Opternative imposes front-end screening requirements to filter out people for whom ophthalmologists generally decline to write prescriptions based on the Technology: Only otherwise-healthy customers between the ages of 18 and 50 are eligible for a prescription, and customers are prohibited from using Opternative's Technology four years in a row without first certifying that they have received a comprehensive eye-health examination.[18]

Opternative's Technology expands access to care: There is real patient demand for more convenient and affordable access to renewed or updated corrective-lens prescriptions.[19] And

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[14] *See* Chaum Aff. at ¶ 2; Bodde Aff. at ¶ 11.

[15] *See* Bodde Aff. at ¶ 7.

[16] *See id.* at ¶¶ 7–9.

[17] *See id.* at ¶¶ 7–8.

[18] *See id.* at ¶¶ 8–9.

[19] *See id.* at ¶ 10; Chaum Aff. at ¶ 4; Windham Aff., Ex. 2 at 153 (Zolman asking rhetorically "how many patients do we see daily who really come in just wanting a new prescription for

prior to the enactment of the ECCPL, South Carolina-licensed ophthalmologists successfully used Opternative's Technology to write or renew prescriptions in appropriate circumstances.[20] But allowing qualified patients to avoid in-person visits when they were not medically necessary was a threat to the business model of optometrists who rely on in-person visits to bolster their retail business selling glasses and contacts.[21] These optometrists sought (and obtained) economic protection from the legislature.[22]

II. Optometrists Drafted And Lobbied For The ECCPL To Protect Their Brick-And-Mortar Business Model From Competition By Opternative's Automated Technology.

The threat Opternative's Technology poses to the commercial viability of brick-and-mortar optometry shops has not gone unnoticed. The American Optometric Association—a national association of optometrists devoted to the promotion of the optometric profession—distributed a model bill to affiliates in 2015 to stop Opternative from operating in states across the country.[23] One such affiliate, the South Carolina Optometric Physicians Association—Defendant-Intervenor here—adapted that bill and waged an aggressive lobbying campaign to get

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glasses and/or contacts?" and remarking that online refractive technology would "allow them to get what they want").

[20] *See* Chaum Aff. at ¶ 2; Bodde Aff. at ¶ 11.

[21] SCOPA Ans. ¶ 20; *see* Windham Aff., Ex. 1 at 66:16–67:9 (Zolman admitting that his revenue from eyeglass sales "would go down" if online refractive tests like Opternative's Technology ever became commercially popular).

[22] *See* Windham Aff., Ex. 5 at 23:13–23:15 (Rivers admitting that "the ECCPL is a bill that SCOPA passed"), 46:22–47:2 (Rivers admitting that "the bill that eventually became the ECCPL was primarily pushed by the optometrists"), 55:16–55:22 (Rivers admitting that SCOPA's "effort to pass the ECCPL [was] prompted by the existence of businesses offering online eye exams").

[23] *See id.*, Ex. 1 at 11:15–13:7 (Zolman describing the AOA's mission); *id.*, Ex. 2 at 181–93 (AOA webinar slides introducing model legislation to state affiliates).

it passed in South Carolina.[24] While e-mail communications reveal that the legislation was designed from the very start to shut Opternative down and protect the optometrists' share of the multi-billion-dollar corrective-lens industry, SCOPA maintained a strict internal policy of not focusing on Opternative in public, instead clothing the law in public-health rhetoric.[25] Nonetheless, internal emails from SCOPA show that when the Eye Care Consumer Protection Law ultimately went into effect, its members dropped the pretext and openly celebrated their success in banning Opternative.[26]

As a direct result of the ECCPL's passage, Opternative was no longer able to offer online vision tests in South Carolina, and was forced to shut down business operations in the state.[27] Before the ECCPL, Opternative had no problem operating in South Carolina, and many South Carolinians actually received corrective-lens prescriptions after a South Carolina-licensed

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[24] *See id.*, Ex. 1 at 16:4–16:21, 22:15–22:21 (Zolman describing SCOPA's mission); *id.*, Ex. 2 at 153–54 (Zolman e-mailing the SCOPA Board after attending the AOA webinar to recommend that SCOPA adapt and push the AOA's model legislation in South Carolina); *id.*, Ex. 5 at 34:17–35:2 (Rivers confirming that "[t]he original draft language [for the ECCPL] came from the American Optometric Association" and admitting that "SCOPA . . . generate[d] a draft based on that language").

[25] *Compare id.*, Ex. 8 at 469 (Rivers forwarding AOA admonition to "continue talking about patient safety"), *with id.*, Ex. 5 at 55:16–55:22, 56:6–56:11 (Rivers admitting that the ECCPL was "prompted by the existence of online eye exams" but that there were "internal discussions at SCOPA about the importance of discussing the ECCPL as if it were not an effort to ban Opternative"); *see also id.*, Ex. 13 at 1258 (Zolman e-mail to SCOPA membership explaining that "We do NOT want to make this an anti-Opternative arguement [sic] as Legislators frown upon legislation that singles out and restricts a specific business").

[26] *See id.*, Ex. 9 at 116 (Rivers e-mail to AOA during veto-override vote, exclaiming: "[T]ake that Opternative!!!!!!"); *id.*, Ex. 3 at 129 (Zolman post-veto override e-mail to SCOPA's membership boasting: "It's with the utmost pleasure to announce that today, Opternative and 'eye exam' kiosks are now **PROHIBITED BY LAW** in the great state of SC!," and "Good-bye Opternative!"); *id.*, Ex. 10 at 203 (SCOPA presentation slide portraying "The Results…" of SCOPA's efforts to get the ECCPL passed and prominently displaying the word "Opternative" with a red circle and strikethrough).

[27] *See* Bodde Aff. at ¶ 13.

ophthalmologist used his medical judgment to write a prescription based on information generated by the Technology.[28] But after the ECCPL passed, no ophthalmologist was willing to use Opternative's Technology.[29] And understandably so: The ECCPL clearly prohibits the use of Opternative's Technology because it requires corrective-lens prescriptions to be based, at least in part, on an examination by a human being (though not necessarily by the prescribing ophthalmologist).[30]

Ophthalmologists have good reason not to test the boundaries of South Carolina law. *See* S.C. Code Ann. §§ 40-1-80, 40-47-80, 40-47-110. If the South Carolina Board of Medical Examiners receives a complaint that a licensee has violated the law, that complaint triggers an investigatory process that lasts at least a year, and can result in ruinous penalties.[31] And the Board has no discretion at all to avoid enforcing the law, which means that ophthalmologists have no grounds for thinking that they would be free to use Opternative or any other Internet-based, computerized vision test, without risking their reputation and careers.[32] Understandably unable to find ophthalmologists willing to disregard the law by using its Technology, Opternative was forced to immediately cease operations in South Carolina—though it is currently in contact with South Carolina ophthalmologists who would continue using the

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[28] *See* Bodde Aff. at ¶ 11; Chaum Aff. at ¶ 2.

[29] *See* Chaum Aff. at ¶ 3.

[30] *See* Windham Aff., Ex. 11 at 67:14–67:18 (Defendants' 30(b)(6) designee Darra Coleman explaining that the ECCPL imposes "some expectation that there will be some type of human involvement").

[31] *See id.* at 10:13–15:17 (Coleman explaining procedures of lengthy case-investigation process), 19:17–19:23 (Coleman responding "No, I would not say so" and "I would not say that that would be a realistic expectation" in response to question abont whether case-investigation process could theoretically conclude in less than a year).

[32] *See id.* at 69:5–69:10 (Coleman explaining that LLR "[doesn't] have the luxury of not enforcing law").

Technology to write corrective-lens prescriptions (where medically appropriate) if the barrier of the ECCPL were removed.[33]

III. The ECCPL Bans Opternative's Technology—And That Is All It Does.

The ECCPL was intended as a ban on Opternative's Technology, rather than as a requirement that patients receive a comprehensive eye-health examination before updating or renewing their corrective-lens prescriptions. Unsurprisingly, then, the ECCPL does a very good job of banning Opternative but nothing at all to ensure that patients receive comprehensive eye-health examinations.

The ECCPL is codified at S.C. Code Ann. sections 40-24-10 and 40-24-20. The law lays out two requirements for a corrective-lens prescription:

> **To be valid, a prescription must contain an expiration date on spectacles or contact lenses of one year from the date of examination by the provider** or a statement of the reasons why a shorter time is appropriate based on the medical needs of the patient. **The prescription must take into consideration medical findings made and refractive error discovered during the eye examination.** If a provider determines a patient is a suitable candidate for a prescription for contact lenses or spectacles, a provider may not thereafter refuse to issue a prescription for spectacles or contact lenses to a patient.

Id. § 40-24-20(B) (emphasis added). It also provides that "[a] prescription for spectacles or contact lenses may not be based solely on the refractive eye error of the human eye or be generated by a kiosk." *Id.* § 40-24-20(C). An "eye examination" is further defined: To be valid, an eye examination "must not be based solely on objective refractive data or information gathered by an automated testing device." *Id.* §§ 40-24-10(3) (providing that an eye examination must include a "visual status") and 40-24-10(9) (defining a visual status).

[33] *See* Bodde Aff. at ¶¶ 13–14; Chaum Aff. at ¶¶ 3–4.

In other words, the ECCPL requires that corrective-lens prescriptions must expire annually, and they must be based at least in part on information collected by a human being. And as Defendants' 30(b)(6) designee confirmed at deposition, these are the *only* constraints the ECCPL places on an ophthalmologist's medical judgment.[34] The ECCPL does not specify what findings an ophthalmologist must make before prescribing corrective lenses.[35] It does not require an ophthalmologist to perform any particular test or to use any particular diagnostic methods before prescribing corrective lenses.[36] All it requires is that prescriptions for corrective lenses be based at least in part on some in-person, human involvement. [37] But the law does not say who the human has to be—it does not need to be the prescribing ophthalmologist (or even someone with a medical license of any kind)—and the law does not say what that involvement needs to consist of—*only that it cannot be computerized.*[38]

In short, prior to the ECCPL's passage, an ophthalmologist could use any method he wanted to determine a person's refractive error and then write a prescription so long as he was satisfied that he had enough information to write a medically appropriate prescription without further examination. After the passage of the ECCPL, an ophthalmologist can still do exactly

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[34] *See* Windham Aff., Ex. 11 at 65:17–65:23 (Coleman admitting that "the ECCPL leaves it to an ophthalmologist's professional judgment exactly what diagnostic methodologies and exactly what medical information he needs before writing a prescription").

[35] *See id.* at 65:4–65:16 (Coleman admitting that the ECCPL "doesn't identify diagnostic methodologies that have to be employed in order to develop the medical findings" or even "specify what those medical findings must be").

[36] *See id.* at 64:16–65:2 (Coleman explaining that the ECCPL has "no explicit requirement" regarding tests that must be performed before writing a corrective-lens prescription).

[37] *See id.* at 67:14–67:18 (Coleman explaining that the ECCPL imposes "some expectation that there will be some type of human involvement").

[38] *See id.* at 67:14–68:10 (Coleman explaining that it is generally within the physician's discretion to use any number of "physician extenders" and that such extenders can even include "unlicensed professionals, such as a medical assistant or a certified nurse assistant").

that—so long as he is sure he has enough information to write a medically appropriate prescription without further examination *and* as long as he is relying at least in part on information generated by a human being instead of information collected by automated software.[39] This does nothing to change the medical standard of care: Ophthalmologists can (and will) still decide what tests and examinations a particular patient needs by using their own medical judgment. But it does a very good job of banning Opternative's Technology by requiring that ophthalmologists insert a human at some point (any point) in the prescription-writing process.

This matters because not everyone who seeks a new corrective-lens prescription actually needs (or will get) a comprehensive eye-health examination. Under the ECCPL, corrective-lens prescriptions expire after only one year. S.C. Code Ann. § 40-24-20(B). But the American Academy of Ophthalmology does not recommend that most people receive comprehensive eye-health examinations on an annual basis. Instead, the American Academy of Ophthalmology recommends that otherwise-healthy people obtain at least ***one*** such examination by the time they reach 40 years old, and that otherwise-healthy people between the ages of 40 and 54 obtain one every 2–4 years. [40]

In short, there are any number of people who might need a renewed or updated corrective-lens prescription but who do not need a new comprehensive eye-health exam. Prior to the ECCPL, such people could get prescriptions (where appropriate) by using Opternative's

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[39] *See id.* at 65:17–65:23, 67:14–67:18.

[40] *See id.*, Ex. 4 at 1–2 ("Adults with no signs or risk factors for eye disease should receive a baseline comprehensive eye evaluation at age 40. Individuals without risk factors aged 40 to 54 should be examined by an ophthalmologist every 2 to 4 years."); *id.*, Ex., 1 at 47:24–48:3 (Zolman admitting that he has no reason to doubt that the American Academy of Ophthalmology's statement conveys the ophthalmological standard of care because "I'm not an ophthalmologist"); *see also* SCOPA Ans. ¶ 16.

Technology without getting a full comprehensive eye-health examination. After the ECCPL, they can still get a new prescription without a full comprehensive eye-health examination, but they must go see a human being—a human being who is not legally required to conduct any particular medical tests. That legal requirement may do a splendid job of ensuring that more people walk into brick-and-mortar shops that sell glasses, but it does essentially nothing to ensure that people get comprehensive eye-health examinations that the American Academy of Ophthalmology says they do not need.

STANDARD OF REVIEW

"Summary judgment is appropriate where the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." *Lawing v. Univar, USA, Inc.*, 415 S.C. 209, 220, 781 S.E.2d 548, 554 (2015). In conducting that analysis, "the court must view the evidence and all reasonable inferences that may be drawn from the evidence in the light most favorable to the non-moving party." *Willis v. Wu*, 362 S.C. 146, 151, 607 S.E.2d 63, 65 (2004). While there are no disputes of material fact here—indeed, Defendants' Motion relies almost exclusively on citations to the allegations of the Complaint—Defendant has failed to show that it is entitled to judgment as a matter of law, and its Motion must therefore be denied.

ARGUMENT

Defendants are not entitled to summary judgment. First, Plaintiff has standing: Undisputed record evidence shows that Plaintiff *was* operating in South Carolina prior to the ECCPL's passage, that it was forced to *stop* operating in South Carolina because of the adoption of the ECCPL, and that it *would resume* operations in South Carolina if Defendants were

enjoined from enforcing the ECCPL. That is a concrete injury redressable by this Court. Second, under the South Carolina Constitution, this Court has a duty to determine whether the record evidence demonstrates that the ECCPL bears a genuine relationship to patient health rather than being mere economic protectionism. Plaintiff has built an extensive record demonstrating that the ECCPL is related to nothing but what it was expressly designed to do: banning Opternative in order to preserve brick-and-mortar optometrists' profits. Defendants' Motion not only fails to address this record evidence, but it is also unsupported by any evidence of its own beyond bare citations to Defendant-Intervenor's interrogatory responses. For both of these reasons, Defendants' Motion must be rejected, and Plaintiff's cross-motion should be granted.

I. Plaintiff Has Standing Because The ECCPL Bans South Carolina-Licensed Ophthalmologists From Using Plaintiff's Technology.

Defendants first wrougly contend that Plaintiff lacks standing. Standing is defined as "a personal stake in the subject matter of a lawsuit." *Sea Pines Ass'n for the Prot. of Wildlife, Inc. v. S.C. Dep't of Natural Res.*, 345 S.C. 594, 600, 550 S.E.2d 287, 291 (2001). To establish standing, a plaintiff must demonstrate that: (1) the plaintiff has suffered an injury; (2) there is a causal connection between that injury and the conduct complained of; and (3) it is likely, and not merely speculative, that the injury will be redressed by a favorable decision. *Sea Pines*, 345 S.C. at 601, 550 S.E.2d at 291. Plaintiff clearly satisfies all three elements.

A. The ECCPL injures Opternative by preventing it from operating its business in South Carolina.

Standing demands an "injury in fact." *Sea Pines*, 345 S.C. at 601, 550 S.E.2d at 291. This requires "an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical.'" *Id.* (quoting *Lujan v. Defenders of*

Wildlife, 504 U.S. 559-61 (1992) (internal quotes and citations omitted)). Plaintiff meets both requirements.

1. Plaintiff's economic interests are legally protected.

The South Carolina Constitution guards against deprivations of "life, liberty, or property." S.C. Const. art. I, § 3. It is well-settled that those interests include the right to engage in a chosen occupation free from unreasonable government interference. *See Joseph v. S.C. Dep't of Labor, Licensing & Regulation*, 417 S.C. 436, 449, 790 S.E.2d 763, 770 (2016) (recognizing physical therapist's interest in practicing her profession and physicians' interest in hiring therapists like her) (plurality). One aspect of the right to engage in a chosen occupation is the overarching liberty interest a plaintiff holds in the pursuit of that occupation. *Brown v. S.C. State Bd. of Educ.*, 301 S.C. 326, 329, 391 S.E.2d 866, 867 (1990) ("The liberty interest at stake is the individual's freedom to practice his or her chosen profession."). Another aspect is the particularized property interest a plaintiff holds in the financial living earned by such pursuit. *Sloan v. S.C. Bd. of Physical Therapy Examiners*, 370 S.C. 452, 484, 636 S.E.2d 598, 615 (2006) ("'It cannot be doubted that a man's trade or profession is his property.'") (quoting *Byrne's Adminstrs. v. Stewart's Adminstrs.*, 3 S.C. Eq. 446, 479, (1812)), *overruled on other grounds by Joseph*, 417 S.C. at 452, 790 S.E.2d at 771–72. Both are economic interests, and deprivation of either constitutes an "injury in fact." Under these cases, Opternative's financial injury in being barred from South Carolina obviously counts as an "injury" to support standing.

Defendants ignore these cases, though, instead relying on *ATC S., Inc. v. Charleston Cty.*, 380 S.C. 191, 669 S.E.2d 337 (2008), to contend that mere "competitive disadvantage" is not a cognizable injury for purposes of standing.[41] But *ATC* is inapposite here: That case involved

[41] *See* Defs.' Mot. Summ. J. 8.

one cell phone-tower company's challenge to a rezoning classification that would have allowed a competing cell phone-tower company to build on a tract of land near one of the first company's towers. *ATC*, 380 S.C. at 193–94, 669 S.E.2d at 338–39. The Supreme Court found that increased business competition is not an injury, and that accordingly, the first company's lawsuit to *prevent* competition "solely to protect its own economic interests" could not proceed. *Id.* at 340.

In short, if Plaintiff were arguing that South Carolina law allowed *someone else* to operate a business to its economic detriment, this case would be controlled by *ATC*. But Plaintiff is instead arguing (and has shown with evidence) that South Carolina law prevents *it* from running its business in the state. That is *exactly* the sort of injury that the South Carolina Supreme Court has recognized as establishing standing to sue.

The evidence supporting Opternative's injury here is overwhelming and undisputed. The ECCPL was expressly designed to prohibit Opternative from operating in South Carolina.[42] As a direct result of the passage of the ECCPL, South Carolina-licensed ophthalmologists refused to use Opternative's Technology in South Carolina.[43] And rightly so, given that Defendants concede that they have no discretion to decline to enforce the ECCPL and that any allegation that

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[42] *See* Windham Aff., Ex. 7 at 501 (AOA providing state affiliates an "update on AOA actions on the Opternative issue" and promising to "make recommendations to state affiliates about suggested strategies to stop this from operating in your state"); *id.*, Ex. 1 at 54:2–54:12 (Zolman admitting that he "had Opternative in mind" when he recommended that the SCOPA Board push the AOA's model legislation); *id.*, Ex. 5 at 55:16–55:22 (Rivers admitting that SCOPA's "effort to pass the ECCPL [was] prompted by the existence of businesses offering online eye exams"); *id.*, Ex. 3 at 129 (Zolman boasting to SCOPA's membership after veto override about SCOPA's efforts to get the ECCPL passed and exclaiming that "Opternative and 'eye exam' kiosks are now **PROHIBITED BY LAW** in the great state of SC!"); *id.*, Ex. 10 at 203 (SCOPA presentation slide portraying "The Results…" of SCOPA's efforts to get the ECCPL passed and prominently displaying the word "Opternative" with a red circle and strikethrough).

[43] *See* Chaum Aff. at ¶ 3; Bodde Aff. at ¶ 13.

a licensed doctor had violated the ECCPL would trigger an investigatory process that would last *at least* a full year, with the doctor's license hanging in the balance.[44] To be sure, Defendants are right to say they have not yet enforced the ECCPL against anyone,[45] but that is because no doctor has dared to violate the law (and because Opternative, therefore, has ceased operating in South Carolina). Defendants do not suggest they will not enforce the law—indeed, they freely admit that they *must* enforce the law[46]—nor do they suggest that South Carolina's ophthalmologists acted unreasonably in abandoning Opternative. Nor could they: The ECCPL bans Opternative's Technology, which is the only reason Opternative stopped operating after the ECCPL passed.[47]

Similarly, Defendants' suggestion that Opternative could get around the ECCPL if an ophthalmologist used its Technology *in addition to* a human examination simply misses the point. Opternative's business model was allowing ophthalmologists to write prescriptions (where appropriate) without requiring an in-person visit. To suggest that the company instead offer a product that can be used while a patient is physically in a physician's office is simply to suggest that it go into a different business. But nothing in South Carolina law suggests that the ability to go into a different business obviates standing. Indeed, the physical therapists in *Joseph* could have provided their services without being employed by a physician. *See* 417 S.C. 436, 790 S.E.2d 763 (2016). The plaintiffs in *Retail Services* could have refrained from acquiring more than three liquor licenses. *See* 419 S.C. 469, 799 S.E.2d 665 (2017). The drive-in

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[44] *See* Windham Aff., Ex. 11 at 10:13–15:17 (Coleman explaining procedures of lengthy case-investigation process), 19:17–19:23 (Coleman responding "No, I would not say so" and "I would not say that that would be a realistic expectation" in response to question about whether case-investigation process could theoretically conclude in less than a year).

[45] Defs.' Mot. Summ. J. 10.

[46] *See id.* at 69:5–69:10 (Coleman explaining that LLR "[doesn't] have the luxury of not enforcing law").

[47] *See* Bodde Aff. at ¶¶ 11–14.

restaurant owner in *Painter* could have simply borne a 50-percent cut to her evening business by closing down shop after midnight each night. *See* 231 S.C. 56, 97 S.E.2d 71 (1957). But the South Carolina Supreme Court decided all of those cases on their merits, and this Court should do the same here.

2. *Destruction of Plaintiff's South Carolina business operations constitutes concrete and particularized harm.*

A plaintiff must have a "real, material, or substantial interest in the subject matter of the action." *Anchor Point, Inc. v. Shoals Sewer Co.*, 308 S.C. 422, 428, 418 S.E.2d 546, 549 (1992). It is difficult to imagine a more "concrete" injury in this sense than the deprivation of a party's actual, day-to-day business, or the past goodwill cultivated by such business, or the future earnings expected from such business—and the South Carolina Supreme Court, again, has repeatedly recognized as much. *See Peek v. Spartanburg Reg'l Healthcare Sys.*, 367 S.C. 450, 455, 626 S.E.2d 34, 37 (2005) (recognizing anesthesiologist's pecuniary interest in her professional practice and business goodwill); *see also Sloan*, 370 S.C. at 483–84, 636 S.E.2d at 614–15 (collecting cases recognizing same principle), *overruled on other grounds by Joseph*, 417 S.C. at 452, 790 S.E.2d at 771–72. This is precisely the sort of harm Plaintiff has endured.[48]

The harm must also be "direct," and "not merely of a general nature which is common to all members of the public." *Joytime Distribs. & Amusement Co. v. State*, 338 S.C. 634, 639–40, 528 S.E.2d 647, 650 (1999). But Opternative—the company at which the ECCPL was expressly aimed, and the company whose business operations in the state ceased as a direct result of the ECCPL—has surely established a harm distinct from that of the general public that now must do without the possibility of an online eye exam, and Defendants do not seriously contend otherwise.

[48] *See* Bodde Aff. at ¶¶ 11–13.

3. *Destruction of Plaintiff's past business operations in South Carolina constitutes actual harm, the threat of such destruction in the future constitutes imminent harm.*

An "injury in fact" is actual or imminent, rather than merely hypothetical. *Sea Pines*, 345 S.C. at 601, 550 S.E.2d at 291. Plaintiff's injury is actual because the plain language of the ECCPL banned Opternative's Technology, forcing Plaintiff to shut down business operations in South Carolina.[49] *See* S.C. Code Ann. §§ 40-24-10(3), (9), and 40-24-20(B). And the ECCPL remains a continuing threat to Plaintiff's economic interests because Plaintiff is currently in touch with South Carolina-licensed ophthalmologists who would use its Technology *but for* the existence of the ECCPL. The only reason Opternative remains closed for business in South Carolina is that the state's ophthalmologists understandably do not want to risk their licenses to practice medicine by violating the ECCPL.[50] *See* S.C. Code Ann. §§ 40-24-20(D) ("Violation of this section constitutes misconduct as provided for in Section[] . . . 40-47-110. A provider who violates this section is subject to the penalties authorized in . . . Chapter 47, Title 40, as applicable.") and 40-47-110(A) ("[U]pon finding misconduct that constitutes one or more of the grounds for disciplinary action [BME] may cancel, fine, suspend, revoke, . . . or restrict, including probation . . . the authorization of a person who has engaged in misconduct.").

Defendants contend that since neither LLR nor BME regulates Opternative, Plaintiff's injuries are merely hypothetical.[51] But the ECCPL regulates ophthalmologists, S.C. Code Ann. §§ 40-24-10(7) and 40-24-20(D), whose willingness to use Opternative's Technology is at the

[49] *See* Bodde Aff. at ¶¶ 11–13.

[50] *See* Chaum Aff. at ¶ 3; Windham Aff., Ex. 11 at 69:5–69:10 (Coleman explaining that LLR "[doesn't] have the luxury of not enforcing law").

[51] *See* Defs.' Mot. Summ. J. 10

core of the company's business model.[52] And both LLR and BME are bound to enforce that law.[53] As a direct result of this prospect of enforcement, licensed ophthalmologists—not hypothetically, but in reality—have stopped using Plaintiffs' Technology in South Carolina and Plaintiff has shut down its operations in the state. In the absence of a court order preventing LLR and BME from fulfilling their duty to enforce the ECCPL, no South Carolina ophthalmologist will resume using Opternative's Technology in the state.

Moreover, an ophthalmologist does not need to break state law and ruin his career in order for Plaintiff to have standing to sue. This case was filed under the Declaratory Judgments Act, which courts have held "should be liberally construed to accomplish its intended purpose of affording a *speedy and inexpensive* method of deciding legal disputes and of settling legal rights and relationships, *without awaiting a violation of the rights* or disturbance of the relationships." *Pond Place Partners, Inc. v. Poole*, 351 S.C. 1, 16, 567 S.E.2d 881, 888–89 (Ct. App. 2002) (emphasis added). The South Carolina Supreme Court made a similar point just last year regarding constitutional challenges to existing statutes or interpretations, noting that "[t]he only viable avenue to seek redress and access to our courts cannot be solely through disregarding our laws." *Joseph*, 417 S.C. at 450, 790 S.E.2d at 770. The upshot is that Opternative need not run through the charade of resuming operations in South Carolina, persuading state-licensed ophthalmologists to risk their careers (and an expensive, lengthy investigation process) and then waiting for Defendants to initiate enforcement of the ECCPL (which they have no discretion to refrain from doing) simply to generate an "injury in fact." The law bans Opternative. Opternative (and the South Carolina-licensed ophthalmologists who used to use its Technology)

[52] *See* Bodde Aff. ¶ 13.

[53] *See* Windham Aff., Ex. 11 at 69:5–69:10.

are obeying the law.[54] But if that law is unconstitutional—and, as discussed below, it is—they want to *stop* obeying it.[55] This is precisely what the Declaratory Judgments Act was designed for, and Defendants' Motion must therefore be denied.

B. The destruction of Plaintiff's South Carolina business operations was directly caused by the ECCPL and Defendants' duty to enforce the ECCPL.

A plaintiff must also establish "a causal connection between the injury and the conduct complained of." *Sea Pines*, 345 S.C. at 601, 550 S.E.2d at 291 (quoting *Lujan*, 504 U.S. at 559–61 (internal quotes and citations omitted)). When challenging a legislative act, this requires the plaintiff to show that, "as a result of that action, a direct injury has been sustained, or that there is immediate danger a direct injury will be sustained." *Joytime Distribs.*, 338 S.C. at 639, 528 S.E.2d at 650.

Both are true here, and *Joseph* is illustrative. There, the Supreme Court had no trouble finding standing where a physical therapist challenged a South Carolina Board of Physical Therapy position statement and judicial precedent interpreting a statute to prohibit physicians from employing and referring patients to physical therapists. *Joseph*, 417 S.C. at 449, 790 S.E.2d at 769–70. The Court found that the plaintiff, a physical therapist, had been injured by the law's restriction on her ability to practice her chosen profession and disparate treatment of her relative to all other healthcare professionals, who could be employed by physicians. *Id.*, 790 S.E.2d at 770. Those were injuries that she *had* suffered and would *continue* to suffer, so long as the challenged law remained on the books. Likewise here, Plaintiff was deprived of the freedom

[54] *See* Chaum Aff. at ¶ 3; Bodde Aff. at ¶ 13.

[55] *See* Chaum Aff. at ¶ 4; Bodde Aff. at ¶ 14.

to engage in its chosen occupation as soon as the ECCPL went into effect, and will continue to suffer that injury until the ECCPL is struck down.[56]

Defendants attempt to distinguish *Joseph* by arguing that while the Board of Physical Therapy's position statement in that case was an "actual act," South Carolina-licensed ophthalmologists here "are not forbidden by the ECCPL—and certainly not by any action of the Board or LLR—from using Opternative's technology."[57] But there is no "actual act" requirement to challenge the constitutionality of a statute under the Declaratory Judgments Act—just the opposite. *See Pond Place Partners*, 351 S.C. at 16, 351 S.E.2d 881, 888–89 (the Act "should be liberally construed to accomplish its intended purpose of affording a speedy and inexpensive method of deciding legal disputes and of settling legal rights and relationships, without awaiting a violation of the rights or disturbance of the relationships"). The plain text of the ECCPL bans (and was *designed* to ban) Plaintiff's technology.[58] *See* S.C. Code Ann. §§ 40-24-10(3), (9), and 40-24-20(B). As such, there is no non-futile act Plaintiff could take (short of persuading its partner physicians to defy the law and await prosecution) that would make its injury any more concrete than it already is.

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[56] *See* Bodde Aff. at ¶¶ 13–14.

[57] *See* Defs.' Mot. Summ. J. 9.

[58] *See* Windham Aff., Ex. 7 at 501 (AOA providing state affiliates an "update on AOA actions on the Opternative issue" and promising to "make recommendations to state affiliates about suggested strategies to stop this from operating in your state"); *id.*, Ex. 1 at 54:2–54:12 (Zolman admitting that he "had Opternative in mind" when he recommended that the SCOPA Board push the AOA's model legislation); *id.*, Ex. 5 at 55:16–55:22 (Rivers admitting that SCOPA's "effort to pass the ECCPL [was] prompted by the existence of businesses offering online eye exams"); *id.*, Ex. 3 at 129 (Zolman boasting to SCOPA's membership after veto override about SCOPA's efforts to get the ECCPL passed and exclaiming that "Opternative and 'eye exam' kiosks are now **PROHIBITED BY LAW** in the great state of SC!"); *id.*, Ex. 10 at 203 (SCOPA presentation slide portraying "The Results..." of SCOPA's efforts to get the ECCPL passed and prominently displaying the word "Opternative" with a red circle and strikethrough).

Finally, Defendants' is just the sort of argument rejected in *Joseph*. While the physical therapist there had not yet faced punishment or discipline as a result of the challenged position statement, the Court explained that she need not willfully violate the law and risk enforcement simply to seek redress of her injuries in court. *Joseph* , 417 S.C. at 450, 790 S.E.2d at 770. And neither should Plaintiff have to risk its business reputation and long-term viability (which it successfully maintains in 39 other states across the country) by asking partnering ophthalmologists to disregard the ECCPL and subject themselves to ruinous fines and penalties.[59] The plain language of the ECCPL—which Defendants admit they are bound to enforce—is sufficient.[60]

C. Enjoining Defendants from enforcing the ECCPL would redress Opternative's injury.

Finally, a plaintiff must show that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Sea Pines*, 345 S.C. at 601, 550 S.E.2d at 291 (quoting *Lujan*, 504 U.S. at 559–61 (internal quotes and citations omitted)). Once again, *Joseph* is instructive. There, where unconstitutional interpretations of a statute restricted a physical therapist's freedom to practice her chosen profession, the Supreme Court found declaratory relief adequate to redress her injuries. *Joseph*, 417 S.C. at 449–50, 790 S.E.2d at 769–70. Similarly here, the ECCPL's ban on Opternative's Technology is the only thing preventing Plaintiff from resuming operations in South Carolina.[61] If Defendants are enjoined from enforcing the ECCPL against licensees who use Opternative's Technology, that barrier would disappear and at least

[59] *See* Bodde Aff. at ¶ 10.

[60] *See* Windham Aff., Ex. 11 at 69:5–69:10.

[61] *See* Bodde Aff. at ¶ 13; Chaum Aff. at ¶ 3.

some state-licensed ophthalmologists would resume using Opternative's Technology in South Carolina.[62] That is textbook redressability.

II. Defendants Are Not Entitled To Summary Judgment Because The ECCPL Is A Purely Protectionist Law That Bears No Relationship To Patient Health.

Defendants also argue that the ECCPL passes constitutional muster on the merits, but their argument fails on multiple fronts. First, Defendants fail to acknowledge that this case is governed by the South Carolina Constitution, not the U.S. Constitution, and that South Carolina courts review economic regulations like the ECCPL with significantly more demanding scrutiny than the federal rational-basis test. Second, Defendants' Motion fails to acknowledge the substantial record evidence demonstrating that the ECCPL is designed purely to advance the economic interests of one group (licensed optometrists) at the expense of others—an end South Carolina courts have consistently held is an illegitimate use of the police power. And third, Defendants' Motion fails (indeed, does not even attempt) to demonstrate the kind of reasonable, evidence-based connection between the ECCPL and the public health or safety that South Carolina courts consistently demand of economic regulations. For all these reasons, Defendants' Motion for Summary Judgment must be denied, and Plaintiff's cross-motion should be granted.

A. The South Carolina rational-basis test controls.

As a preliminary matter, much of Defendants' argument is premised on a misguided view of the relevant standard. This case raises claims under Article I, Section 3 of the South Carolina Constitution, and courts in this state have developed an extensive jurisprudence interpreting that Constitution independent of the U.S. Constitution. Defendants would have this Court depart from that jurisprudence and instead apply federal law to state-law claims. It should not do so.

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[62] *See* Bodde Aff. at ¶ 14; Chaum Aff. at ¶ 4.

Defendants essentially ask this Court to apply the most deferential form of federal rational-basis review, citing to the U.S. Supreme Court's decision in *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 364 (1973) (among other federal authorities) for the proposition that Plaintiff must "negative every conceivable basis which might support" the ECCPL.[63] But even if this case were governed by the federal test—and it is not—mere "conceivability" in the absence of record evidence would not suffice. That was the standard applied in *Williamson v. Lee Optical of Oklahoma, Inc.*, 348 U.S. 483, 487 (1955) (dreaming up various justifications legislators might have had for banning opticians from fitting already-prescribed lenses into new eyeglass frames unless customers first obtained an additional prescription), which modern federal courts have begun to cabin as "a zenith of . . . judicial deference to state economic regulation." *St. Joseph Abbey v. Castille*, 712 F.3d 215, 221 (5th Cir. 2013); *see also Craigmiles v. Giles*, 312 F.3d 220, 224 (6th Cir. 2002) (invoking *Lehnhausen* before applying recent federal trend of skepticism towards regulations with doubtful justifications and a close fit to anti-competitive effects).[64]

In any event, *no* version of the federal rational-basis test governs this case. South Carolina courts have flatly disclaimed deference to the federal judiciary on questions of state-constitutional interpretation. *State v. Forrester*, 343 S.C. 637, 643, 541 S.E.2d 837, 840 (2001) ("[T]he federal Constitution sets the floor for individual rights . . . the state constitution establishes the ceiling."); *State v. Austin*, 306 S.C. 9, 16, 409 S.E.2d 811, 815 (Ct. App. 1991) ("It is firmly established that state courts may interpret their won constitutions in such a way as

[63] *See* Defs.' Mot. Summ. J. 14–15.

[64] *See* Pl.'s Mot. Summ. J. 21–22.

to expand rights conferred by the Federal Constitution.").[65] Instead, decades of caselaw reveal that South Carolina courts interpreting their own Constitution have articulated an independent formulation of the rational-basis test: (1) courts look to see whether a law's *actual* purpose is legitimate; and (2) courts examine the record for evidence that, in the real world, a law *actually* furthers that purpose (rather than another, illegitimate purpose).[66] That is the test that applies here. And under that test—which the Defendants' Motion does not even discuss—the ECCPL cannot hope to survive.

B. The ECCPL is a purely protectionist law, and protectionism is not a legitimate government end.

The core of Plaintiff's argument is that the ECCPL is nothing more than anti-competitive, protectionist legislation designed by South Carolina optometrists to shut Opternative down and protect their bottom line.[67] But Defendants' Motion fails to even acknowledge Plaintiff's contentions about protectionism, much less address the substantial record evidence supporting them, instead apparently hoping that the Court will simply ignore the obviously protectionist nature of the law. Whatever the merits of Defendants' argument under federal law (which, as noted above, are dubious), it is utterly meritless as a matter of controlling *state* law.

Unlike federal courts, which sometimes look past obvious economic protectionism, the South Carolina Supreme Court has for decades—and as recently as earlier this year—consistently rejected attempts to use the police power simply to stifle competition. *See, e.g.*, *Retail Servs. & Sys., Inc. v. S.C. Dep't of Revenue*, 419 S.C. 469, 474, 799 S.E.2d 655, 667 (2017) (plurality) (rejecting law limiting owner to three retail liquor licenses because economic

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[65] *See also* Pl.'s Mot. Summ. J. 22–24.

[66] *See also id.* at 29–34 (collecting and discussing cases applying that test).

[67] *See id.* at 25–28 (setting forth that argument at length).

protectionism for a certain class of retailers was not a constitutionally sound basis for regulating liquor sales); *Joseph*, 417 S.C. at 452–53, 790 S.E.2d at 771–72 (plurality) (striking down arbitrary restriction on physicians' employment and referral practices as merely anti-competitive regulation designed to protect therapist's personal economic interests).[68]

In short, decades of unbroken precedent follows a simple rule: Where a challenged law appears designed to further merely private economic interests, and the record is bereft of evidence that the law serves any other legitimate purpose, courts in South Carolina will not hesitate to recognize economic protectionism as the true motivation behind that law and strike it down. *See Retail Servs.*, 419 S.C. at 474, 799 S.E.2d at 667 ("[T]here [is] no indication in the record that these provisions exist for any other purpose than economic protectionism . . . ."). That is exactly what happened in *Joseph*, where the Supreme Court rejected a law restricting physicians from employing and referring patients to physical therapists, while allowing physical

[68] *See also, e.g.*, *Kirven v. Cent. States Health & Life Co.*, 409 S.C. 30, 42–43, 760 S.E.2d 794, 801 (2014) (rejecting retroactive application of statutory definition to existing insurance contracts because it appeared that insurance industry had merely convinced General Assembly to contract for them by fiat); *ATC S., Inc. v. Charleston Cty.*, 380 S.C. 191, 198, 669 S.E.2d 337, 340 (2008) (denying standing to cellphone-tower company seeking to use zoning system to prevent competitor from building tower on nearby land because increased business competition is not a cognizable injury); *G-H Ins. Agency, Inc. v. Cont'l Ins. Co.*, 278 S.C. 241, 248–49, 294 S.E.2d 336, 340–41 (1982) (striking down law forbidding auto-insurance providers from terminating agents where it appeared that predominant purpose was merely to protect private profits of insurance agents rather than any broader social interest); *Painter v. Town of Forest Acres*, 231 S.C. 56, 61, 97 S.E.2d 71, 73 (1957) (rejecting ordinance requiring all businesses to close at midnight where ordinance would have destroyed lawful enterprises and appeared directed at respondent with that purpose in mind); *McCoy v. Town of York*, 193 S.C. 390, 8 S.E.2d 905, 907–09 (1940) (striking down petroleum-vehicle restrictions so specific as to apply to only one filling station because restrictions appeared designed to discriminate against that station to benefit of all other local stations); *City of Orangeburg v. Farmer*, 181 S.C. 143, 186 S.E. 783, 785 (1936) (rejecting ordinance declaring door-to-door solicitation a nuisance where no public-health justification appeared and ordinance was passed not due to complaints by homeowners but at request of city's Retail Merchants Association).

therapists to do so amongst themselves. *See* 417 S.C. at 446, 453, 790 S.E.2d at 768, 771–72.[69] While the government claimed the distinction was intended to guard against conflicts of interest, the Court saw through that justification to strike the restriction down, explaining: "[This law] appears merely to be anti-competitive protectionist legislation designed to protect personal financial interests, which is driven by reimbursement purposes, rather than actual benefits to patients." *Id.* at 452–53, 790 S.E.2d at 771–72.

Similarly here, the overwhelming evidence indicates that the ECCPL was intended to protect South Carolina optometrists' personal financial interests rather than to serve patient health. While the Court in *Joseph* made an inference about the corrupt purpose of the challenged law based on the lack of any plausible connection to a legitimate justification, here there is actually *direct evidence* that the ECCPL was designed by the very group that stands to benefit economically from its enforcement.[70]

Ignoring this evidence entirely, Defendants ask this Court to rely on the bare assertion that the ECCPL was intended to promote comprehensive eye-health exams so that certain diseases that might be missed during an online vision test do not go undetected.[71] But

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[69] While the lead opinion in *Joseph* commanded only two votes, two Justices dissented on the grounds that the appellants lacked standing while calling the lead opinion otherwise "laudable." 417 S.C. at 466, 790 S.E.2d at 799 (Beatty, J., dissenting).

[70] *See* Windham Aff., Ex. 7 at 501 (AOA e-mail to state affiliate on "the Opternative issue" and forecasting plan to "stop this from operating in your state"); *id.*, Ex. 2 at 152–53 (Zolman post-webinar e-mail to SCOPA Board stressing that "kiosks and online eye exams" posed "a huge threat to our profession" and recommending that SCOPA adapt the AOA's model legislation for a legislative campaign); *id.*, Ex. 5 at 23:13–23:15 (Rivers admitting that "the ECCPL is a bill that SCOPA passed"), 46:22–47:2 (Rivers admitting that "the bill that eventually became the ECCPL was primarily pushed by the optometrists"); *id.*, Ex. 3 at 129 (Zolman boasting to SCOPA's membership after veto override about SCOPA's efforts to get the ECCPL passed and exclaiming that "Opternative and 'eye exam' kiosks are now **PROHIBITED BY LAW** in the great state of SC!").

[71] *See* Defs.' Mot. Summ. J. 3–4 (quoting SCOPA interrogatory responses).

Defendants cannot avoid record evidence by ignoring it—and (as discussed below) even in the *absence* of evidence of protectionist intent, bare assertions of public purpose are insufficient to survive constitutional scrutiny in South Carolina. Defendants' Motion must therefore be denied.

C. The ECCPL lacks a real and substantial relationship to patient health, and thereby violates both due process and equal protection.

The best Defendants can muster in defense of the ECCPL is to say that comprehensive eye-health examinations are good, and that certain diseases can be detected in the course of such exams. But that rationale has nothing to do with the ECCPL, which: (1) requires prescriptions to be renewed annually (even though the relevant ophthalmological guidelines do not call for comprehensive exams that frequently); and (2) in any event, does not require ophthalmologists to conduct in-person, comprehensive exams at all—only that some information (any information) be collected by a human (any human) who then reports that information to the ophthalmologist. This falls far short of the kind of genuine relationship to public health and safety that South Carolina courts consistently demand under the South Carolina Constitution's independent due-process and equal-protection guarantees.

1. The ECCPL lacks a reasonable relationship to patient health, which violates due process.

Defendants are correct that the standard for reviewing all substantive-due-process challenges to state statutes is: "Whether [the statute] bears a reasonable relationship to any legitimate interest of government." *R.L. Jordan Co. v. Boardman Petroleum, Inc.*, 338 S.C. 475, 488, 527 S.E.2d 763, 765 (2000). But Defendants misconstrue that test, ignoring the word "reasonable" and pretending that it is coterminous with the federal test (which asks for a "rational" or "conceivable" relationship). South Carolina courts do not look for "conceivable" justifications; instead, they consistently look to see whether laws have *plausible* justifications. In

practice, this means requiring that the relationship between a law and its purported end have at least some basis in fact, and rejecting mere speculation as a substitute for that relationship. *See, e.g.*, *Retail Servs.*, 419 S.C. at 475–76, 799 S.E.2d at 668 (plurality) (striking down law limiting owner to three retail liquor licenses absent record evidence of alleged safety concerns); *Joseph*, 417 S.C. at 452–53, 790 S.E.2d at 771–72 (rejecting employment and referral restriction on physical therapists and surgeons because appellants failed to articulate basis for law rooted in actual benefits to patients) (plurality); *see also Lurey v. City of Laurens*, 265 S.C. 217, 222, 217 S.E.2d 226, 228 (1975) (principle of avoiding judicial lawmaking "does not suggest that this Court should abdicate its obligation to closely scrutinize legitimate constitutional questions").[72] Under that test, the ECCPL must fail.[73]

Joseph illustrates why. In that case, the question was whether a statutory interpretation banning physicians from employing and referring patients to physical therapists was rationally related to the goal of preventing conflicts of interests. *Joseph*, 417 S.C. at 443–46, 790 S.E.2d at 766–68. The Court observed that if the statute was actually intended to do that, it would have simply prevented referral-for-pay situations. *Id.* at 452, 790 S.E.2d at 771. Instead, all it did was "deprive[] physicians of their right to practice medicine in the best interests of their patients."

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[72] *See also, e.g.*, *Kirven*, 409 S.C. at 43, 760 S.E.2d at 801 (striking down retroactive application of statutory definition to existing insurance contracts absent showing that actual language of definition addressed some important societal problem); *G-H Ins. Agency*, 278 S.C. at 248–49, 294 S.E.2d at 340 (rejecting law forbidding auto-insurance providers from terminating agents where experience revealed that provision lacked tailoring that should have been obvious given purpose of law); *McCoy*, 193 S.C. 390, 8 S.E.2d at 907–09 (striking down petroleum-vehicle restrictions for lack of real connection to actual dangers involved in handling petroleum despite recitation of protective purpose in preamble); *Orangeburg*, 181 S.C. 143, 186 S.E. at 785 (rejecting ordinance banning door-to-door solicitation where appellant offered testimony to effect that solicitation was harmless and ordinance lacked tailoring to valid public health concern despite numerous less-restrictive alternatives).

[73] *See* Pl.'s Mot Summ. J. 29–33 (setting forth Plaintiff's affirmative due-process argument at length).

Id., 790 S.E.2d at 771. The Court found the interpretation arbitrary and, therefore, unconstitutional. *Id.* at 453, 790 S.E.2d at 771–72.

Similarly, in *Retail Services*, the Court was not persuaded (as the dissent noted) by the fact that the challenged statute's protectionist justifications were "listed *after* several non-protectionist motives, such as promoting temperance by discouraging business practices that promote alcohol consumption." *Retail Servs.*, 419 S.C. at 480, 799 S.E.2d at 670 (dissenting opinion). These notional rationales, the plurality pointed out, were simply "not supported by the record below." 419 S.C. at 475, 799 S.E.2d at 668.

Here, Defendants have offered only a single, hypothetical justification for the ECCPL, unsupported by any record evidence: that if patients take online vision tests, certain diseases that *could* be detected during a more comprehensive eye-health exam, *might* be missed.[74] But that justification holds no water for a number of reasons.

At its core, all the ECCPL requires is that: (1) corrective-lens prescriptions expire annually, S.C. Code Ann. § 40-24-20(B); and (2) ophthalmologists base such prescriptions on medical findings and refractive error discovered during an eye exam—except online vision tests, *id.* §§ 40-24-10(3), (9). Just like the statutory interpretation in *Joseph*, which deprived physicians of the right to practice in the best interests of their patients, the ECCPL deprives South Carolina-licensed ophthalmologists from using their medical judgment to write corrective-lens prescriptions for patients who need them.[75] It does so despite SCOPA's admission that there is real patient demand for more convenient and affordable access to updated prescriptions, and

[74] *See* Defs.' Mot. Summ. J. 3–4 (quoting SCOPA interrogatory responses).

[75] *See* Chaum Aff. at ¶ 3.

that Opternative's Technology would help meet this demand.[76] It does so despite optometrist Michael Zolman (the ECCPL's legislative architect)'s admission that in some circumstances, updating a corrective-lens prescription without first conducting a comprehensive eye-health exam can actually *improve* a patient's quality of life—and that he himself has actually done so.[77] And it does so against the convictions of the licensed ophthalmologists who have actually used Opternative's Technology to write prescriptions for patients who needed them, according to their medical judgment and within their standard of care.[78]

Moreover, nothing in the ECCPL requires or even encourages a comprehensive eye-health exam. But just like in *Joseph*, there are multiple obvious ways in which the ECCPL *could have* directly addressed Defendants' concern about undetected diseases, if that were truly the law's motivating concern (which it was not): The law could have required that the relevant "medical findings" be made during an in-person, comprehensive eye exam—it does not.[79] It could have required ophthalmologists to physically examine patients for certain ocular-pathological risk factors before writing prescriptions—it does not.[80] It could have even required ophthalmologists to take particular medical facts into account before writing prescriptions—it

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[76] *See* Windham Aff., Ex. 2 at 153 (Zolman asking rhetorically "how many patients do we see daily who really come in just wanting a new prescription for glasses and/or contacts?" and remarking that online refractive technology would "allow them to get what they want"); *see also, e.g.*, Bodde Aff. at ¶¶ 10–11; Chaum Aff. at ¶¶ 3–4.

[77] *See* Windham Aff., Ex. 1 at 32:8–33:14, 47:5–48:3.

[78] *See* Chaum Aff. at ¶¶ 2, 4.

[79] *See* Windham Aff., Ex. 11 at 65:17–65:23 (Coleman admitting that "the ECCPL leaves it to an ophthalmologist's professional judgment exactly what diagnostic methodologies and exactly what medical information he needs before writing a prescription").

[80] *See id.* at 64:16–65:2 (Coleman explaining that the ECCPL has "no explicit requirement" regarding tests that must be performed before writing a corrective-lens prescription).

does not.[81] It does not require these things because for most people, annual comprehensive eye-health examinations are unnecessary, and South Carolina law relies on ophthalmologists (like other doctors) to exercise their medical judgment on a case-by-case basis—*unless* the ophthalmologist is using computerized technology.

The upshot is that the ECCPL has essentially nothing to do with patient health—and Defendants actually admit they possess no evidence that the ECCPL furthers that end.[82] But it bears a striking relationship to South Carolina optometrists' economic interests: The ban on online vision tests like Opternative means that patients seeking updated corrective-lens prescriptions must continue visiting optometrists' brick-and-mortar offices—where, conveniently, optometrists can attempt to sell them expensive eyeglass frames (as most of them do).[83] And the annual expiration requirement keeps them coming on a regular basis, which boosts optometrists' revenue stream.[84]

Defendants cite two South Carolina cases in support of their argument that the ECCPL bears a reasonable relationship to a legitimate government interest, but both are clearly

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[81] *See id.* at 65:4–65:16 (Coleman admitting that the ECCPL "doesn't identify diagnostic methodologies that have to be employed in order to develop the medical findings" or even "specify what those medical findings must be").

[82] *See id.* at 54:22–55:7, 55:9–56:1 (Coleman admitting that Defendants have no evidence that the ECCPL actually protects the public health or safety).

[83] *See id.*, Ex. 1 at 65:5–66:15 (Zolman admitting that optometrists attempt post-appointment eyeglass sales "most of the time"); *see also id.*, Ex. 5 at 28:20–28:22 (SCOPA Executive Director Jackie Rivers admitting that "most South Carolina optometrists sell eyeglass frames").

[84] *Compare* SCOPA Ans. ¶ 20 (admitting on information and belief the allegations of Paragraph 48 of Plaintiff's Complaint) *with* Compl. ¶ 48 (alleging that "many professional optometrists make the majority of their revenue from selling expensive frames in their brick-and-mortar offices rather than from professional fees earned from conducting traditional in-person eye examinations"); *see* Windham Aff., Ex. 5 at 28:20–28:22 (SCOPA Executive Director Jackie Rivers admitting that "most South Carolina optometrists sell eyeglass frames"); *id.*, Ex. 1 at 66:16–67:9 (Zolman admitting that his revenue from eyeglass sales "would go down" if online refractive tests like Opternative's Technology ever became commercially popular).

distinguishable. The first, *Denene, Inc. v. City of Charleston*, involved a city ordinance requiring all commercial establishments that served alcohol for on-site consumption to close at 2:00 a.m. 359 S.C. 85, 97–98, 596 S.E.2d 917, 923–24 (2004). Bar owners challenged the restriction nnder Article I, Section 3, relying in part on *Painter*, 231 S.C. 56, 97 S.E.2d 71 (cited in Plaintiff's opening brief). *Id.* at 98, 596 S.E.2d at 923. The Supreme Court explained that *Painter* was distinguishable because there, "the Court found that the ordinance would seriously impair, if not destroy, many lawful businesses" and "seemed to be directly aimed at destroying Painter's business." *Id.*, 596 S.E.2d at 923. Since the ordinance in *Denene* was only a limited measure designed to maintain safety and quietude during the early morning hours—based on *actual record evidence* tending to show the burden otherwise imposed on residents' quality of life—the Court found it bore a reasonable relationship to a legitimate purpose. *Id.* at 93, 596 S.E.2d at 921.

The ECCPL is much more like the arbitrary ban rejected in *Painter* than the limited, evidence-based restriction imposed in *Denene*. Just as in *Painter*, the ECCPL actually destroyed Plaintiff's South Carolina business operations.[85] And just as in *Painter*, the ECCPL not only "seemed" designed to do so—it *actually was* designed to do so.[86] Moreover, unlike in *Denene*,

[85] *See* Bodde Aff. at ¶ 11–13; Windham Aff., Ex. 10 at 203 (SCOPA presentation slide portraying "The Results…" of SCOPA's efforts to get the ECCPL passed and prominently displaying the word "Opternative" with a red circle and strikethrough).

[86] *See id.*, Ex. 7 at 501 (AOA providing state affiliates an "update on AOA actions on the Opternative issue" and promising to "make recommendations to state affiliates about suggested strategies to stop this from operating in your state"); *id.*, Ex. 1 at 54:2–54:12 (Zolman admitting that he "had Opternative in mind" when he recommended that the SCOPA Board push the AOA's model legislation); *id.*, Ex. 5 at 55:16–55:22 (Rivers admitting that SCOPA's "effort to pass the ECCPL [was] prompted by the existence of businesses offering online eye exams"); *id.*, Ex. 3 at 129 (Zolman boasting to SCOPA's membership after veto override about SCOPA's efforts to get the ECCPL passed and exclaiming that "Opternative and 'eye exam' kiosks are now **PROHIBITED BY LAW** in the great state of SC!").

where the government produced record evidence tending to show the real-world basis for the scope of the restriction imposed, Defendants here have completely failed to produce any evidence of the real-world basis for the ECCPL. That makes sense, given that Defendants outright admit they possess no such evidence.[87] In short, *Denene* does not aid Defendants' case—it undermines it.

The other case, *Curtis v. State*, involved a challenge to a law criminalizing the sale of urine with the intent of helping customers defraud drug-screening tests. 345 S.C. 557, 565–66, 549 S.E.2d 591, 595 (2001). While the law in that case destroyed the plaintiff's business, it did so because that business was designed to help people commit fraud, and the government very reasouably wanted to prevent fraud. But *Curtis* is clearly distinguishable here: The ECCPL does not outlaw fraud; it bans licensed ophthalmologists from using their medical judgment to incorporate technology like Opternative's into their practice of medicine to expand care to patients who otherwise might not get it—something every other kind of medical doctor in South Carolina is allowed to do. *See* S.C. Code Ann. § 40-47-37. To compare a law banning Opternative with a law thwarting fraudulent urine-traffickers, is absurd. In any event, *Curtis* was also a purely federal constitutional challenge, while this case was brought exclusively under the South Carolina Constitution. *See id.* at 570–76, 549 S.E.2d at 597–61. As explained above, only the latter governs this case.

In sum, just like in *Joseph* and unlike in *Denene*, the record here is devoid of any evidence that the ECCPL furthers a public health or safety purpose. The law hinders patient health by preventing ophthalmologists from using online vision tests like Opternative to write corrective-lens prescriptions—prescriptions their patients want—when their judgment indicates

[87] *See id.*, Ex. 11 at 54:22–55:7, 55:9–56:1 (Coleman admitting that Defendants have no evidence that the ECCPL actually protects the public health or safety).

that it would be medically appropriate and accord with the ophthalmological standard of care. And it lacks any of the obvious tailoring that would be expected of a law actually designed to address a concern about undetected diseases. Accordingly, the ECCPL is arbitrary, does not bear a reasonable relationship to patient health, and cannot stand Article I, Section 3.

2. The ECCPL lacks a fair and substantial relationship to patient health, which violates equal protection

Defendants also contend that the ECCPL satisfies equal protection, offering two chief arguments: first, that the ECCPL's classifications are only "imagined"; second, that in any case, "undiagnosed diseases of the eye are a legitimate public health concern, and that legislation requiring an in-person comprehensive eye examination in order to increase the chance of detecting these diseases is reasonably related to [that purpose]."[88] Both points miss the mark.

The ECCPL draws two clear classifications: First, the law penalizes South Carolina-licensed ophthalmologists who use their medical judgment to write corrective-lens prescriptions based on "medical findings" generated automatically, but does not penalize ophthalmologists who base prescriptions on precisely the same information, *some* of which was collected manually by a human being. *See* S.C. Code Ann. §§ 40-24-10(3), (9), and 40-24-20(B). Second, the law forbids South Carolina-licensed ophthalmologists from using telehealth technologies to provide services according to their medical judgment and within the relevant standard of care, while all other South Carolina-licensed physicians are statutorily permitted to do just that. *Compare id.*, *with* S.C. Code Ann. § 40-47-37 (permitting the use of telemedical technologies in medical practice so long as the physician honors the relevant standard of care).

Relying overwhelmingly on federal caselaw—Defendants cite exactly one South Carolina case (*Denene*, distinguished above at *supra* p. 32) in support of its equal-protection

[88] *See* Defs.' Mot. Summ. J. 12, 15.

argument—Defendants would have this Court weigh those classifications under a more deferential test. But as repeatedly emphasized above, South Carolina courts have developed a distinct test under their own, independent Constitution: In brief, the basic mandate of equal protection is that government classifications must be "reasonable, not arbitrary, and must rest upon some ground of difference having a fair and substantial relation to the object of the legislation, so that all persons similarly circumstanced shall be treated alike." *Harbit v. City of Charleston*, 382 S.C. 383, 396, 675 S.E.2d 776, 783 (Ct. App. 2009) (citation omitted). As in the due-process context, while this is not a heavy burden, it does still require that classifications find their basis in *facts*, not fancy. *Daniel v. Cruz*, 268 S.C. 11, 14, 231 S.E.2d 293, 294 (1977) ("If there is no *real* difference between localities, persons, occupations, or property, the State cannot make one." (emphasis added) (citation omitted)).[89] The ECCPL fails that test.[90]

As for the first classification, *Hanvey* is instructive. There, a patient was admitted to a charitable hospital for a hip replacement suffered complications, and sued the hospital seeking actual and punitive damages of $200,000. *Hanvey v. Oconee Mem'l Hosp.*, 308 S.C. 1, 2–3, 416 S.E.2d 623, 624 (1992). The hospital invoked a statute specifically capping liability for charitable hospitals at $100,000, which the patient then challenged under Article I, Section 3. *Id.*

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[89] *See, e.g.*, *Joseph*, 417 S.C. at 452, 790 S.E.2d at 771 (plurality) (law prohibiting physicians from employing physical therapists and referring patients to them was not calculated to further asserted end); *Hanvey v. Oconee Mem'l Hosp.*, 308 S.C. 1, 5, 416 S.E.2d 623, 626 (1992) (law lacked rational basis for distinguishing between charitable hospitals and other medical providers for purposes of limiting liability); *Broome v. Truluck*, 270 S.C. 227, 230–31, 241 S.E.2d 739, 740 (1978) (law lacked rational basis for drawing statute-of-limitations distinctions for recovery against various professionals whose work involved designing improvements to real estate); *Daniel*, 268 S.C. at 14, 231 S.E.2d at 294 (law prohibiting practice of fortunetelling in some counties but not others was not based on any real difference between fortunetellers); *Gasque, Inc. v. Nates*, 191 S.C. 271, 2 S.E.2d 36, 44 (1939) (law imposing maximum-hours caps on certain manufacturing and mercantile establishments but not others was not based on any material differences between such establishments).

[90] *See* Pl.'s Mot Summ. J. 33–37 (setting forth that argument at length).

at 4–5, 416 S.E.2d at 625–26. The South Carolina Supreme Court found "no rational basis for distinguishing between charitable hospitals, on the one hand, and medical providers of goods and services, such as the Red Cross, on the other," and struck the cap down. *Id.* at 5, 416 S.E.2d at 626.

Similarly here, there is no real difference between information collected manually by a human being and the *same* information when collected automatically. The ECCPL would allow South Carolina-licensed ophthalmologists to use Opternative's Technology to write corrective-lens prescriptions based on informatiou collected by a physical person who manually recorded patients' responses using, say, a clipboard.[91] But the same prescriptiou based on the same information would be banned if the ophthalmologist received that information directly from Opternative's Technology, over the Internet.[92] Information does not become tainted simply because it was generated automatically, and there is no valid health or safety reason to pretend that it does.

As for the second classification, *Joseph* is again instructive. There, a statute was interpreted to prohibit physicians from employing and referring patients to physical therapists, despite the fact that physicians were generally allowed to do so for all other types of healthcare professionals. *Joseph*, 417 S.C. at 442–43, 790 S.E.2d at 766–67. The government claimed the classification was intended to protect patients and government-sponsored programs from conflicts of interest, but the Court observed that "the PTs stand alone in South Carolina," *id.* at

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[91] *See* Defs.' Mot. Summ. J. 9 ("[A] South Carolina-licensed ophthalmologist may still use Opternative's technology to assist him or her in making a determination to write a prescription for spectacles or contact lenses. He or she simply cannot solely base the prescription on the refractive eye error of the human eye or be generated [sic] by a kiosk.").

[92] *See* Windham Aff., Ex. 11 at 67:11–67:18 (Coleman explaining that the ECCPL imposes "some expectation that there will be some type of human involvement").

442–43, 790 S.E.2d at 766–67, and found the distinction "arbitrary and not calculated to avoid the legislative purpose," *id.* at 452, 790 S.E.2d at 771. That classification violated equal protection, too. *Id.*, 790 S.E.2d at 771.

Similar to the physical therapists in *Joseph*, who were accorded arbitrarily preferential treatment, ophthalmologists "stand alone" in South Carolina as the *only* physicians forbidden from using telehealth technologies to provide services according to their medical judgment and within the relevant standard of care. *See* S.C. Code Ann. §§ 40-24-10(3), (9), and 40-24-20(B). All other South Carolina-licensed physicians are statutorily permitted to do so without running afoul of a concern about undetected diseases in their respective practice areas. *Compare id.*, *with* § 40-47-37. And Defendants have not produced any evidence of the sort of "real difference" between ophthalmologists and all other physicians that would warrant singling the former out for disparate treatment. Again, they fully admit they have no such evidence.[93]

In sum, Defendants contend that the ECCPL was designed to guard against certain undetected eye diseases. But the record is utterly devoid of evidence that would help to explain how either of the two distinctions discussed above alleviate that concern. The argument for the ECCPL seems to boil down to: "If Opternative is banned, then patients will need to see their optometrists more frequently—where, perhaps, they will receive comprehensive eye-health exams." While that sort of purely speculative argument may have carried the day in *Lee Optical*, it is not the stuff of which "fair and substantial" relationships are made. The South Carolina Constitution, equal protection, and common sense demand more.

CONCLUSION

[93] *See* Windham Aff., Ex. 11 at 54:22–55:7, 55:9–56:1 (Coleman admitting that Defendants have no evidence that the ECCPL actually protects the public health or safety).

The ECCPL is a purely protectionist law that bears no relationship to patient health, which violates both the due-process and equal-protection guarantees of the South Carolina Constitution. Relying on inapposite tests and obviously distinguishable cases, Defendants ask this Court to turn a blind eye to the naked protectionism throughout the record based on nothing more than brute speculation. Under Article I, Section 3 and South Carolina's rich jurisprudence interpreting it, that is not sufficient. Plaintiff therefore respectfully requests this Court to deny Defendants' motion for summary judgment.

Respectfully submitted,

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Columbia, South Carolina
September 27, 2017.

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FIFTH JUDICIAL CIRCUIT
COUNTY OF RICHLAND	)	
	)	Civil Action No. 2016-CP-40-06276
Opternative, Inc.,	)	
Plaintiff,	)	
v.	)	**DEFENDANT-INTERVENOR'S MEMORANDUM OF LAW IN RESPONSE TO THE PARTIES' MOTIONS FOR SUMMARY JUDGMENT**
South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation,	)	
Defendants,	)	
and	)	
South Carolina Optometric Physicians Association,	)	
Defendant-Intervenor.	)	

RICHLAND COUNTY
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JEANNETTE W. WALKER
CLERK OF COURT

Defendant-Intervenor South Carolina Optometric Physicians Association ("SCOPA"), by and through its undersigned counsel, submits this memorandum of law in response to the Motion for Summary Judgment filed by Defendants South Carolina Board of Medical Examiners ("BME") and South Carolina Department of Labor, Licensing and Regulation ("LLR") (collectively, "Defendants") on July 12, 2017 and the Motion for Summary Judgment filed by Plaintiff Opternative, Inc. ("Plaintiff" or "Opternative") on September 7, 2017. For the reasons set forth below, SCOPA respectfully requests that this Court grant Summary Judgment to Defendants. Alternatively, SCOPA would respectfully request that Plaintiff's Motion be denied. SCOPA is simultaneously filing affidavits of Dr. Mark E. Robinson and Dr. Melvin D. Shipp, attached hereto as Exhibits 1 and 2, respectively, as further support for Defendants' Motion.

FACTUAL BACKGROUND

Plaintiff initiated this action on October 20, 2016, seeking a declaratory judgment that portions of the Eye Care Consumer Protection Law, S.C. Code Ann. §§ 40-24-10, et seq., enacted

on May 11, 2016 ("ECCPL") are unconstitutional because they result in both a denial of equal protection and substantive due process. The ECCPL establishes minimum parameters for issuing prescriptions for corrective lenses in South Carolina:

> **SECTION 40-24-20.** Valid prescription required to dispense spectacles or contact lenses; penalties.
>
> (A) A person in this State may not dispense spectacles or contact lenses to a patient without a valid prescription from a provider
>
> (B) To be valid, a prescription must contain an expiration date on spectacles or contact lenses of one year from the date of examination by the provider or a statement of the reasons why a shorter time is appropriate based on the medical needs of the patient. The prescription must take into consideration medical findings made and refractive error discovered during the eye examination. If a provider determines a patient is a suitable candidate for a prescription for contact lenses or spectacles, a provider may not thereafter refuse to issue a prescription for spectacles or contact lenses to a patient.
>
> (C) A prescription for spectacles or contact lenses may not be based solely on the refractive eye error of the human eye or be generated by a kiosk.
>
> (D) Violation of this section constitutes misconduct as provided for in Sections 40-37-110 and 40-47-110. A provider who violates this section is subject to the penalties authorized in Chapter 37, Title 40 or Chapter 47, Title 40, as applicable.

S.C. Code Ann. § 40-24-20 (Supp. 2016).

Opternative challenges sections 40-24-20(C) and (D) of the ECCPL, alleging these provisions violate Article I, Section 3 of the South Carolina Constitution. It also challenges Section 40-24-10(9) of the ECCPL, which provides that vision assessments:

> may not be based solely on objective refractive data or information generated by an automated testing device, including an auto refractor or other electronic refractive-only testing device, to provide a medical diagnosis or to establish a refractive error for a patient as part of an eye examination.

Opternative is a healthcare technology company that has produced a computer interface which allows ophthalmologists and optometrists to collect refractive data and other information from patients ("Technology"). The Technology is designed to be used by a patient without having

an ophthalmologist or optometrist in the room. *See* Shipp Aff., ¶ 7; Robinson Aff., ¶ 5. Opternative's Technology can be accessed by individuals through Opternative's website, and it relies on an individual's subjective self-reporting to collect refractive data using a computer. Per the website, the use of Opternative's Technology does not constitute a comprehensive eye examination. *See* Shipp Aff., ¶¶ 8-10; Robinson Aff., ¶ 8.

SCOPA is an association of optometric physicians practicing in South Carolina. Doctors of optometry are known as "optometrists." Optometrists are independent primary health care professionals for the eye. Optometrists examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures as well as identify related systemic conditions affecting the eye. *See* Shipp Aff., ¶ 6.

Ophthalmologists are Ophthalmologists are medical doctors specializing in eye and vision care, who by study and training are qualified to diagnose and treat ocular diseases, perform eye exams and surgeries and prescribe lenses to correct vision problems. Ophthalmologists who practice in South Carolina are licensed and regulated by BME. *See* Robinson Aff. ¶¶ 3-4.

Both optometrists and ophthalmologists are under an affirmative obligation to look after the health and safety of their patients, which requires them to use their judgment to determine whether their patients' complaints or symptoms pertaining to their eyesight or eye health are indicators of systemic or body-wide disease processes or pathologies. They are likewise obliged to make such determinations even when the disease processes or pathologies are asymptomatic. *See* Shipp Aff., ¶ 22; Robinson Aff., ¶ 14.

The ECCPL expressly regulates both licensed ophthalmologists and licensed optometrists. See S.C. Code Ann. § 40-24-10(7) (defining "provider" to include both professions); S.C. Code Ann. § 40-24-20 (prescribing penalties for "provider[s]" who violate the ECCPL).

Conducting comprehensive eye examinations is within the scope of practice of both optometrists and ophthalmologists. Comprehensive eye examinations consist of, but are not limited to, the following: a review of the patient's health history; measuring visual acuity, both aided and unaided; performing an examination with a slit lamp of the anterior segments of the eyes and eyelids; performing an internal ophthalmoscopic examination through a dilated pupil, including evaluation of the optic nerve head, macular and peripheral retina; performing a subjective refraction; performing tonometry; evaluating pupils; assessing ocular motility and eye alignment; performing confrontation visual field or similar screening field; performing other tests and procedures as indicated by the patient's chief complaint, case history or objective signs and symptoms discovered during the course of the eye examination; making a diagnosis and formulating a treatment plan; seeking consultation and/or making referrals for assessment/treatment to other health providers as appropriate. *See* Shipp Aff., ¶ 21; Robinson Aff., ¶ 10.

Opternative's Technology generates a set of data about a user and the user's ocular refractive error. This set of data is sent to a licensed ophthalmologist, who determines if a corrective-lens prescription is appropriate. *See* Shipp Aff., ¶ 11; Robinson Aff., ¶ 9. It collects information by soliciting a user's responses to questions and visual stimuli; it does not measure objective data about the user's eyes or eye health. *See* Shipp Aff., ¶ 12; Robinson Aff., ¶ 11. Opternative's Technology cannot detect or aid in diagnosing diseases of the eye or systemic diseases. *See* Shipp Aff., ¶ 13. Opternative's Technology does not perform a corneal examination and evaluation. *See* Robinson Aff., ¶ 13.

Both optometrists and ophthalmologists are authorized to issue prescriptions for corrective lenses, including both spectacles and contact lenses. A contact lens is a medical device that can be used to correct vision, or for cosmetic or therapeutic reasons. A contact lens evaluation is a set of diagnostic tests and procedures performed in addition to a comprehensive eye examination. These tests and procedures include a measurement of the corneal curvature (keratometry or corneal topography) and an evaluation of the anterior segment and tear layer of the eye in relation to the contact lens fit. A poorly fit contact lens can cause irritation to the eyes. Continuing to wear the irritating contact lens for a prolonged time can create pain and cause scarring and vision loss for a patient. A patient may not have any symptoms from a poorly fit contact lens, but scarring and vision loss can develop nonetheless. Such consequences of a poorly fit contact lens can only be detected by a corneal evaluation. *See* Shipp Aff., ¶ 14; Robinson Aff., ¶ 12.

Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination. There is a risk that individuals may mistakenly believe that they have received a comprehensive eye examination after receiving a prescription for spectacles or contact lenses from an ophthalmologist who only relies upon Opternative's Technology. It is possible that some of those individuals may have an asymptomatic eye or systemic disease. *See* Shipp Aff., ¶ 15; Robinson Aff., ¶ 15.

In addition to assessing eye and vision problems, an eye examination may be the first opportunity to detect diabetes and other health conditions. Examples include high blood pressure, hypercholesterolemia, and certain inflammatory diseases. *See* Shipp Aff., ¶ 16; Robinson Aff., ¶ 16. Diabetes is currently the nation's seventh leading cause of death in the United States. Diabetes is also a risk factor for heart disease and stroke, and a leading cause of kidney disease and blindness in

adults. Early detection can allow early treatment and management of both systemic and eye-related diabetic changes. *See* Shipp Aff., ¶ 17. One of the more debilitating eye-related outcomes associated with type 2 diabetes in adults is vision impairment, including blindness. Diabetes-related eye conditions include, but are not limited to, refractive changes, cataracts, diabetic retinopathy, and glaucoma. Diabetic retinopathy is among the leading causes of preventable blindness in the United States. *See* Shipp Aff., ¶ 18. Most symptoms associated with diabetic eye disease progress slowly, and unnoticeably; therefore, comprehensive dilated eye examinations are necessary to diagnose, prevent and manage these conditions. *See* Shipp Aff., ¶ 19. Importantly, diabetic eye disease can be detected and diagnosed during a routine comprehensive dilated eye examination. *See* Shipp Aff., ¶ 20.

Opternative claims the ECCPL "effectively prohibits ophthalmologists from conducting Exams or writing prescriptions based on Opternative's Technology." It further claims that the ECCPL is mere economic protectionist legislation that violates the South Carolina Constitution.

LEGAL STANDARD

Summary judgment shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Rule 56(c), SCRCP. "In determining whether any triable issue of fact exists, the evidence and all inferences which can reasonably be drawn therefrom must be viewed in the light most favorable to the nonmoving party." *Quail Hill, LLC v. County of Richland*, 387 S.C. 223, 235, 692 S.E.2d 499, 505 (2010). Even when the evidentiary facts are not disputed, if the conclusions to be drawn from them are, summary judgment should be denied. Summary judgment is not appropriate

when further inquiry into the facts is desirable to clarify the application of law. *Coker v. Cummings*, 381 S.C. 45, 49, 671 S.E.2d 383, 385 (2008).

Statutes are presumed constitutional, and a law that neither creates a suspect class nor abridges a fundamental right is given only minimal equal protection scrutiny. *Faircloth v. Finesod*, 938 F.2d 513 (4th Cir. 1991). A statute is presumed constitutional and will not be declared unconstitutional unless its repugnance to the constitution is clear and beyond a reasonable doubt. *Sojourner v. Town of St. George*, 383 S.C. 171, 679 S.E.2d 182 (2009). Constitutional constructions of statutes are not only judicially preferred, they are mandated. *State v. McGrier*, 378 S.C. 320. 663 S.E.2d 15 (2008).

When the constitutionality of a statute is at issue, "every presumption will be made in favor of its validity and no statute will be declared unconstitutional unless its invalidity appears so clearly as to leave no doubt that it conflicts with the constitution." *South Carolina Dept. of Social Servs. v. Sarah W.*, 402 S.C. 324, 334, 741 S.E.2d 739, 745 (2013); *Dunes West Golf Club, LLC v. Town of Mount Pleasant*, 401 S.C. 280, 737 S.E.2d 601 (2013); *McMaster v. Columbia Bd. Of Zoning Appeals*, 395 S.C. 499, 719 S.E.2d 663 (2011). Accordingly, the burden is on the challenging party to prove the unconstitutionality of the statute. *Home Health Serv. v. S.C. Tax Comm'n*, 312 S.C. 324, 327, 440 S.E.2d 375, 377 (1994); citing *Gold v. South Carolina Board of Chiropractic Examiners*, 271 S.C. 74, 245 S.E.2d 117 (1978) (emphasis added).

Those attacking the rationality of a legislative classification have the burden to negative every conceivable basis which might support it. *FCC v. Beach Communications*, 508 U.S. 307 (1993); *accord McLeod v. Starnes*, 396 S.C. 647, 723 S.E.2d 198 (2012) (a classification is presumed reasonable and will remain valid unless and until the party making an equal protection

challenge proves beyond a reasonable doubt that there is no admissible hypothesis upon which it can be justified).

"In order to prove a denial of substantive due process, a party must show that he was arbitrarily and capriciously deprived of a cognizable property interest rooted in state law." *Harbit v. City of Charleston*, 382 S.C. 383, 394, 675 S.E.2d 776, 782 (Ct. App. 2009) (citing *Sunset Cay, LLC v. City of Folly Beach*, 357 S.C. 414, 430, 593 S.E.2d 462, 470 (2004)). "The State's deprivation of the property interest must fall so far beyond the outer boundaries of legitimate governmental authority that no process could remedy the deficiency." *Id.*

ARGUMENT

I. Defendants' Motion for Summary Judgment should be granted.

Defendants argue that Opternative has no standing to pursue its claims in this action and that the ECCPL is constitutional and supported by a rational basis. SCOPA adopts and incorporates by reference Defendants' arguments in support of its request for summary judgment. It offers the following additional arguments in favor of the ECCPL's constitutionality as further support for Defendants' motion.[1]

(A) Rational basis is the applicable standard.

The Parties do not dispute that the determination of whether the ECCPL violates the Equal Protection Clause turns upon the application of the rational basis test. *See* Plaintiff's Motion for Summary Judgment, p. 20; Defendants' Motion for Summary Judgment, p. 14-15. However, in its Motion Opternative argues that there is a distinction between South Carolina's articulation of the

[1] Because this case concerns a constitutional challenge that the parties are attempting to resolve by way of cross-motions for summary judgment, and because the burden of proving that a statute is unconstitutional falls squarely upon Opternative, SCOPA will devote most of the within memorandum upon the infirmities of Opternative's equal protection and due process arguments.

rational basis test and the federal courts' use of the test. Plaintiff's Motion for Summary Judgment, p. 20. SCOPA submits that no such distinction exists.

As Optemative acknowledges in its Motion, Courts generally analyze equal protection challenges under one of three standards: (1) rational basis, (2) intermediate scrutiny, or (3) strict scrutiny. *See* Plaintiff's Motion, p. 20. If the classification does not implicate a suspect class or abridge a fundamental right, the rational basis test is used. *Denene, Inc. v. City of Charleston*, 359 S.C. 85, 596 S.E.2d 917 (2004). South Carolina's equal protection jurisprudence reveals no discernable difference between its application of the rational basis test to questions of equal protection under the South Carolina Constitution and the federal courts' use of the standard to measure equal protection under the United States Constitution. Simply put, under the rational basis test, the requirements of equal protection are satisfied when: (1) the classification bears a reasonable relation to the legislative purpose sought to be affected; (2) the members of the class are treated alike under similar circumstances and conditions; and (3) tbe classification rests on some reasonable basis. *Denene*, 359 S.C. at 85; *Bodman v. State*, 403 S.C. 60, 742 S.E.2d 363 (2013); *Harleysville Mut. Ins. Co. v. State*, 401 S.C. 15, 736 S.E.2d 651 (2012); *Sunset Cay, LLC v. City of Folly Beach*, 357 S.C. 414, 593 S.E.2d 462 (2004); *Fraternal Order of Police v. South Carolina Dep't of Rev.*, 352 S.C. 420, 430, 574 S.E.2d 717, 722 (2002); *Gary Concrete Prods., Inc. v. Riley*, 285 S.C. 498, 504, 331 S.E.2d 335, 339 (1985).

Likewise, the test for a substantive due process claim is "[w]hether [a statute] bears a reasonable relationship to any legitimate interest of government." *R.L. Jordan Co. v. Boardman Petroleum, Inc.*, 338 S.C. 475, 478, 527 S.E.2d 763, 765 (2000).

Optemative argues that South Carolina courts conduct a "robust review" of economic regulations (Plaintiff's Motion for Summary Judgment, p. 23). This assertion has no support in

South Carolina law. *See, e.g. pp. 6-7, infra.* Its attempt to draw parallels with how Texas courts have reviewed that state's constitution strains credulity and ignores dozens of South Carolina cases that consistently intermingle federal rational basis test enunciations with those arising under the South Carolina Constitution. *See, e.g. In re Treatment & Care of Luckabaugh,* 351 S.C. 122, 568 S.E.2d 338 (2002); *Harleysville Mut. Ins. Co. v. State,* 401 S.C. 15, 736 S.E.2d 651 (2012); *State v. Thompson,* 349 S.C. 346, 563 S.E.2d 325 (2002).

Opternative relies heavily upon *Joseph v. SC Dep't of Labor, Licensing & Regulation,* 417 S.C. 436, 790 S.E.2d 763 (2016), to make its case that South Carolina's rational basis test is unique. *Joseph* involved a leglislative classification that treated physical therapists differently from other healthcare providers and prohibited them, and only them, from being employed by physicians. The South Carolina Supreme Court concluded "there is no plausible reason as to why physical therapists are so different from other health care professionals...." This finding was not the result of some heightened or "robust" review; the Court discerned the absence of a rational basis on the face of the statute itself, and none of the parties could offer a reasonable explanation for the classification in the course of the litigation. This result is consistent with modern rational basis review at the federal level, just as it comports with *Williamson v. Lee Optical of Oklahoma, Inc.*, 348 U.S. 483 (1955). *See, e.g., Engquist v. Oregon Dep't of Agric.*, 553 U.S. 591 (2008); *Board of Trs. v. Garrett*, 531 U.S. 356 (2001).

(B) Opternative cannot prove beyond a reasonable doubt that the ECCPL violates the Equal Protection Clause.

(i) SCOPA's efforts to lobby for the ECCPL have no bearing upon the issues before the Court.

Opternative expends much of its brief to this Court recounting the efforts made by SCOPA and its affiliates to develop and lobby for the passage of legislation that eventually became the

ECCPL. SCOPA does not hide from the exercise of its constitutional rights to participate in the legislative process by urging members of the South Carolina General Assembly to pass laws that protect the health and safety of its members' patients, as it is incumbent upon its members to look after their patients' well-being. *See* Shipp Aff., ¶ 22, Robinson Aff., ¶ 14. SCOPA is justifiably proud of the campaign it pursued to enact the ECCPL, which was overwhelmingly embraced by both the House of Representatives and Senate, even despite Governor Haley's veto. Plaintiff's Motion for Summary Judgment, p. 11.

Regardless of how SCOPA and its members feel about the ECCPL, the resolution of the issues before the Court does not depend, and is not aided in any respect, by examining their involvement in the legislative process. Opternative's inclusion of this history in its Motion is a tellingly obvious attempt to divert the Court's attention away from the only real issue before it—whether the ECCPL bears some reasonable relationship to a salutary public purpose. It most certainly does.

(ii) <u>The ECCPL is reasonably related to its legislative purpose.</u>

The ECCPL protects the public health and welfare because it prevents citizens from unwittingly putting their eye health at risk by obtaining a prescription for corrective lenses without a comprehensive eye examination. *See* Shipp Aff., ¶ 15; Robinson Aff., ¶ 15. Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination. *See* Shipp Aff., ¶ 15; Robinson Aff., ¶ 15. The provisions of the ECCPL are reasonably necessary to protect and uphold the applicable standard of care eye care professionals in South Carolina, which requires them to use their medical judgment to determine whether their patients' complaints or symptoms pertaining to their eyesight or eye health are indicators of systemic or body-wide disease

processes or pathologies. They are likewise obliged to make such determinations even when the disease processes or pathologies are asymptomatic. *See* Robinson Aff., ¶ 14. Accordingly, because the South Carolina constitution grants the General Assembly the authority to legislate for the protection of the public health and welfare, and because the ECCPL does just that, this Court should leave the ECCPL intact.

Optemative argues that the ECCPL does nothing to protect the public health and safety, ignoring the evidence in the record to the contrary. For instance, it fails to acknowledge that one year prescriptions for corrective lenses are consistent with national optometric standards, *see* Shipp. Aff., ¶ 25, and with extant South Carolina and federal law concerning contact lenses. *See, e.g.*, S.C. Code Ann. § 37-25-10 *et seq.* (Rev. ed. 2015, as amended); 15 U.S.C. ch. 102 *et seq.*; 16 C.F.R. § 315.1. It likewise glosses over the fundamental requirement of the ECCPL—that corrective lens prescriptions must be based on more than just a refractive examination. *See* S.C. Code Ann. § 40-24-20 (Supp. 2016). This requirement establishes a baseline for corrective lens prescriptions, just as other laws and regulations establish minimum requirements in the healthcare context and otherwise. *See, e.g.*, S.C. Code Ann. § 40-33-32 (outlining minimum standards for licensure as a nurse); S.C. Code Ann. § 40-57-135 (establishing minimum standards for real estate brokers-in-charge management agreements); S.C. Code Ann. § 37-15-30 (setting minimum standards for using a contest as a ruse to promote the sale of goods, property or services). The ECCPL need not spell out what particular steps an optometrist or ophthalmologist needs to take during a comprehensive eye examination for it to survive rational basis scrutiny. Both the General Assembly and the common law have long recognized that the standard of care for professionals across a wide range of disciplines is too nuanced and fact-specific to be established by legislative act. *See, e.g.*, S.C. Code Ann. § 15-36-100 (Supp. 2016) (expert witness must attest to standard of care and its breach as a

prerequisite to bringing a claim for professional negligence); *Dawkins v. Union Hosp. Dist.*, 408 S.C. 171, 758 S.E.2d 501 (2014) (expert testimony required in medical malpractice action).

Furthermore, there is nothing in the ECCPL that makes it illegal for ophthalmologists to rely upon Opternative's Technology in the course of treating a patient; it just proscribes writing prescriptions for patients based *solely* upon the refractive error that the Technology measures.

The ECCPL's legislative purpose is ostensibly to protect the public from receiving inadequate eye care. Because there is an identifiable risk that the law addresses (*see* Shipp Aff., ¶ 26; Robinson Aff., ¶¶ 12-13), Opternative cannot meet its evidentiary burden to overcome the presumption of constitutionality.

(iii) The ECCPL treats all ophthalmologists and optometrists alike under similar circumstances and conditions.

Unquestionably, the ECCPL creates a bright line rule for *all* ophthalmologists and optometrists to follow. This is not a case in which some ophthalmologists or optometrists are treated differently than others. *Compare Daniel v. Cruz*, 268 S.C. 11, 231 S.E.2d 293 (1977) (no reason to treat fortune tellers in one county differently from those in another). Nor are ophthalmologists and optometrists being treated differently from other health care providers, as the ECCPL only applies to conduct that falls within ophthalmologists and optometrists' scope of practice. *Compare Joseph v. S.C. Dep't of Labor, Licensing &* Regulation, 417 S.C. 436, 790 S.E.2d 763 (2016) (physical therapists treated differently than other healthcare providers); *Broome v.* Truluck, 270 S.C. 227, 241 S.E.2d 739 (1978) (different statutes of limitations for different professionals involved in making improvements to real property).

(iv) The classification in the ECCPL has a reasonable basis.

Opternative argues that there is "no evidence here that the ECCPL furthers a public health or safety purpose." It proposes scenarios in which the ECCPL could have better addressed the patient

health and safety purpose that drove the ECCPL to become law. In highlighting the ECCPL's alleged shortcomings, it purports to show how the law is nothing more than an economic protection measure. Plaintiff even goes so far as to say "where the evidence reveals no tendency in a law to serve its purported purpose, and there appear to be obvious means by which it might have done so, that law is arbitrary and cannot survive rational-basis review." Plaintiff's Motion for Summary Judgment, p. 30. This broad, self-serving statement is neither supported by the record nor rooted in South Carolina rational basis jurisprudence. In fact, this appears to be a subtle attempt to have this Court apply an intermediate level of scrutiny in a situation where that is unwarranted. *Cf. Clark v. Jeter*, 486 U.S. 456 (1988) (to withstand intermediate scrutiny, a statutory classification must be substantially related to an important governmental objective).

In *Joseph*, the Supreme Court held that the statute at issue "deprives physicians of the right to practice medicine in the best interest of their patients" by not being able to hire physical therapists. Opternative draws a parallel with that case, claiming the ECCPL deprives ophthalmologists of their right to practice medicine in the best interest of their patients. The comparison fails, because the ECCPL addresses a particular public health risk (*see* Shipp and Robinson Aff.s), whereas it was impossible to find any such risk to the public health and welfare that the statute in *Joseph* was allegedly designed to mitigate.

The text of the ECCPL in no way prevents ophthalmologists from using their medical judgment to write corrective lens prescriptions. If anything, it prevents Opternative, and other similar healthcare technology providers, from fulfilling a market desire for convenience, *to the detriment of ophthalmologists' patients.* Unlike in *Joseph*, the ECCPL does not prevent ophthalmologists and optometrists from practicing medicine in best interest of their patients. To the contrary, the ECCPL prevents corrective lens prescriptions from being issued without an

examination that takes into consideration a patient's overall health. Addressing that risk is clearly within the General Assembly's constitutional prerogative, and the ECCPL clearly has a reasonable basis.

(C) Opternative cannot prove beyond a reasonable doubt that the ECCPL violates its right to substantive due process.

Although the analysis of Opternative's due process claim is largely identical to its equal protection claim, it is nonetheless clear that the ECCPL bears a reasonable relationship to the State's legitimate interest in protecting the eye and systemic health of South Carolina citizens. Whether couched in terms of "legitimacy" or "reasonableness," the ECCPL's utility in tackling traditional police power concerns easily survives rational basis scrutiny.

II. Alternatively, Opternative's Motion for Summary Judgment should be denied because it has stymied SCOPA's discovery efforts.

Opternative claims that it is entitled to summary judgment because "...the undisputed evidence reveals the ECCPL to be nothing more than a protectionist law designed to ban Opternative's Technology in order to protect South Carolina optometrists' outdated business model from competition, and protectionism is not a legitimate use of the state's police power." *See* Plaintiff's Motion, p. 20. Clearly, the evidence in the record disputes Opternative's assertion.[2]

If the Court is inclined to grant Opternative's Motion for Summary Judgment, SCOPA would submit that doing so at this stage of the litigation is premature, as Opternative has prevented SCOPA from obtaining the discovery it has sought, leaving SCOPA with no choice but to file a Motion to Compel. Given that procedural posture, SCOPA submits that summary judgment would be premature.

[2] Although SCOPA asserts that the evidence in the record disputes Opternative's constitutional claims, it does not contend that Opternative has adduced record evidence that would prevent the Court from granting Defendants' Motion for Summary Judgment.

CONCLUSION

For the above-stated reasons, SCOPA respectfully requests that this Court deny Plaintiff's grant Defendants' Motion for Summary Judgment, or, in the alternative, deny Opternative's Motion for Summary Judgment.

Respectfully submitted,

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Attorneys for Defendant-Intervenor SCOPA

October 2, 2017

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FIFTH JUDICIAL CIRCUIT
COUNTY OF RICHLAND	)	
	)	Civil Action No. 2016-CP-40-06276
Opternative, Inc.,	)	
Plaintiff,	)	
v.	)	**AFFIDAVIT OF MARK E. ROBINSON, M.D., M.P.H.**
	)	
South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation,	)	
Defendants,	)	
and	)	
South Carolina Optometric Physicians Association,	)	
Defendant-Intervenor.	)	

RICHLAND COUNTY FILED
2017 OCT -3 AM 10:27
JEANNETTE W. WALKER
C.C.P. & G.S.

PERSONALLY appeared before me Mark E. Robinson, M.D., M.P.H., who deposes and states that the following is based upon his own personal knowledge, except those matters stated upon information and belief, and as to those matters he believes them to be true:

1. My name is Mark E. Robinson, M.D., M.P.H. I am over the age of 21 years, of sound mind, and have personal knowledge of matters set forth herein. I am authorized to make this Affidavit and have reviewed the allegations of the Plaintiff's Complaint in the above-captioned action and the provisions of the South Carolina Eye Care Consumer Protection Law ("ECCPL").

2. Presently, I am a Neuro-ophthalmologist practicing at Palmetto Health/University of South Carolina. I have held this position since 2015. Prior to this position, I was a practicing

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Ophthalmologist in the State of Virginia for six (6) years. I received my Bachelor of Science, Doctor of Medicine and Masters in Public Health from the University of North Carolina, Chapel Hill.

3. Ophthalmologists are medical doctors specializing in eye and vision care, who by study and training are qualified to diagnose and treat ocular diseases, perform eye exams and surgeries and prescribe lenses to correct vision problems.

4. Ophthalmologists who practice in South Carolina are licensed and regulated by the BME.

5. Opternative is a healthcare technology company that has produced certain technology which allows ophthalmologists and optometrists to collect refractive data and other information from patients using a computer ("Technology"). The Technology is designed to be used by a patient without having an ophthalmologist or optometrist in the room.

6. Opternative's Technology can be accessed by individuals through Opternative's website.

7. Opternative's Technology relies on an individual's subjective self-reporting to collect refractive data using a computer.

8. The use of Opternative's Technology does not constitute a comprehensive eye examination.

9. Opternative's Technology generates a set of data about a user and the user's ocular refractive error. This set of data is sent to a licensed ophthalmologist, who determines if a corrective-lens prescription is appropriate.

10. Ophthalmologists conduct comprehensive eye examinations as part of their practice. Comprehensive eye examinations consist of, but are not limited to, the following: a

review of the patient's health history; measuring visual acuity, both aided and unaided; performing a slit lamp examination of the anterior segments of the eyes and eyelids; performing an internal ophthalmoscopic examination through a dilated pupil, including evaluation of the optic nerve head, macular and peripheral retina; performing a refraction; performing tonometry; evaluating pupils; performing confrontation visual field or similar screening field; performing other tests and procedures as indicated by the patient's chief complaint, case history or objective signs and symptoms discovered during the course of the eye examination; making a diagnosis and formulating a treatment plan.

11. Opternative's Technology collects information by soliciting a user's responses to questions and visual stimuli; it does not measure objective data about the user's eyes.

12. A contact lens is considered a medical device that can be used to correct vision, or for cosmetic or therapeutic reasons. A contact lens evaluation is a set of diagnostic tests and procedures performed in addition to a comprehensive eye examination. These tests and procedures include a measurement of the corneal curvature (keratometry or corneal topography) and an evaluation of the anterior segment and tear layer of the eye in relation to the contact lens fit.

13. Corneal irritation and contact lens over-wear increase the risk of a corneal infection. Corneal infections from contact lens wear are not rare and they can cause scarring and loss of vision. Corneal irritation and signs of contact lens over-wear can be detected on corneal examination. Also, a face-to-face visit with an eye care provider allows the provider to emphasize the importance of not over-wearing contact lenses and the importance of contact lens hygiene. A patient's symptoms may be minimal prior to an infection occurring. Opternative's Technology does not perform a corneal evaluation.

14. Ophthalmologists are under an affirmative obligation to look after the health and safety of their patients, which requires them to use their medical judgment to determine whether their patients' complaints or symptoms pertaining to their eyesight or eye health are indicators of systemic or body-wide disease processes or pathologies. They are likewise obliged to make such determinations even when the disease processes or pathologies are asymptomatic.

15. Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination.

16. An ophthalmologist that conducts a comprehensive eye examination can detect and diagnose certain diseases of the eye, such as glaucoma, cataracts, macular degeneration, binocular vision disorders and corneal dystrophy. They can also detect diabetes, hypertension, hypercholesterolemia, auto-immune disorders and other systemic diseases.

17. The American Academy of Ophthalmology is a national organization of ophthalmologists that, among other things, helps set the standard of care for ophthalmologists nationwide.

18. The official American Academy of Ophthalmology policy regarding comprehensive eye health exams is that "The frequency of ocular examinations should be based on the presence of visual abnormalities and the probability of visual abnormalities developing." American Academy of Ophthalmology Policy Statement, available at https://www.aao.org/Assets/ff742943-87aa-421d-9461-c04f1dd29956/635609992584670000/frequency-of-ocular-exams-2015-pdf (last visited August 23, 2017).

19. The American Academy of Ophthalmology recommends that adults with no signs or risk factors for eye disease should receive a comprehensive medical eye evaluation at age 40 if they have not previously received one. For asymptomatic individuals or individuals without risk factors aged 40 to 54 years old, the Academy's recommended interval for evaluations is 2 to 4 years. For individuals aged 55 to 64 years old, the Academy's recommended interval for evaluations is 1 to 3 years.

20. It is my opinion to a reasonable degree of medical certainty that almost all practicing eye care providers are very rarely providing a refraction without an eye exam, unless they had previously given the patient an eye examination within the prior year. I cannot remember ever doing so myself. Although giving a refraction online in and of itself would be low risk, if it results in patients not obtaining an eye examination, at a population level, there will be a certain amount of disease that is missed. Also, as previously stated, contact lens wearers are at risk for corneal infections and eye examinations are helpful in reducing that risk.

FURTHER AFFIANT SAYETH NAUGHT.

Mark E. Robinson

Mark E. Robinson, M.D., M.P.H.

SWORN TO BEFORE ME THIS
2nd of ~~September~~ October 2017.

_____ (Seal)
Notary Public for North Carolina
My Commission Expires: 12/3/17

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FIFTH JUDICIAL CIRCUIT
COUNTY OF RICHLAND	)	
	)	Civil Action No. 2016-CP-40-06276
Opternative, Inc.,	)	
Plaintiff,	)	
v.	)	**AFFIDAVIT OF DR. MELVIN DOUGLAS SHIPP**
	)	
South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation,	)	
Defendants,	)	
and	)	
South Carolina Optometric Physicians Association,	)	
Defendant-Intervenor.	)	

RICHLAND COUNTY FILED
2017 OCT -3 AM 10:27
JEANNETTE W. WALKER, C.C.P. & G.S.

PERSONALLY appeared before me Dr. Melvin Douglas Shipp, who deposes and states that the following is based upon his own personal knowledge, except those matters stated upon information and belief, and as to those matters he believes them to be true:

1. My name is Dr. Melvin Douglas Shipp, OD, MPH, DrPH. I am over the age of 21 years, of sound mind, and have personal knowledge of matters set forth herein. I am authorized to make this Affidavit and have reviewed the allegations of the Plaintiff's Complaint, the Answer filed South Carolina Board of Medical Examiners ("BME") and South Carolina Department of Labor, Licensing and Regulation ("LLR") (collectively, "Defendants"), the Answer filed by Defendant-Intervenor South Carolina Optometric Physicians Association ("SCOPA") in the above-captioned action.

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2. I received my Bachelor of Science degree from Indiana University in May of 1970 and my Doctor of Optometry in May of 1972. I received my Master of Public Health degree from Harvard University in June of 1980 and my Doctor of Public Health at the University of Michigan in 1996. I have been licensed to practice Optometry since 1972. I have been teaching since 1976.

3. I was the Dean of The Ohio State University College of Optometry from 2004 to 2014. Prior to this appointment, I was a member of the faculty at the University of Alabama at Birmingham School of Optometry. While at UAB, I also served as Assistant Dean of Clinical Services and Director of Clinics.

4. I have served as a consultant, panelist, and reviewer for several federal institutions—notably, the Food and Drug Administration, the Health Resources and Services Administration, and the National Eye Institute (NEI) of the National Institutes of Health. I was a member of the NEI National Advisory Eye Council (1989-1993), and from 1990 to 1995, a member of the NEI Planning Committee for the National Eye Health Education Project (NEHEP), a nationwide program with the goal of preventing blindness through public and professional education programs. From 2011 to 2012, I served as President of the American Public Health Association, the world's largest and oldest public health association.

5. Presently, I am a Former Dean and Professor Emeritus. I have held this position since retiring from The Ohio State University College of Optometry in July of 2014.

6. Doctors of optometry are known as "optometrists." Optometrists are independent primary health care professionals for the eye. Optometrists examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures as well as identify related systemic conditions affecting the eye.

7. It is my understanding that Opternative is a healthcare technology company that has produced certain technology which allows ophthalmologists and optometrists to collect refractive data and other information from patients using a computer ("Technology"). The Technology is designed to be used by a patient without having an ophthalmologist or optometrist in the room.

8. It is my understanding that Opternative's Technology can be accessed by individuals through Opternative's website.

9. It is my understanding that Opternative's Technology relies on an individual's subjective self-reporting to collect refractive data using a computer.

10. Per the website, it is my understanding that the use of Opternative's Technology does not constitute a comprehensive eye examination.

11. It is my understanding that Opternative's Technology generates a set of data about a user and the user's ocular refractive error. This set of data is sent to a licensed ophthalmologist, who determines if a corrective-lens prescription is appropriate.

12. It is my understanding that Opternative's Technology collects information by soliciting a user's responses to questions and visual stimuli; it does not measure objective data about the user's eyes or eye health.

13. It is my understanding that Opternative's Technology cannot detect or aid in diagnosing diseases of the eye or systemic diseases.

14. It is my understanding that Opternative's Technology does not perform a corneal examination and evaluation. A contact lens is considered a medical device that can be used to correct vision, or for cosmetic or therapeutic reasons. A contact lens evaluation is a set of diagnostic tests and procedures performed in addition to a comprehensive eye examination.

These tests and procedures include a measurement of the corneal curvature (keratometry or corneal topography) and an evaluation of the anterior segment and tear layer of the eye in relation to the contact lens fit. A poorly fit contact lens can cause irritation to the eyes. Continuing to wear the irritating contact lens for a prolonged time can create pain and cause scarring and vision loss for a patient. A patient may not have any symptoms from a poorly fit contact lens, but scarring and vision loss can develop nonetheless. Such consequences of a poorly fit contact lens can only be detected by a corneal evaluation.

15. Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination. There is a risk that individuals may mistakenly believe that they have received an eye examination after receiving a prescription for spectacles or contact lenses from an ophthalmologist or optometrist following an Opternative examination. It is possible that some of those individuals may have an asymptomatic eye or systemic disease.

16. In addition to assessing eye and vision problems, an eye examination may be the first opportunity to detect diabetes and other health conditions. Examples include, high blood pressure, hypercholesterolemia, and certain inflammatory diseases.

17. Diabetes is currently the nation's 7th leading cause of death in the United States. Diabetes is also a risk factor for heart disease and stroke, and a leading cause of kidney disease and blindness in adults. Early detection can allow early treatment and management of both systemic and eye related diabetic changes.

18. One of the more debilitating eye related outcomes associated with type 2 diabetes in adults is vision impairment, including blindness. Diabetes related eye conditions include, but

are not limited to, refractive changes, cataracts, diabetic retinopathy, and glaucoma. Diabetic retinopathy is among the leading causes of preventable blindness in the United States.

19. Most symptoms associated with diabetic eye disease progress slowly, and unnoticeably, therefore, comprehensive dilated eye examinations are necessary to diagnose, prevent and manage these conditions.

20. Importantly, diabetic eye disease can be detected and diagnosed during a routine comprehensive dilated eye examination.

21. Optometrists are qualified to (and do) conduct comprehensive eye examinations. Comprehensive eye examinations consist of, but are not limited to, the following: a review of the patient's health history; measuring visual acuity, both aided and unaided; performing an examination with a slit lamp of the anterior segments of the eyes and eyelids; performing an internal ophthalmoscopic examination through a dilated pupil, including evaluation of the optic nerve head, macular and peripheral retina; performing a subjective refraction; performing tonometry; evaluating pupils; assessing ocular motility and eye alignment; performing confrontation visual field or similar screening field; performing other tests and procedures as indicated by the patient's chief complaint, case history or objective signs and symptoms discovered during the course of the eye examination; making a diagnosis and formulating a treatment plan; seeking consultation and/or making referrals for assessment/treatment to other health providers as appropriate.

22. Optometrists are under an affirmative obligation to look after the health and safety of their patients, which requires them to use their optometric judgment to determine whether their patients' complaints or symptoms pertaining to their eyesight or eye health are indicators of

systemic or body-wide disease processes or pathologies. They are likewise obliged to make such determinations even when the disease processes or pathologies are asymptomatic.

23. An optometrist that conducts a comprehensive eye exam can detect and diagnose certain diseases of the eye, such as glaucoma, cataracts, macular degeneration, binocular vision disorders and corneal dystrophy. They can also detect diabetes, hypertension, hypercholesterolemia, auto-immune disorders and other systemic diseases.

24. The American Optometric Association is a national organization of optometrists that, among other things, helps set the standard of care for optometrists nationwide.

25. The American Optometric Association recommends that adults between the ages of 18 and 64 who are asymptomatic and who are not considered "at risk" should have comprehensive eye examination every two years. Such patients who are 61 years old or older should have comprehensive eye examinations annually. Patients who are "at risk" meet one or more of the following conditions: (1) have diabetes, hypertension, or a family history of ocular disease; (2) work in occupations that are highly demanding visually or are particularly hazardous to the eye; (3) wear contact lenses; (4) have had eye surgery; or (5) have other health concerns or conditions. "At risk" patients between the ages of 18 and 60 years should have comprehensive eye examinations every one to two years, as recommended. Such "at risk" patients who are 61 years old or older should have comprehensive eye examinations annually, or as recommended.

26. It is my opinion, to a reasonable degree of certainty as an optometrist and a public health professional, that the South Carolina Eye Care Consumer Protection Law appropriately addresses the risk to public health that is created when members of the public are allowed to obtain corrective lenses merely by undergoing a refractive examination.

FURTHER AFFIANT SAYETH NAUGHT.

Dr. Melvin Douglas Shipp

SWORN BEFORE ME THIS
28th of September 2017.

(Seal)
Notary Public for Arizona
My Commission Expires:

BRANDON REISH
NOTARY PUBLIC - ARIZONA
MARICOPA COUNTY
My Commission Expires
April 16, 2018

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IN THE COURT OF COMMON PLEAS FOR THE FIFTH JUDICIAL CIRCUIT

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND Opternative, Inc., Plaintiff, v. South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation, Defendants, South Carolina Optometric Physicians Association, Defendant-Intervenor.	Civil Action No. 2016-CP-40-06276

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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ISSUES PRESENTED

In 2016, South Carolina made it legal for doctors to practice telemedicine, including writing prescriptions, as long as doing so would meet the standard of care that applies during an in-person visit. At the same time, however, the state adopted the Eye Care Consumer Protection Law (ECCPL), which banned eye doctors from prescribing corrective lenses based on information collected using telemedicine. The ban—which treats eye doctors who prescribe corrective lenses differently than all other doctors who use telemedicine—was drafted by a small group of optometrists to ban competition from Plaintiff Visibly's online vision testing business.[1] The issues presented are:

1. Does the ECCPL violate South Carolina's equal protection clause, S.C. Const. art. I, § 3, either on its face or as applied to eye doctors who want to use Visibly's online vision testing software?

2. Does the ECCPL violate South Carolina's due process clause, S.C. Const. art. I, § 3, either on its face or as applied to eye doctors who want to use Visibly's online vision testing software?

[1] Visibly was originally called Opternative (as the caption indicates) but changed its name to Visibly in 2018 while this case was on appeal from a dismissal for supposed lack of standing. *See Opternative, Inc. v. S.C. Bd. of Med. Exam'rs*, 437 S.C. 258, 878 S.E.2d 861 (2022) (affirming Court of Appeals decision that Opternative had standing to sue).

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INTRODUCTION

South Carolina has two different approaches to telemedicine regulation: one for eye doctors who prescribe corrective lenses and one for all other doctors who prescribe anything else. The Telemedicine Act, enacted in 2016 to expand access to online care, empowers doctors to prescribe using telemedicine as long as they meet the medical standard of care. The ECCPL, drafted by brick-and-mortar optometrists to shut out online competition, bans eye doctors from prescribing corrective lenses using telemedicine—even if doing so would meet the standard of care and benefit countless patients.

The ECCPL violates Article I, Section 3 of the South Carolina Constitution. First, it violates the equal protection clause. That clause forbids laws that create irrational distinctions between similar groups. The ECCPL does exactly that. It bans eye doctors from prescribing lenses based on information collected via telemedicine even though eye doctors are just as qualified as their peers, even though lenses can be prescribed via telemedicine consistent with the standard of care, and even though the supposed reason for the differential treatment—undiagnosed hidden diseases—would apply equally to all other doctors who use telemedicine. That's a classic equal protection violation.

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Second, the ECCPL violates Article I, Section 3's due process clause, which requires economic laws to rationally further a legitimate state purpose. Here, the ECCPL's only asserted purpose is that banning online lens prescriptions will force patients to visit doctors in person, where doctors might detect hidden diseases. But the ECCPL does not require doctors to take any steps that would uncover hidden diseases. It allows doctors to prescribe lenses based on the same information Visibly collects. The ECCPL merely requires that the information be collected by a human being (not even a doctor) rather than an online service. But forcing people to take in-person tests when there are safe, FDA-cleared online alternatives is irrational—which is why the Telemedicine Act empowers all other doctors to use telemedicine in all other contexts.

The ECCPL does not rationally protect patient health. It merely bans online competition with brick-and-mortar optometrists—an illegitimate use of state power. Because there are no disputed material facts,[2] the Court should grant this motion for summary judgment, declare that the ECCPL violates Article I, Section 3, and enjoin its enforcement against Visibly.

[2] Visibly's summary judgment evidence is compiled in the appendix to this motion. Record cites will follow the form App __.

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UNDISPUTED MATERIAL FACTS

I. Visibly allows patients to renew their lens prescriptions online.

A. Visibly's online vision test.

Visibly is a technology company that invented an FDA-cleared online vision test. App 3, 6 (Foley Aff. ¶¶ 2, 4, 20).[3] Visibly's test "allows customers with prior corrective lens prescriptions to take an online vision test and have their results sent to a licensed eye doctor (an ophthalmologist or an optometrist), who can then use that information to help determine whether it is appropriate to renew the customer's prescription." App 3 (*id.* ¶ 4). Visibly's test offers an innovation on the traditional lens-prescription model.

Under the traditional model, a patient visits an eye doctor to have her vision tested. App 74–75 (O'Brien Aff. ¶¶ 5–7).[4] The patient looks at a chart from a distance while the doctor or an assistant asks the patient to identify symbols on the chart. App 74–75 (*id.* ¶¶ 6–8); App 236 (Shipp Dep. 44:4–9).[5] The doctor uses the patient's responses to determine if the patient is seeing well or needs corrective lenses. App 74 (O'Brien Aff. ¶ 5); App 236 (Shipp Dep. 44:4–7). If the patient already has glasses or contact lenses and wears them while looking at the chart, the doctor can also use

[3] Mr. Foley is Visibly's CFO and COO. App 3 (Foley Aff. ¶ 2).

[4] Dr. O'Brien is a licensed ophthalmologist. App 74 (O'Brien Aff. ¶ 2).

[5] Dr. Shipp is a licensed optometrist. App 249 (Shipp Aff. ¶ 1).

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the patient's responses to determine "how well that person is able to see with their current prescription." App 236 (Shipp Dep. 44:4–22).

Visibly's online vision test works the same way. Indeed, the FDA deems Visibly's test an online "Visual Acuity Chart." App 20 (Foley Aff., Ex. 2 (P00420)). To take the test, patients go to Visibly's website and answer screening questions about their age, prior lens prescription, most recent eye-health exam, and medical history (e.g., symptoms, medications, or conditions that may affect the eyes). App 3 (*id.* ¶ 5). Visibly's software then guides patients through a vision test that patients take by looking at images on a computer screen, standing a certain distance away, and using their smartphone to report their responses. App 4 (*id.* ¶¶ 9–10).

Once the test is complete, qualifying patients' results and responses to the screening questions are sent to a licensed eye doctor for review, in the same way that an assistant would hand the patient's responses to a doctor for in-person review. App 76, 78 (O'Brien Aff. ¶¶ 12, 19–20).[6] A patient whose information is sent to a doctor is not guaranteed a prescription. "Rather, Visibly requires its partnering eye doctors to abide by their professional duty to determine, based on the

[6] Patients do not qualify to have their information sent to an eye doctor for review if they do not have a prior lens prescription, have never had an eye-health exam, their test results show that their vision has changed, or their screening question responses show that they have conditions or are taking drugs that may affect their eyes/vision. App 3–4 (Foley Aff. ¶¶ 6–7); App 80 (O'Brien Aff. ¶ 26).

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information they have about each individual customer, whether it is medically appropriate to renew the customer's lens prescription based on the applicable standard of care." App 5–6 (Foley Aff. ¶ 16). If a doctor decides that it would be improper to renew the patient's lens prescription for any reason, the doctor cannot and will not issue a prescription. App 6 (*id.* ¶ 19). But if a doctor decides that it would be proper to renew the patient's prescription based on the information available, the doctor will do so. App 6 (*id.* ¶ 18).

B. Visibly safely expands access to care.

Visibly does not offer—and does not claim to offer—a comprehensive eye-health exam. App 4, 14, 19 (Foley Aff. ¶ 8 & Ex. 1 (P00414) (website disclaimer that Visibly "does not perform or replace a comprehensive eye examination"), Ex. 2 (P00419) (FDA document recognizing same)). Eye-health exams use a slew of procedures—a tonometer to gauge eye pressure, a pupil dilation to look inside the eye, a slit lamp to look at the retina, an ophthalmoscope to examine the optic nerve (among others)—to assess total eye health and detect diseases. App 253 (Shipp Aff. ¶ 21). While these exams are generally important, they "are not always medically necessary for otherwise-healthy patients." App 78 (O'Brien Aff. ¶ 21).

The American Academy of Ophthalmology (AAO) sets the standard of care for ophthalmologists. App 79 (*id.* ¶ 23); *see also* App 242 (Shipp Dep. 68:13–69:24

(optometrist agreeing that the AAO's standards are "consistent with what I understand to be reasonable")). The AAO recommends that patients with no signs or risk factors for eye disease should get an eye-health exam at least once by age 40; once every 2–4 years after that until age 54; once every 1–3 years after that until age 64; and then once every 1–2 years moving forward. App 79, 101–02 (O'Brien Aff. ¶ 23 & Ex. 3 (P00500–501)).

Consistent with the AAO's recommendations, every eye doctor who has testified in this case agrees that it can be beneficial to prescribe lenses in between more detailed eye-health exams. App 77–78 (O'Brien Aff. ¶¶ 17–18 (ophthalmologist who has written prescriptions using Visibly testifying that those patients "benefitted from increased access to vision care")); App 348–49 (Chaum Aff. ¶¶ 2, 4 (South Carolina ophthalmologist testifying that, when it was legal to do so, he used Opternative to prescribe "lenses for multiple individual patients" who enjoyed "improve[d] . . . access" to care)); App 237–38 (Shipp Dep. 47:24–48:24, 50:8–18 (optometrist testifying that if a healthy patient just wanted a lens prescription, the appointment "would not [involve] a comprehensive eye exam" but would instead involve "a very problem-focused exam")); App 116 (Zolman Dep. 32:8–33:1 (South Carolina optometrist testifying that where a patient was not able to visit his office,

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he renewed the patient's lens prescription without an eye-health exam and the prescription "improve[d] her quality of life")).

In other words, Visibly is safe. As Dr. O'Brien, an ophthalmologist who has used Visibly for years, testified: "The key to safely using telemedicine in any medical practice, including an ophthalmological practice, is to evaluate each patient on a case-by-case basis and to ensure that using telemedicine meets the relevant standard of care." App 76 (O'Brien Aff. ¶ 14). Visibly is designed around that principle and requires eye doctors to follow it. App 5–6 (Foley Aff. ¶ 16). The results speak for themselves: Tens of thousands of patients across dozens of states are using Visibly. App 7 (Foley Aff. ¶¶ 22–24); App 77–78 (O'Brien Aff. ¶ 18). Yet there is no evidence that any patient has ever been harmed by Visibly or from a prescription issued by one of its partnering doctors. App 7–8 (Foley Aff. ¶¶ 25–28); App 77–78 (O'Brien Aff. ¶ 18).

Since hitting the market in 2014, Visibly has experienced "a genuine demand for [its] services." App 344 (Bodde Aff. ¶ 10). Especially among patients who lack ready access to care: "patients in rural areas, patients with lower incomes who work long hours or have multiple jobs, handicapped patients, and patients with children, who are often unable or unwilling to travel to a doctor's office just to take a vision test." App 75 (O'Brien Aff. ¶ 9); App 7 (Foley Aff. ¶ 24). For a time—when Visibly

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was still called Opternative—it operated in South Carolina too. App 8–9 (Foley Aff. ¶ 30); App 344–45 (Bodde Aff. ¶ 11); App 348 (Chaum Aff. ¶ 2). But that changed in 2016.

II. SCOPA drafted the ECCPL to shut out online competition.

A. SCOPA mobilized to destroy Visibly's business.

Vision care is big business. In 2014, the total vision-care market generated over $35 billion in revenue, $23 billion of which came from the sale of glasses and contact lenses alone. App 270, 294 (SCOPA000153, 177). And optometrists—who prescribe and sell lenses and frames—have a major stake in this market. Michael Zolman, an optometrist affiliated with the South Carolina Optometric Physicians Association (SCOPA),[7] testified that about half of optometrists' appointments come from patients seeking lens prescriptions, and that optometrists try to sell lenses after these appointments "most of the time." App 111–12, 123–24 (Zolman Dep. 9:2–11:5, 65:5–66:15). SCOPA agrees that "most South Carolina optometrists sell eyeglass frames," App 186 (Rivers Dep. 28:20–22), and that these sales often comprise a majority of optometrists' profits, SCOPA Ans. ¶ 20.

[7] SCOPA is a local advocacy group for optometrists and the Defendant-Intervenor in this case. App 181–83 (Rivers Dep. 9:25–11:11, 15:18–16:8).

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Visibly—which offers patients a way to renew their lens prescriptions online—threatens optometrists' profits. SCOPA Ans. ¶ 20; App 124 (Zolman Dep. 66:16–67:9). So not long after Visibly entered the market as Opternative, the American Optometric Association (AOA)[8] announced a national campaign to address "the Opternative issue." App 323 (SCOPA000501). In 2015, the AOA hosted a webinar for its local affiliates on how online vision care technologies would impact the optometry business. App 298–310 (SCOPA000181–193). The webinar announced that the AOA had drafted a model bill and recommended that local affiliates push the bill in their states to "Fight" online vision care. App 295–96 (SCOPA000178–179).

SCOPA answered the call. After the webinar, Zolman—who ran SCOPA's lobbying efforts at the time—warned SCOPA's leadership that online vision care would pose "a huge threat to our profession" and impact the "business side" of optometry. App 270–71 (SCOPA000153–154); App 120–21 (Zolman Dep. 51:3–5, 54:2–12). He urged SCOPA to "address [the issue] quickly and attack aggressively," explaining that the "AOA is on the ball and recently drafted a bill that can be modified on a state-by-state basis to prevent this . . . [which] is something we definitely want to do." App 270 (SCOPA000153).

[8] The AOA is a national advocacy group for optometrists. App 112 (Zolman Dep. 11:15–13:7). SCOPA is a subsidiary of the AOA. App 183 (Rivers Dep. 15:18–16:8).

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SCOPA took Zolman's advice. Over the next few months, SCOPA adapted the AOA's bill and lobbied for its passage as the ECCPL. App 130 (SCOPA000152); App 185, 188 (Rivers Dep. 23:13–15, 34:17–35:2 ("the ECCPL is a bill that SCOPA passed")). While SCOPA tried to hide its economic motives—taking care to avoid mentioning Opternative because "[l]egislators frown upon legislation that singles out and restricts a specific business" (App 329 (SCOPA0001258))—internal emails show that the ECCPL was always designed to shut Opternative down. App 193 (Rivers Dep. 55:16–22, 56:6–11 (Rivers agreeing that SCOPA pushed the ECCPL to ban "online eye exams" and there were "internal discussions at SCOPA about the importance of discussing the ECCPL as if it were not an effort to ban Opternative")).

The ECCPL hit a snag when then-Gov. Haley vetoed the bill for "us[ing] health practice mandates to stifle competition for the benefit of a single industry . . . . put[ting] us on the leading edge of protectionism, not innovation." S.C. State Library (Digital Collections), *Veto of R.178, S.1016*, https://tinyurl.com/a7w4kfdy (emphasis omitted).

But SCOPA rallied to override the veto, and when the ECCPL finally passed, SCOPA celebrated the law's crushing impact on Opternative's business. App 263 (SCOPA000116) ("[T]ake that Opternative!!!!!!); App 268 (SCOPA000129) ("It's with the utmost pleasure to announce that Opternative and 'eye exam' kiosks are now

PROHIBITED BY LAW in the great state of SC!"). Months later, when the AOA asked SCOPA to present for other state affiliates on what it had achieved, SCOPA put it this way (App 320 (SCOPA000203)):

B. The ECCPL bans doctors from using Visibly.

The ECCPL bans eye doctors from prescribing lenses based on information collected by Visibly and similar online technologies. Under the law, a valid lens prescription "must take into consideration medical findings made and refractive error discovered during [an] eye examination." S.C. Code Ann. § 40-24-20(B). Eye exams, in turn, need a "visual status," *id.* § 40-24-10(3), which cannot be "based

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solely on . . . information generated by an automated testing device," *id*. § 40-24-10(9). It's an oddly phrased law—but it bans Visibly just as SCOPA hoped it would.

Notably, the ECCPL does not say what the "examination" must involve or what "findings" must support a lens prescription. Nor, in practice, are there any substantive requirements that doctors must follow: The law imposes "no explicit [testing] requirement," "doesn't say how the eye examination is to be conducted," "doesn't identify diagnostic methodologies that have to be employed in order to develop the medical findings," and does not "specify what those medical findings must be." App 225–26 (Coleman Dep. 64:16–66:17).[9] All the ECCPL requires is "some type of human involvement" in the exam—even if the human is just an "unlicensed professional[]." App 226 (*id.* at 67:3–68:2).

Put another way, the ECCPL does not regulate the information on which a lens prescription must be based. It remains perfectly legal (as it always has been) to renew a prescription based entirely on a patient's self-reported medical history and responses to images on an eye chart. ECCPL merely requires that at least some of this information be collected by a human being—who need not be licensed, trained, or qualified in any way. This arbitrary requirement achieves nothing except what

[9] Ms. Coleman testified as the Rule 30(b)(6) designee for Defendants. App 215 (Coleman Dep. 6:1–7:12).

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SCOPA always wanted: to protect brick-and-mortar optometrists from online competition.

The ECCPL destroyed Visibly's South Carolina business. After the law passed, eye doctors could no longer prescribe corrective lenses "based solely on . . . information generated by an automated testing device." S.C. Code Ann. § 40-24-10(9). That made it impossible for Visibly to operate in South Carolina. App 345 (Bodde Aff. ¶ 12); App 348 (Chaum Aff. ¶ 3); App 8–9 (Foley Aff. ¶¶ 29, 31).

There are no other legal barriers at play here. Visibly is FDA-cleared. App 6, 16 (Foley Aff. ¶ 20 & Ex. 2). And the Telemedicine Act embraces telemedicine for doctors who "adhere to the same standard of care as a licensee employing more traditional in-person medical care," S.C. Code Ann. § 40-47-37(A)—a rule Visibly's partnering eye doctors can follow by renewing lens prescriptions in between more detailed eye-health exams. App 78–80 (O'Brien Aff. ¶¶ 19–25). If the ECCPL were struck down, Visibly would promptly resume operating in South Carolina. App 9 (Foley Aff. ¶ 32).

LEGAL STANDARD

Summary judgment is proper when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled

to judgment as a matter of law." Rule 56(c), SCRCP. The movant has the initial burden of showing that there is no material factual dispute. *Ellis v. Davidson*, 358 S.C. 509, 518, 595 S.E.2d 817, 822 (Ct. App. 2004). The movant can meet that burden by showing that there is no evidence in the record supporting the nonmovant's case. *See Lanham v. Blue Cross & Blue Shield of S.C., Inc.*, 349 S.C. 356, 361, 563 S.E.2d 331, 333 (2002). The burden then shifts to the nonmovant to identify specific facts in the record that show there is a genuine issue for trial. *Ellis*, 358 S.C. at 518–19, 595 S.E.2d at 822.

ARGUMENT

The ECCPL violates Article I, Section 3 of the South Carolina Constitution in two ways. ***First***, the ECCPL violates Article I, Section 3's equal protection clause because it irrationally treats doctors who prescribe lenses differently than all other doctors who use telemedicine to prescribe anything else. ***Second***, the law violates Article I, Section 3's due process clause because banning online lens prescriptions does not rationally further patient health or any other legitimate interest. Because there are no disputes of material fact and Visibly is entitled to judgment as a matter of law, the Court should grant Visibly's motion.

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I. The ECCPL violates South Carolina's equal protection clause.

Article I, Section 3 forbids the state from denying "equal protection." To provide equal protection, the ECCPL must pass the "rational basis test." *Denene, Inc. v. City of Charleston*, 359 S.C. 85, 91, 596 S.E.2d 917, 920 (2004). Which means that if the ECCPL (1) "treats similarly situated entities differently," then (2) "the legislative body [must have] a rational basis for the disparate treatment." *Joseph v. S.C. Dep't of Lab., Licensing & Regul.*, 417 S.C. 436, 451, 790 S.E.2d 763, 771 (2016) (plurality) (citing *Ed Robinson Laundry & Dry Cleaning, Inc. v. S.C. Dep't of Revenue*, 356 S.C. 120, 124, 588 S.E.2d 97, 99 (2003)).[10] This test, while deferential, has teeth: Courts can and do strike down economic laws that fail to advance a legitimate state purpose. *See, e.g.*, *Joseph*, 417 S.C. at 451–52, 790 S.E.2d at 771 (striking down law that banned physical therapists from working for physicians); *Retail Servs. & Sys. v. S.C. Dep't of Revenue*, 419 S.C. 469, 474–75, 799 S.E.2d 665, 667–68 (2017) (plurality) (striking down cap on number of liquor permits a store could obtain). This Court should do the same.

[10] Alternatively, the ECCPL violates equal protection if its disparate treatment lacks "a rational relationship to a legitimate governmental purpose." *Joseph*, 417 S.C. at 451, 790 S.E.2d at 771 (cite omitted). Because that analysis largely overlaps with what Visibly must prove to prevail on its due process claim, Visibly incorporates Section II, *infra*, by reference here to avoid duplicative briefing.

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A. The ECCPL treats doctors who prescribe lenses differently than all other doctors who use telemedicine.

The first equal protection prong asks if "the law treats similarly situated entities differently." *Joseph*, 417 S.C. at 451, 790 S.E.2d at 771 (cite omitted). The ECCPL does. South Carolina doctors are broadly allowed to prescribe based on information collected via telemedicine if they "adhere to the same standard of care as a licensee employing more traditional in-person medical care." S.C. Code Ann. § 40-47-37(A). By contrast, eye doctors are banned from prescribing lenses—and only lenses—"based solely on . . . information generated by an automated testing device." *Id.* §§ 40-24-20(B)–(C), 40-24-10(3), 40-24-10(9). That's disparate treatment.

Moreover, both groups of doctors are similarly situated. Groups are similarly situated when they have the same "trade," *Ed Robinson Laundry*, 356 S.C. at 124, 588 S.E.2d at 99, or when they are part of the same industry. *See, e.g.*, *Hanvey v. Oconee Mem'l Hosp.*, 308 S.C. 1, 5, 416 S.E.2d 623, 626 (1992) (charity hospitals were similarly situated to other providers of medical services); *Jackson v. Raffensperger*, 308 Ga. 736, 737, 843 S.E.2d 576, 578 (2020) (lactation aides with different training and focuses were similarly situated).

Joseph is a clear guide. There, a group of physical therapists challenged a law that forbade them from working for physicians. In striking down the law, a plurality of the South Carolina Supreme Court held that the physical therapists were similarly

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situated to other healthcare professionals (e.g., "occupational therapists, speech pathologists, and nurse practitioners") who were not subject to the law. 417 S.C. at 452, 790 S.E.2d at 772.[11] Similarly here, doctors who prescribe lenses are similarly situated to all other doctors who use telemedicine to prescribe anything else.

B. There is no rational difference between doctors who prescribe lenses and all other doctors who use telemedicine.

The second equal protection prong requires "a rational basis for the disparate treatment." *Joseph*, 417 S.C. at 451, 790 S.E.2d at 771 (cite omitted). There must be a "real difference" between the two groups. *Daniel v. Cruz*, 268 S.C. 11, 14, 231 S.E.2d 293, 294 (1977) (cite omitted). And that difference must be rationally connected to the law's purpose. *In re Luckabaugh*, 351 S.C. 122, 150, 568 S.E.2d 338, 352 (2002); *see also Standard Oil Co. v. City of Spartanburg*, 66 S.C. 37, 44 S.E. 377, 379 (1903) ("[A]ll classification . . . must primarily depend on purpose, the problem presented."). Here, there is nothing about doctors who prescribe lenses that could justify treating them differently than all other doctors who use telemedicine.

[11] The lead opinion in *Joseph* was a plurality, but the relevant analysis drew no dissent. One justice would have reached the same result on statutory grounds. 417 S.C. at 455, 790 S.E.2d at 773 (Kittredge, J., concurring). And two more justices dissented on standing grounds but praised the majority's opinion as otherwise "laudable." *Id.* at 466, 790 S.E.2d at 779 (Beatty, J., dissenting).

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The only legitimate purpose that anybody has offered for the ECCPL is that barring patients from getting lens prescriptions online will force them to visit doctors in person, which "may" uncover hidden diseases. App 337 (SCOPA Resp. Interrogatory 1). But that is not a "real difference" when it comes to telemedicine. *Daniel*, 268 S.C. at 14, 231 S.E.2d at 294. Any patient seeing any doctor for any reason could have a hidden disease. Yet dermatologists, cardiologists, endocrinologists, psychiatrists, family doctors, and all other doctors are allowed to prescribe using telemedicine. *See* S.C. Code Ann. § 40-47-37(A). Eye doctors are just as qualified as these other doctors to use telemedicine in a way that accounts for hidden diseases. App 76 (O'Brien Aff. ¶ 12).

South Carolina Supreme Court caselaw confirms that the ECCPL's disparate treatment is irrational. In *Joseph*, the Court struck down the PT employment ban because it saw no "plausible reason as to why PTs are so different from other health care professionals that they must be singled out and provided disparate treatment for self-referral purposes." 417 S.C. at 452–53, 790 S.E.2d at 771–72. In *Hanvey*, the Court struck down a law that reduced only charity hospitals' liability because it saw "no rational basis for distinguishing between charitable hospitals . . . and medical providers of other goods and services" for liability purposes. 308 S.C. at 5, 416 S.E.2d

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at 626.[12] The ECCPL similarly treats doctors who prescribe lenses differently than all other doctors who use telemedicine—even though any patient seeing any doctor could have a hidden disease. That violates equal protection.

II. The ECCPL violates South Carolina's due process clause.

Article I, Section 3 also forbids the state from "depriv[ing] [any person] of life, liberty, or property without due process of law." To survive, the ECCPL must bear "a reasonable relationship to any legitimate interest of government." *R.L. Jordan Co. v. Boardman Petroleum, Inc.*, 338 S.C. 475, 477–78, 527 S.E.2d 763, 765 (2000); *see also Planned Parenthood S. Atl. v. State*, 438 S.C. 188, 250, 882 S.E.2d 770, 803–04 (2023), *reh'g denied* (Feb. 8, 2023) (law "must be reasonably designed to accomplish its purposes"). The ECCPL fails this test because it does nothing to protect patient health. Instead, it merely protects brick-and-mortar optometrists from online competition—an illegitimate use of state power.

A. The ECCPL does not rationally protect patient health.

Defendants admit they "have no evidence within our possession relating to the impact on public safety of the ECCPL." App 224 (Coleman Dep. 54:22–56:1). But

[12] *See also Broome v. Truluck*, 270 S.C. 227, 230–31, 241 S.E.2d 739, 740 (1978) (finding "[n]o rational basis" for law that granted architects, engineers, and contractors immunity from liability for harm caused by improvements to real property because "architects, engineers, and contractors are not the only persons whose negligence in the improvement of real property may cause damage or injury to others").

the law's problems run far deeper than the State's lack of evidence. Recall SCOPA's asserted basis for the law: barring patients from getting lens prescriptions online "may" help detect hidden diseases. App 337 (SCOPA Resp. Interrogatory 1). There are at least three reasons to reject SCOPA's assertion.

First, SCOPA's premise is that patients who can't get lens prescriptions online might visit eye doctors in person, where they might get full eye-health exams. But the ECCPL does not require eye-health exams. It requires that prescriptions be based on "medical findings made . . . during [an] eye examination"—defined (bizarrely) to mean a "visual status" *that is not* "based solely on . . . information generated by an automated testing device[.]" S.C. Code Ann. §§ 40-24-20(B), 40-24-10(9). None of that requires doctors to check for hidden diseases before prescribing lenses. App 225–26 (Coleman Dep. 64:16–66:17). Indeed, it does not require *doctors* to examine patients at all; "some type of human involvement" by an "unlicensed professional[]" is enough. App 226 (*id.* at 67:3–68:2).

The result? The ECCPL allows eye doctors to prescribe lenses without conducting eye-health exams. And doctors can prescribe those lenses based on the same information Visibly collects: (1) a patient's self-reported medical history and (2) the patient's responses to what they see on an eye chart. The ECCPL's only real-world impact is that now, a human being must collect the information on which the

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prescription is based. Online tools like Visibly are banned. Untrained human beings with clipboards are not. That's irrational, and it does nothing to ensure that doctors will detect hidden diseases.

Second, the record confirms that eye doctors can follow the Telemedicine Act's main safety rule—"adher[ing] to the same standard of care as a licensee employing more traditional in-person medical care," S.C. Code Ann. § 40-47-37(A)—when prescribing lenses. The standard of care is simple and undisputed: Low-risk patients should get an eye-health exam once by age 40; once every 2–4 years after that until age 54; once every 1–3 years after that until age 64; and then once every 1–2 years after that. App 79, 101–02 (O'Brien Aff. ¶ 23 & Ex. 3 (P00500–501)); *see also* App 242 (Shipp Dep. 68:13–69:24 (SCOPA's expert, an optometrist, agreeing that the AAO standard "is consistent with what I understand to be reasonable")). That standard leaves ample room for eye doctors to prescribe lenses in between more detailed eye-health exams.

Indeed, every eye doctor who has testified in this case both *agrees* that it can be beneficial to prescribe lenses without also performing an eye-health exam and has *personally done so*. App 77–78 (O'Brien Aff. ¶¶ 17–18 (ophthalmologist who has written prescriptions using Visibly testifying that those patients "benefitted from increased access to vision care")); App 348–49 (Chaum Aff. ¶¶ 2, 4 (ophthalmologist

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who used Opternative before the ECCPL passed testifying that he prescribed "lenses for multiple individual patients" in South Carolina who enjoyed "improve[d] . . . access" to care)); App 237–38 (Shipp Dep. 47:24–48:24, 50:8–18 (SCOPA's expert, an optometrist, testifying that if a healthy patient just wanted a lens prescription, the appointment "would not [involve] a comprehensive eye exam" but would instead involve "a very problem-focused exam")); App 116 (Zolman Dep. 32:8–33:1 (South Carolina optometrist affiliated with SCOPA testifying that where a patient was not able to visit his office, he renewed the patient's lens prescription without an eye-health exam and the prescription "improve[d] her quality of life")). SCOPA's asserted justification for the ECCPL defies how real eye doctors actually practice.

Third, South Carolina's broader approach to telemedicine fatally undermines SCOPA's assertion. If the mere possibility of hidden diseases could justify banning doctors from prescribing *lenses* via telemedicine, then it would justify banning doctors from prescribing *anything* via telemedicine. But the legislature rejected that idea when it adopted the Telemedicine Act, which recognizes that empowering doctors to expand access to care using online tools is good for patients. It defies logic and common sense to suggest that when it comes to corrective lenses—but not the countless other plainly more dangerous devices and substances a doctor might

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prescribe—doctors cannot be trusted to use FDA-cleared tools like Visibly. The ECCPL does not rationally protect patient health.

B. The ECCPL merely protects optometrists from online competition, which is not a legitimate use of state power.

The reason the ECCPL fails to protect public health is that SCOPA wrote it for another purpose: to protect brick-and-mortar optometrists from online competition. Optometrists' businesses often depend on selling lenses in their stores. SCOPA Ans. ¶ 20; App 111–12, 124–25 (Zolman Dep. 9:25–11:5, 65:5–66:15). When Visibly entered the market as Opternative, the AOA drafted a bill to address "the Opternative issue." App 323 (SCOPA000501). SCOPA then adapted that bill to "address [the issue] quickly and attack aggressively" because it thought Opternative would pose "a huge threat to our profession" and impact "the business side" of optometry. App 270–71 (SCOPA000153–154); App 120–21 (Zolman Dep. 51:3–5, 54:2–12). And when the ECCPL finally passed, SCOPA bragged "with the utmost pleasure" about how "Opternative . . . [was] now **PROHIBITED BY LAW**." App 268 (SCOPA000129). SCOPA's summary of what it achieved says it all (App 320 (SCOPA000203)):

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SCOPA 000203

But the South Carolina Supreme Court has repeatedly struck down laws that have little connection to the public welfare and dish out "mere favor[s]" to certain market groups. *City of Laurens v. Anderson*, 75 S.C. 62, 55 S.E. 136, 137 (1906). In *Retail Services*, most recently, the Court struck down a cap on the number of liquor permits a store could obtain because "there [was] no indication in this record that these provisions exist for any other purpose than economic protectionism," which "is not a constitutionally sound basis for regulating liquor sales." 419 S.C. at 474–75, 799 S.E.2d at 667–68 (plurality). In *G-H Insurance Agency, Inc. v. Continental Insurance Co.*, similarly, the Court struck down a law that forbade insurers from firing agents because "the predominant purpose of the challenged provision was to protect the

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private interests of affected agents rather than any broader societal interest." 278 S.C. 241, 248–49, 294 S.E.2d 336, 340–41 (1982) (cite omitted).

The most helpful case, though, is *Joseph*. There, the state argued that a law banning physical therapists from working for physicians was meant to prevent conflicts of interest. 417 S.C. at 443–46, 452, 790 S.E.2d at 766–68, 771. But the Court held that an employment ban was an irrational way to prevent "receiving or giving illegal kickbacks and participating in referral-for-pay agreements"—especially when the law could have addressed those things directly, and when no other professionals (only PTs) were subject to the ban. *Id*. The Court then exposed the law for what it was: "anti-competitive protectionist legislation intended to protect [PTs'] personal financial interests . . . rather than actual benefits to patients." *Id*.

The ECCPL is more of the same. Like the physical therapists in *Joseph*, eye doctors who prescribe lenses "stand alone in South Carolina" as the only ones excluded from the Telemedicine Act. *Id.* at 442, 790 S.E.2d at 766. As in *Joseph*, the ECCPL takes the drastic step of "depriv[ing] physicians of their right to practice medicine in the best interests of their patients" while failing to require the one thing that would further its alleged purpose: full eye-health exams to check for hidden diseases. *Id.* at 452, 790 S.E.2d at 771. And just like the law in *Joseph*, the ECCPL's

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only real effect is to preserve some optometrists' business models by shutting out competition. *Id*. That violates due process.

* * *

This case is not complex. The ECCPL bans eye doctors from using FDA-cleared tools like Visibly to prescribe lenses. It does this by requiring in-person "exams" that can be performed by anybody (licensed or not) and that do not even have to check for hidden diseases—the supposed point of the law. It defies the standard of care and how real eye doctors—including SCOPA's own witnesses—practice. And it treats eye doctors who prescribe lenses differently than all other doctors who prescribe anything else—even though there is no real difference between the two groups. On this record, there is no reason to believe the ECCPL achieves anything other than what SCOPA hoped it would: shutting out online competition. Accordingly, the ECCPL violates Article I, Section 3 and Visibly is entitled to judgment as a matter of law.

CONCLUSION

For these reasons, the Court should grant Visibly's motion for summary judgment and strike down the ECCPL.

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Respectfully submitted,

By: /s/ W. Logan Lewis

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Opternative, Inc. v. S.C. Board of Medical Examiners, et al.
(Civil Action No. 2016-CP-40-06276)

AFFIDAVIT OF PAUL FOLEY
(APP 1-APP 71)

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IN THE COURT OF COMMON PLEAS FOR THE FIFTH JUDICIAL CIRCUIT

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND Opternative, Inc., Plaintiff, v. South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation, Defendants, South Carolina Optometric Physicians Association, Defendant-Intervenor.	Civil Action No. 2016-CP-40-06276

AFFIDAVIT OF PAUL FOLEY

I, Paul Foley, submit the following testimony under oath:

1. I am a citizen of the United States over eighteen years of age. I am of sound mind and fully competent to make this affidavit, which I make knowingly and based on my personal knowledge.

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2. I am currently the Chief Financial Officer and Chief Operating Officer for Visibly, Inc. (called Opternative, Inc., from 2012 through 2018) and have worked for the company since 2016.

3. As Visibly's CFO and COO, I am familiar with the company's business model, technology, operations, history, and corporate structure.

4. Visibly is a technology company that has produced software that allows customers with prior corrective lens prescriptions to take an online vision test and have their results sent to a licensed eye doctor (an ophthalmologist or an optometrist), who can then use that information to help determine whether it is appropriate to renew the customer's prescription.

5. To take Visibly's test, customers start by visiting Visibly's website (www.govisibly.com) and answering a series of screening questions about their age, existing lens prescription, most recent comprehensive eye health exam, and medical history (e.g., health conditions, symptoms, medications, and past procedures that may affect the customer's eyes).

6. Customers whose responses to the screening questions indicate that they have never had a corrective lens prescription cannot obtain a prescription through Visibly.

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7. Customers whose responses to the screening questions indicate that they have never had a comprehensive eye health exam cannot obtain a prescription through Visibly.

8. Visibly's website provides the following disclaimer to customers to ensure they are aware that its vision test is not a comprehensive eye health exam: "The [test] does not perform or replace a comprehensive eye examination, nor does it assess eye health. Consult an eye care professional for a comprehensive eye examination yearly or any time you are experiencing pain or discomfort. This test is not intended to diagnose, treat, mitigate, or cure disease." Attached as Exhibit 1 is a true and correct copy of the webpage on which this disclaimer appears.

9. After customers answer the screening questions, Visibly's software then prompts customers with a series of written and audio questions that guide them through a vision test.

10. During the test, customers view a series of images on a computer screen while wearing their existing corrective lenses and standing 10 feet away, and use a smartphone to report responses to what they see.

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11. Throughout the test, Visibly's software reminds customers that honest answers are important.

12. Once the test is complete, Visibly's software sends all of the customer's recorded responses—to both the vision test and the screening questions—to a licensed eye doctor for review.

13. In total, Visibly's test takes 5–10 minutes and costs nothing to complete. However, customers must pay $35 to have their information sent to an eye doctor for review.

14. Visibly's partnering eye doctors use Visibly's software to collect information about customers in order to determine whether it is medically appropriate to renew their lens prescriptions.

15. Visibly's partnering eye doctors do not use Visibly to diagnose customers' underlying health conditions or symptoms (other than visual acuity) or to perform a contact lens fitting.

16. When one of Visibly's partnering eye doctors receives a customer's information, they have no obligation to renew that customer's lens prescription. Rather, Visibly requires its partnering eye doctors to abide by their professional duty to determine, based on the information they have about each individual

customer, whether it is medically appropriate to renew the customer's lens prescription based on the applicable standard of care.

17. In other words, Visibly's software is simply a tool that partnering eye doctors can use to gather information about a customer and then use their own judgment to determine whether it would be medically appropriate to renew that patient's lens prescription.

18. If a partnering eye doctor determines that it would be medically appropriate to renew a customer's lens prescription, the customer will typically receive that prescription through Visibly's website within 24 hours.

19. If a partnering eye doctor determines that it would not be medically appropriate to renew a customer's lens prescription based on the information available to the doctor, the customer cannot receive a prescription through Visibly.

20. Visibly's online vision test has been cleared by the U.S. Food and Drug Administration (FDA) for marketing to adults aged 22–40. Attached as Exhibit 2 is a true and correct copy of an August 12, 2022 letter from the FDA to Visibly confirming the same.

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21. During the COVID-19 pandemic, Visibly marketed its online vision test to customers aged 18–55 under an FDA policy that waived enforcement of certain marketing regulations in order to increase access to vision care. As of the date of this affidavit, the FDA's enforcement waiver is set to expire on November 7, 2023. Attached as Exhibit 3 is a true and correct copy of the FDA's policy and later-issued guidance document.

22. Visibly is currently marketing its online vision test in dozens of states across the country to the extent legally allowed by the FDA.

23. In the dozens of states where Visibly is offering its online vision test, partnering eye doctors are using Visibly to renew customers' lens prescriptions where medically appropriate.

24. In the dozens of states where Visibly is offering its online vision test, customers—including rural, low-income, handicapped, and busy people who would otherwise be unable or unwilling to visit a doctor's office—are benefiting from increased access to vision care.

25. Visibly has a policy of reviewing and investigating customer complaints and of reporting any adverse health events (i.e., harmful, damaging, painful, or the life-threatening health conditions or symptoms) to the FDA.

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26. I am not aware of Visibly ever having received a customer complaint regarding an adverse health event from taking Visibly's online vision test or from receiving a lens prescription from one of Visibly's partnering eye doctors.

27. I am not aware of any customer ever having experienced an adverse health event from taking Visibly's online vision test or from receiving a lens prescription from one of Visibly's partnering eye doctors.

28. Visibly has never had occasion to report to the FDA any adverse health events associated with a customer taking Visibly's online vision test or with receiving a lens prescription from one of Visibly's partnering eye doctors.

29. Visibly is not currently operating in South Carolina based on Visibly's understanding that the Eye Care Consumer Protection Law (ECCPL), S.C. Code Ann. §§ 40-24-10 & 40-24-20, prohibits eye doctors from writing lens prescriptions for customers based solely on information collected remotely by Visibly's online vision testing software (which is the only way the software is designed to be used).

30. From 2014 through 2016, when Visibly was still called Opternative, South Carolina eye doctors used an earlier FDA-registered version of Visibly's

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online vision test to collect information from patients remotely and to prescribe corrective lenses for patients based on that information.

31. After the ECCPL was enacted in May 2016, however, South Carolina eye doctors were no longer willing to use Visibly's online vision test to collect information from patients remotely and to prescribe corrective lenses for patients based on that information (because it was illegal), so Visibly was forced to shut down its South Carolina operations.

32. If the ECCPL were repealed or struck down in court, Visibly would immediately begin marketing its online vision test to South Carolina customers to the extent allowed by the FDA.

33. This testimony is true and correct to the best of my knowledge.

FURTHER AFFIANT SAYETH NOT.

Paul N Foley

Paul Foley, CFO, [redacted], Visibly, Inc.
COO

SWORN to and subscribed before me:

Andrew Baumann

This the 10 day of May, 2023

Notary public for the State of Florida

My commission expires 10/5/2025

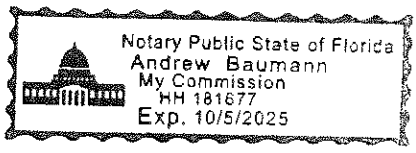

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EXHIBIT 1

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Opternative

Renew your vision prescription online for $35

Renew your vision prescription using our online vision test. It takes about 6 minutes and most prescriptions are issued within 2 hours.

Renew My Rx Online
(https://app.govisibly.com/signup/new)

Do I qualify for an online vison test?

How it Works

1.

You take the test online

You'll need your phone, your computer, and 10 feet of space. The test takes about 6 minutes to complete.

2.

A doctor reviews your results

A licensed optometrist or opthalmologist in your region will review and dispense your results.

3.

Use your results to see visibly

Access your results anywhere and anytime through our online portal.

Renew My Rx Online (https://app.govisibly.com/signup/new)

Take our test, Renew your Rx.

We know you're busy. So we've made prescription renewal easy: take our online vision test at any time from the comfort of your home.

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Our test is all you need to get a renewed vision prescription. The test will take about 6 minutes and over 90% of our prescriptions are issued in under 24 hours.

Get Your Prescription (https://app.govisibly.com/signup/new)

Benefits

Convenient

Take your eye exam from the comfort of your home. It takes about 6 minutes.

Accessible

Access your prescription through your device anywhere and at any time.

Doctor Approved

All prescriptions are issued by an eye care professional licensed in your state.

FAQs

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What do I need to take the online vision test? ()

How do I know if I'm eligible? ()

When should I use the online vision test? ()

Our test helps you renew your glasses or contacts prescription from home by evaluating your visual acuity in your current correction and sending the results for review by a licensed doctor in your state.

It's best suited for people whose vision has not changed, have recently completed a comprehensive eye exam, and are:

- Looking to renew an expired prescription, or
- Looking to purchase glasses or contacts

If our test detects that your vision has changed we will not renew your prescription and recommend that you see an in-person doctor.

The Visibly Digital Acuity Product does not perform or replace an initial eye examination. Consult an eye care professional if you have not previously had an eye examination.

The Visibly Digital Acuity Product does not perform or replace a comprehensive eye examination, nor does it assess eye health. Consult an eye care professional for a comprehensive eye examination yearly or any time you are experiencing pain or discomfort. This test is not intended to diagnose, treat, mitigate, or cure disease.

Copyright © Visibly. Terms of Use (/terms-of-use/) Service Agreement (/service-agreement/) Privacy Policy (/privacy-policy/) Privacy Practices (/privacy-practices/) Fulfillment Policy (/fulfillment-policy/) Patent Information (/patents/)

Visibly Digital Acuity Product, a version of which is 510(k) pending, and the Single Device Acuity Product are manufactured and distributed by Visibly, Inc. and operate under the Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices during the Coronavirus Disease (COVID-19) Public Health Emergency issued by the FDA in April 2020. Neither product has been approved by the FDA. The data and recommendations made by the Visibly Digital Acuity Product and Single Device Acuity Product are adjunctive (supporting) recommendations that will be used by an Eye Care Provider, along with your medical history and profile, prior corrective eyewear prescriptions, and subjective data provided about your vision. It is the responsibility of the patient to provide accurate information through the process as all of this information will be relied upon as accurate by the reviewing Eye Care Provider. All Eye Care Providers are associated with Optimized Eyecare, P.C., or other entities that provide clinical services. Visibly, Inc. is an independent entity that does not provide any eyecare or clinical services.

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EXHIBIT 2

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September 30, 2022

Visibly, Inc.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K220090
Trade/Device Name: Visibly Digital Acuity Product
Regulation Number: 21 CFR 886.1150
Regulation Name: Visual Acuity Chart
Regulatory Class: Class I
Product Code: QTO

Dear Janice Hogan:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 12, 2022. Specifically, FDA is updating this SE Letter as an administrative correction because of a typo in the Indications for Use form.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Elvin Ng, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 240-402-4662, Elvin.Ng@fda.hhs.gov.

Sincerely,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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August 12, 2022

Visibly, Inc.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K220090
Trade/Device Name: Visibly Digital Acuity Product
Regulation Number: 21 CFR 886.1150
Regulation Name: Visual Acuity Chart
Regulatory Class: Class I
Product Code: QTO
Dated: January 11, 2022
Received: January 11, 2022

Dear Janice Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tieuvi H. Nguyen -S

for Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page

510(k) Number *(if known)*

K220090

Device Name

Visibly Digital Acuity Product

Indications for Use *(Describe)*

The Visibly Digital Acuity Product (VDAP) is a web-based, self-guided software application intended for use by adults, ages 22 to 40, who have the capability to perform a self-test at home, to aid in the evaluation of visual acuity with or without correction. The software allows users to view and respond to displayed optotypes and uses the responses to categorize a patient's visual acuity into one of two categories, with an individual output for each eye:

- TRUE - visual acuity that is consistent with normal vision
- FALSE - visual acuity that is not consistent with normal vision

The Visibly Digital Acuity Product recommendations are intended to be supportive recommendations that will be used by an eye care provider, along with the patient's medical history and profile, prior corrective eyewear prescriptions, and subjective vision data. The Visibly Digital Acuity Product does not provide screening or diagnosis of eye health or other disease, nor is it intended to replace an in-person eye exam.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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510(k) SUMMARY
Visibly, Inc.'s Visibly Digital Acuity Product
K220090

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Visibly, Inc.
207 E Ohio Street, #233
Chicago, IL 60611
Phone: 217-971-4852
Contact Person: Paul Foley CFO/COO

Date Prepared: August 11, 2022

Name of Device

Visibly Digital Acuity Product

Classification Name

Visual Acuity Chart (21 CFR 886.1150, Class I, Product Code QTO)

Predicate Devices

Predicate Device:

Vimetrics, LLC Central Vision Analyzer (CVA-1000)

Reference Devices:

SoloHealth, Inc. SoloHealth Station (K113402)

Vital Art and Science, Inc. MyVisionTrack Model 005 (K143211)

Intended Use / Indications for Use

The Visibly Digital Acuity Product (VDAP) is a web-based, self-guided software application intended for use by adults, ages 22 to 40, who have the capability to perform a self-test at home, to aid in the evaluation of visual acuity with or without correction. The software allows users to view and respond to displayed optotypes and uses the responses to categorize a patient's visual acuity into one of two categories, with an individual output for each eye:

- TRUE - visual acuity that is consistent with normal vision
- FALSE - visual acuity that is not consistent with normal vision

The Visibly Digital Acuity Product recommendations are intended to be supportive recommendations that will be used by an eye care provider, along with the patient's medical history and profile, prior corrective eyewear prescriptions, and subjective vision data. The Visibly Digital Acuity Product does not provide screening or diagnosis of eye health or other disease, nor is it intended to replace an in-person eye exam.

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Technological Characteristics

The Visibly Digital Acuity Product is a web-based, software application intended for use by adults, at home, to aid in the evaluation of visual acuity with or without correction. The standalone software application allows the user to interface with the software via a web browser on two internet-enabled devices:

- A computer screen (the Display) which displays optotypes.
- A touchscreen mobile device (the Remote) which operates as a remote control and interface for the user to respond to prompts related to the optotypes appearing on the Display while standing 10 feet away.

The software allows users to view and respond to displayed optotypes and uses the responses to categorize a user's vision acuity into one of two buckets: (1) TRUE - visual acuity that is consistent with normal vision (2) FALSE - visual acuity that is not consistent with normal vision.

A table comparing the key features of the subject, predicate, and reference devices is provided below.

	Visibly Digital Acuity Product (subject)	**Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)**	**SoloHealth Station (reference)**	**MyVisionTrack Model 0005 (reference)**
510(k)	K220090	K100095	K113402	K143211
Product Code	QTO	HOX, Chart, Visual Acuity	DXN, Automated Blood Pressure Monitor HOX, Chart, Visual Acuity	HOQ, Amsler grid
Indications for Use	The Visibly Digital Acuity Product (VDAP) is a web-based, self-guided software application intended for use by adults, ages 22 to 40, who have the capability to perform a self-test at home, to aid in the evaluation of visual acuity with or without correction. The software allows users to view and respond to	The CVA-1000 is intended for use under the direct supervision of an ophthalmologist or optometrist in the measurement of vision at fixation in one or both eyes, with or without optical correction.	The SoloHealth Station is intended to be used by the general public so that a user can measure his/her own blood pressure and pulse rate and his/her own weight. Additionally, the SoloHealth Station is intended to screen adults for clarity of central vision. SoloHealth Station does not provide a general	The myVisionTrack® Model 0005 is intended for the detection and characterization of central 3 degrees metamorphopsia (visual distortion) in patients with maculopathy, including age-related macular degeneration and diabetic retinopathy, and as an aid in monitoring

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	Visibly Digital Acuity Product (subject)	**Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)**	**SoloHealth Station (reference)**	**MyVisionTrack Model 0005 (reference)**
	displayed optotypes and uses the responses to categorize a patient's visual acuity into one of two categories, with an individual output for each eye: ● TRUE - visual acuity that is consistent with normal vision ● FALSE - visual acuity that is not consistent with normal vision The Visibly Digital Acuity Product recommendations are intended to be supportive recommendations that will be used by an eye care provider, along with the patient's medical history and profile, prior corrective eyewear prescriptions, and subjective vision data. The Visibly Digital Acuity Product does not provide screening or diagnosis of eye health or other disease, nor is it intended to replace an in-person eye exam.		screening of visual function and does not provide a diagnosis of eye health or other disease. The SoloHealth Station only screens clarity of central vision. Users should consult their personal physicians if they have concerns regarding their eyesight.	progression of disease factors causing metamorphopsia. It is intended to be used by patients who have the capability to regularly perform a simple self-test at home. The myVisionTrack® Model 0005 is not intended to diagnose; diagnosis is the responsibility of the prescribing eye-care professional.

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	Visibly Digital Acuity Product (subject)	**Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)**	**SoloHealth Station (reference)**	**MyVisionTrack Model 0005 (reference)**
Intended Population	Adults, ages 22 to 40	General Public	General Public	Patients at high risk or already diagnosed with maculopathy
Prescription or OTC	OTC	Prescription	OTC	Prescription home use by patients
Device Type	Web-based software application	Device with electronic display	Device with electronic display	Downloadable application to cell phone or tablet
Hardware Platform	Display: Computer, laptop or tablet Remote: Touchscreen smartphone or mobile device	Display: Computer, 2 LCD computer monitors, keyboard, mouse	Display: LCD computer monitor, Interactive Central Vision Panel	Display: User supplied cell phone or tablet
Software Design	Interactive software platform with audio and visual prompts	Interactive software platform with audio and visual prompts. It has two panels: Interactive Central Vision Panel and Chart Panel	Interactive software platform with audio and visual prompts	Interactive software platform with visual prompts
Target Presentation	Landolt C optotypes with crowding bars, facing 4 different directions (openings at 180, 270, 0, and 90 degrees) Optotypes are presented singly	Multiple and Individual optotypes (depending on the panel selected)	Multiple optotypes as well as sentences and paragraphs	Distorted and undistorted shapes
How/Where Used	At home	Clinical environments	Non-clinical environments	At home
Test Administration	Self-administration	Setup and Testing Method is selected by HCP	Self-administration	Self-administration

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	Visibly Digital Acuity Product (subject)	Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)	SoloHealth Station (reference)	MyVisionTrack Model 0005 (reference)
		Testing process is completed via self-administration		
Test Procedure Summary	Based on optotypes presented on the Display, the user will select what object they see on their Remote. The following outputs are generated for Eye Care Provider (ECP) review: (1) user-inputted data confirmed during Qualification; (2) Visual Acuity output by eye classifying the individual eye's vision into one of the following buckets: • TRUE - visual acuity that is consistent with normal vision • FALSE - visual acuity that is not consistent with normal vision	Chart Panel: A monitor, viewed by the patient, presents traditional symbol charts with progressive 0.1 logMAR gradations of symbol size, each of which may be presented in the following Michelson contrasts of black letters presented against a white background in a range of progressively reduced contrasts. The examiner may view on the physician monitor what is presented to the patient on the patient monitor so he can mark the letters that are correctly identified, allowing either line-by-line or letter-by-letter scoring. The total letters read correctly are recorded as well as the smallest line read correctly in which the traditional method of scoring is utilized. Interactive Central Vision Panel: A monitor is viewed by	Near distance screening is simulated at 17 inches through a series of prompts on the computer monitor where patients are asked to view the clarity of sentences and letters at different sizes. Far distance screening is simulated at 11 feet through a view finder on the device. Patients are asked to determine the clarity of a set of letters.	The myVisionTrack® Model 0005 implements a shape discrimination hyperacuity (SDH) vision test. The distorted shape is created by modulating the radius of the circle with a sinusoid. The user is shown four circles and asked to identify the distorted circle.

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	Visibly Digital Acuity Product (subject)	Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)	SoloHealth Station (reference)	MyVisionTrack Model 0005 (reference)
		the patient in which automated measurements are conducted by an interactive computer program at logMAR 0.05 gradations of symbol size. The patient sits in a chair in the darkened examination room with or without optical correction (spectacles, contact lenses, or trial lenses) and with one eye or both eyes exposed, he/she views in a mirror at the end of the room an LCD monitor (patient monitor) mounted on the wall next to the examiner's desk (total distance entered into the computer program at the time of installation). The examiner selects the method of operation and contrasts to be tested by keyboard and mouse interaction and with information presented on the physician's working monitor.		

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Performance Data

The following testing is provided to support the safety and performance of the VDAP:

- Luminance Testing was completed to demonstrate that the luminance of the Display hardware is above the minimum threshold for luminance (80 cd/m^2) in accordance with: (1) ANSI Z80.21-2010(R2015). American National Standard for Ophthalmics - Instruments - General-Purpose Clinical Visual Acuity Charts; (2) ISO 8596:2017. Ophthalmic optics - Visual acuity testing - Standard and clinical optotypes and their presentation and (3) International Council of Ophthalmology (1984) Visual Acuity Measurement Standard.

- Optotype Sizing Testing was conducted to validate each optotype size rendered during the VDAP test. For each of the 22 optotypes presented by the visual acuity test, the arc length of optotype gap and the optotype diameter were measured using manufacturer-calibrated Mitutoyo Digital Calipers. All measurements of arc length and optotype diameter were ±5% of the pre-specified size equivalent for each LogMar Size.

- Human Factors testing to confirm that the VDAP can be used safely and effectively by the intended users in the intended use environment – i.e., adults aged 22 to 40 years old in a home environment (n=18). This testing established that the overall residual risk of use errors with the VDAP have been mitigated to an acceptable level. Therefore, VDAP can be used without use errors or problems that could result in an inaccurate visual acuity assessment.

- The controlling software for the VDAP presents a “moderate” level of concern as defined in FDA’s “Guidance for the Content of Premarket Submission for Software Contained in Medical Devices” (May 2005). The appropriate supportive software documentation was provided, including a hazard analysis. Verification and validation activities demonstrated that VDAP functioned as intended. In addition, since the VDAP is sent to a medical device data system (MDDS) that is necessary for viewing by clinicians, Visibly provided software documentation consistent with a minor level of concern for the MDDS per the FDA Guidance "Multiple Function Device Products: Policy and Considerations" (July 2020).

- Potential cybersecurity risks were addressed by providing the documentation requested in the FDA Guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” (October 2014). The software mitigates or prevents the unauthorized access, modification, misuse and unauthorized use of information that is stored, accessed or transferred.

A prospective, multi-center clinical study was also completed (n=329) to evaluate the safety and effectiveness of the VDAP compared to an ETDRS Visual Acuity (VA) Lane Test. This study evaluated the agreement of the VDAP with the ETDRS VA Lane Test as well as the reproducibility of the VDAP. The primary agreement endpoints were the PPV, defined as the proportion of study eyes with VA of 20/25 or better for which ETDRS VA was also 20/25 or better, and the NPV, defined as the proportion of study eyes with VDAP VA worse than 20/25 for which ETDRS VA was also worse than 20/25. Supportive analyses included a subgroup analysis for performance stratified by the actual, measured viewing distance from which the subjects took the VDAP test.

Selection of the study eye occurred after subjects exited the study following the completion of VDAP and ETDRS assessments of each eye. The study eye was selected based upon the

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subject's first VDAP VA assessment. If one of the subject's eyes had "20/25 of Better" VDAP VA and the other eye had "Worse than 20/25" VDAP VA, the eye with the "Worse than 20/25" was selected as the study eye. If both eyes had the same VDAP VA, the study eye was selected randomly.

The observed PPV, NPV, sensitivity, and specificity for study eyes were as follows: (97.3%, 95% CI: 95.2% - 99.4%), (48.1%, 95% CI: 38.6% - 57.6%), 79.7% (95% CI: 74.9% - 84.5%) and 89.5% (95% CI: 81.5% - 97.4%). The observed PPV, NPV, sensitivity, and specificity for non-study eyes were as follows: (94.5%, 95% CI: 91.9% - 97.2%), (50.9%, 95% CI: 37.5% - 64.4%), 90.9% (95% CI: 87.6% - 94.2%) and 64.3% (95% CI: 49.8% - 78.8%).

Observed agreement performance in sensitivity and specificity diverged between the Study Eye and Non-Study Eye cohorts due to the study eye selection methodology discussed above. As a result, a pooled analysis combining Study Eye and Non-Study Eyes was completed.
The observed PPV, NPV, sensitivity, and specificity for the pooled Study Eye and Non-Study Eye cohort were as follows: (95.8%, 95% CI: 93.6% - 97.6%), (49.1%, 95% CI: 40.0% - 58.1%), 85.5% (95% CI: 81.9% - 88.9%) and 78.8% (95% CI: 69.1% - 87.6%).

PPV and NPV in the pooled cohort are similar to what was observed in Study Eye and Non-Study Eye Cohorts. Sensitivity and Specificity for the pooled cohort reflect true device performance for these metrics as they are not impacted by the study eye selection methodology in the way the Study Eye and Non-Study Eye Cohorts were.
The secondary agreement endpoint was subject level agreement, defined as the proportion of subjects with matching VDAP and ETDRS classifications (20/25 or Better vs. Worse than 20/25) for both eyes (study eye and non-study eye). The secondary reproducibility endpoint was subject level reproducibility, defined as the proportion of subjects with matching VDAP VA Classifications for the two VDAP tests for both eyes.

The subject level agreement was as follows: 75.9% (95% CI: 71.3% - 80.5%). The subject level reproducibility was as follows: 82.8% (95% CI: 78.7% - 86.9%).

The primary reproducibility endpoint was the proportion of study eyes with matching VDAP VA classifications for the two VDAP tests. The observed reproducibility for Study Eyes (89.3%, 95% CI: 85.9% - 92.6%) was statistically significantly greater than the performance goal of 75% (p-value < 0.0001). There were no safety concerns found with VDAP assessments throughout the study. Furthermore, the reproducibility of the VDAP was confirmed in this study, and the PPV and NPV results of VDAP demonstrate that the selected cut off point of 20/25 Snellen is appropriate. Therefore, the device performance was adequate to support an indication for use as an aid in the assessment of visual acuity.

Conclusion

The VDAP is as safe and effective as the predicate device. The VDAP also shares similar technological characteristics as the reference devices. The VDAP has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the VDAP and its predicate devices raise no new issues of safety or effectiveness. Furthermore, performance data demonstrate that the VDAP is as safe and effective as the predicate device. Therefore, the VDAP is substantially equivalent.

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EXHIBIT 3

This guidance is intended to remain in effect until November 7, 2023, unless superseded by a revised final guidance before that date. For further information, refer to 88 FR 15417, March 13, 2023, available at https://www.federalregister.gov/d/2023-05094.

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Contains Nonbinding Recommendations

Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

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Guidance for Industry and Food and Drug Administration Staff

April 2020

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)

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Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or the Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," available at https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders and the FDA webpage titled "Search for FDA Guidance Documents" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number 20025 and complete title of the guidance in the request.

Questions

For questions about this document, contact 1-888-INFO-FDA or CDRH-COVID19-Ophthalmic@fda.hhs.gov.

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Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or the Agency) plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide a policy to help expand the capability of remote ophthalmic assessment and monitoring devices to facilitate patient care while reducing patient and healthcare provider contact and exposure to COVID-19 during this pandemic.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service (PHS) Act.

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Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled "Process for Making Available Guidance Documents Related to Coronavirus Disease 2019," available at https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf, this guidance is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named SARS-CoV-2 and the disease it causes has been named Coronavirus Disease 2019 (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[1] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[2]

FDA believes the policy set forth in this guidance may help address these urgent public health concerns by helping to expand the availability and capability of remote ophthalmic assessment and monitoring devices. Modified use of these devices may facilitate patient management by health care providers while reducing the need for in-person treatment during the COVID-19 public health emergency and may help reduce the risk of exposure for patients and health care providers to SARS-CoV-2.

III. Scope

The enforcement policies described in this guidance apply to the following devices that assess or monitor ophthalmic parameters. These devices have the potential to be connected to a wireless network through Bluetooth, Wi-Fi, or cellular connection to transmit a patient's ophthalmic parameters directly to their eye care provider or other monitoring entity. Some of these devices also have the potential to apply algorithms to transform a patient's ophthalmic parameters into a novel

[1] Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx).

[2] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

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index or alarm that may aid an eye care provider in the diagnosis of a particular condition or disease state/severity or be used in the context of a telemedicine visit, with the patient at home, allowing the eye care provider to assess specific ophthalmic parameters remotely.

A. Visual Acuity Charts, Visual Field Devices, and General-Use Ophthalmic Cameras

Visual acuity charts, visual field devices, and general-use ophthalmic cameras allow assessment and/or imaging of the eye to assist eye care providers in detecting or monitoring the progression of ocular conditions or diseases. Visual acuity charts are charts that are used to test the clarity or sharpness of vision. Visual field devices include perimeter devices used to test the peripheral visual field, as well as Amsler grids used to test the central visual field. General-use ophthalmic cameras are devices that are used to take photographs of the eye and surrounding area. In general, these devices are exempt from premarket notification [510(k)] requirements, but may remain subject to other general controls, such as Registration and Listing requirements in 21 CFR Part 807. The classification regulations and associated product codes for these devices, to which the policy in this guidance applies, are listed in Table 1:

Table 1 - Visual Acuity Charts, Visual Field Devices, and General-Use Ophthalmic Cameras

Classification Regulation	Device Type	Product Code[3]	Device Classification
21 CFR 886.1120	Camera, Ophthalmic, General-use	PJZ	II (exempt)[4]
21 CFR 886.1150	Visual Acuity Chart	HOX	I (exempt)[5]
21 CFR 886.1330	Amsler Grid	HOQ	I (exempt)[6]
21 CFR 886.1605	Perimeter, AC-powered	HOO	I (exempt)[7]
21 CFR 886.1605	Perimeter, Automatic, AC-powered	HPT	I (exempt)[8]

[3] For more information see the Product Classification Database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.

[4] These devices are exempt from submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, subject to the limitations in 21 CFR 886.9. FDA clearance is not required before marketing the device in the United States; however, manufacturers are required to register their establishment and comply with other postmarket reporting requirements.

[5] These devices are exempt from submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, subject to the limitations in 21 CFR 886.9; however, manufacturers are required to register their establishment. The device type is also exempt from the current good manufacturing practice requirements of the quality system regulations in 21 CFR 820, with the exception of records (see 21 CFR 820.180) and complaint handling (see 21 CFR 820.198). FDA clearance is not required before marketing the device in the United States; however, manufacturers are required to register their establishment.

[6] *Ibid.*

[7] *Ibid.*

[8] *Ibid.*

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B. Tonometers

Tonometers are devices intended to measure intraocular pressure by applying a known force on the globe of the eye and measuring the amount of indentation or force produced or to measure intraocular tension by applanation (applying a small flat disk to the cornea). In general, manufacturers of tonometers are required to submit a premarket notification pursuant to section 510(k) of the FD&C Act and 21 CFR 807.81 to FDA and receive FDA clearance prior to marketing these devices in the United States, as well as comply with postmarketing requirements. The classification regulation and associated product codes for tonometers, to which the policy in this guidance applies, are listed in Table 2:

Table 2 - Tonometers

Classification Regulation	Device Type	Product Code[9]	Device Classification
21 CFR 886.1930	Tonometer, AC-powered	HKX	II
21 CFR 886.1930	Tonometer, Manual	HKY	II

IV. Policy

In the context of the COVID-19 public health emergency, expanding the capability of remote ophthalmic assessment and monitoring devices may help facilitate patient care while reducing patient and healthcare provider contact and risk of exposure to SARS-CoV-2.[10] For that reason, FDA does not intend to object to limited modifications to the indications, functionality, hardware, and/or software, of 510(k)-cleared devices for remote assessment and monitoring of ophthalmic parameters, or distribution and use of these device types that are exempt from submission of a 510(k), during the declared public health emergency without compliance with certain regulatory requirements, as discussed in further detail below, where such devices do not create an undue risk in light of the public health emergency. Examples of such modifications include:

- For devices previously intended for use in healthcare facilities, a change to the indications regarding use in the home setting;
- Modifications of non-portable devices to include portable or handheld device features;
- Modifications to devices, including changes in hardware or software, to include virtual reality or mobile technology for remote assessment or monitoring capability.

In developing this policy, FDA's intent is to foster the continued availability of safe and effective medical devices while being flexible regarding modifications made to devices for remote assessment

[9] For more information see the Product Classification Database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.

[10] In a press release dated March 18, 2020 (available at https://www.aao.org/newsroom/news-releases/detail/ophthalmologists-urged-to-cease-non-emergency-care), the American Academy of Ophthalmology recommended that all ophthalmologists immediately cease providing any in-person treatment other than urgent or emergent care.

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and monitoring of ophthalmic parameters in response to the COVID-19 public health emergency.

A. Modifications to the Indications and Functionality of Remote Ophthalmic Assessment and Monitoring Devices

(1) Visual Acuity Charts, Visual Field Devices, and General-Use Ophthalmic Cameras

For the duration of the public health emergency, FDA does not intend to object to limited modifications to the indications, functionality, hardware, and/or software, of the devices in Table 1 without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency: submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81[11], where such submission would be required,[12] Quality System Regulation requirements in 21 CFR Part 820 where such requirements are applicable, Reports of Corrections and Removals requirements in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20.

Examples of circumstances where FDA currently believes a modification to a device in Table 1 would not create such undue risk include:

1) Indications and functionality designed to permit the use of the device for monitoring and/or assessment of the ophthalmic parameters, if such devices are not indicated or designed for such.
2) Indications and functionality designed to permit the use of the device for home use and/or by consumers rather than eye care providers.
3) Indications and functionality designed to permit the use of the device for a telemedicine consultation, allowing the eye care provider to assess specific ophthalmic parameters remotely.
4) Devices containing software and/or hardware intended to implement intended device functionality for use directly by consumers at home (e.g., visual acuity assessment, visual field assessment, image capture).
5) Devices containing software and/or hardware intended to facilitate remote access (e.g., addition of wireless or Bluetooth capability).

Examples of circumstances where FDA currently believes distribution and use of the device or modifications to these devices would create such an undue risk include:

[11] For further guidance on modifications that trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA, refer to "Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff," https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device.

[12] Certain modifications to the indications and functionality of these devices may require premarket notification subject to the limitations of the exemption under 21 CFR 886.9.

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1) The device is intended to determine when patients need immediate clinical intervention to assure patient safety; or
2) The device is intended to be solely or primarily relied upon by the eye care provider or patient to make a clinical diagnosis or treatment decision.

(2) Tonometers

For the duration of the declared public health emergency, FDA does not intend to object to limited modifications to the indications, functionality, hardware, and/or software, of the devices in Table 2 without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, where the modification does not create an undue risk in light of the public health emergency. FDA currently believes a modification does not create such undue risk in the following scenario:

1) The device is intended only for the purpose of measuring intraocular pressure;
2) The device is handheld or portable;
3) The mechanism of measurement is either non-contact, rebound, or transpalperbral;
4) The device is intended for the purpose of supporting or providing adjunctive recommendations to the eye care provider or patient about prevention, diagnosis or treatment of ocular conditions; and
5) The eye care provider and/or patient can independently review the basis for any diagnostic or treatment recommendations.

Examples of circumstances where FDA currently believes a modification would create such an undue risk include:

1) The device is intended to determine when patients need immediate clinical intervention to assure patient safety;
2) The device is intended to be solely or primarily relied upon by the eye care provider or patient to make a clinical diagnosis or treatment decision;
3) The modifications add the functionality to acquire, process, or analyze a pattern or signal from a signal acquisition system that was not present in the FDA-cleared device; or
4) Modifications are made to device components that have direct contact with the eye.

B. Validation of Modifications to the Functionality of Remote Ophthalmic Assessment and Monitoring Devices

In designing, evaluating, and validating modifications made under this policy to hardware and/or software, FDA recommends doing so in accordance with FDA recognized standards for the specific device type, including (as applicable):

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- ANSI/AAMI ES60601-1:2005 (R2012) and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012: – *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*
- ANSI/AAMI/IEC 60601-1-2:2014 – *Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests*
- IEC 60601-1-11:2015 – *Medical Electrical Equipment Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment*
- ANSI Z80.21-2010 (R2015) *American National Standard for Ophthalmics - Instruments - General-Purpose Clinical Visual Acuity Charts*
- ISO 10940-2009 *Ophthalmic Instruments - Fundus Cameras*
- ANSI Z80.10-2014 *American National Standard for Ophthalmics - Ophthalmic Instruments – Tonometers*
- ISO 15004-1 First Edition 2006-06-01 *Ophthalmic Instruments - Fundamental Requirements and Test Methods - Part 1: General Requirements Applicable to All Ophthalmic Instruments*
- ANSI Z80.36-2016 *American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments*
- AAMI TIR69: 2017 – *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*
- ANSI/IEEE C63.27: 2017 – *American National Standard for Evaluation of Wireless Coexistence*
- ANSI/AAMI/IEC 62304 – *Medical Device Software – Software Life Cycle Processes*

For any such hardware and/or software changes, FDA also recommends considering the following FDA guidance documents related to common device modifications:

- Radio Frequency Wireless Technology in Medical Devices[13]
- Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices[14]

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[15] For more information regarding use of consensus standards in regulatory submissions, refer to FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[16]

In addition, for any such changes, manufacturers should develop and implement appropriate

[13] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff.
[14] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices.
[15] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.
[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

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cybersecurity controls to assure device cybersecurity and maintain device functionality and safety. The following online resources may be helpful in developing and maintaining these cybersecurity controls:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices[17]
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices[18]
- Postmarket Management of Cybersecurity in Medical Devices[19]

C. Labeling of Modified Devices

In addition, FDA recommends that the devices described in this guidance use labeling that helps users better understand the device modifications. FDA recommends that the labeling include the following elements:

1) A clear description of the available data on the device's new indications, and/or functions including information regarding:
   a. Device performance;
   b. Method of determining any diagnostic or treatment recommendations; and
   c. Potential risks.
2) Adequate instructions for use for the intended user and indicated environment(s) of use. The labeling should highlight the differences in design compared to the unmodified version of the device, along with instructions for mitigating any known risks associated with these differences.
3) Information so that the eye care provider and/or patient can independently review the basis for any diagnostic or treatment recommendations.
4) For devices previously cleared for use only in a hospital or other health care facility and for which the environment of use has been expanded to include in-home use, adequate instructions for use in the home setting with appropriate lay terminology.
5) For FDA-cleared devices, clear distinction delineating FDA-cleared indications from those that are not FDA-cleared. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared by FDA. For exempt devices listed in Table 1, FDA recommends that the labeling include a statement about indications outside the limitations of exemption in 21 CFR 886.9 for that device type.
6) A prominent notice to both the patient and eye care provider that recommendations provided by the device are adjunctive (supporting) and should not be solely or primarily relied upon to prevent, diagnose, or treat ocular conditions.

[17] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices.
[18] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0.
[19] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-management-cybersecurity-medical-devices.

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Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry, Other Stakeholders, and Food and Drug Administration Staff

Document issued on March 27, 2023.

The draft of this document was issued on December 23, 2021.

For questions about this document, contact the Regulation, Policy, and Guidance Staff at RPG@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2021-D-1118. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number GUI00021011 and complete title of the guidance in the request.

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Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry, Other Stakeholders, and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA plays a critical role in protecting the United States (U.S.) from threats such as emerging infectious diseases, including Coronavirus Disease 2019 (COVID-19). FDA is committed to providing timely guidance to support response efforts to the COVID-19 pandemic. FDA

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recognizes that it will take time for device[1] manufacturers,[2] device distributors, healthcare facilities, healthcare providers, patients, consumers, and FDA to adjust from policies adopted and operations implemented during the COVID-19 public health emergency (PHE) to "normal operations."[3] To provide a clear policy for all stakeholders and FDA staff, the Agency is issuing this guidance to describe FDA's general recommendations for a phased transition process with respect to devices that fall within certain enforcement policies issued during the COVID-19 PHE, including recommendations regarding submitting a marketing submission, as applicable, and taking other actions with respect to these devices.

FDA is concurrently issuing a companion transition guidance to describe FDA's recommendations for devices issued emergency use authorizations (EUAs) related to COVID-19.[4] The companion transition guidance does not include phases as described in this transition plan for devices that fall within enforcement policies and instead relies on the advance notice(s) of termination process required under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA believes that these transition guidances will help prepare manufacturers and other stakeholders for the transition to normal operations and foster compliance with applicable requirements under the FD&C Act and its implementing regulations.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of

[1] Section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act provides that the term "device" means:

> "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
>
> (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (C) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term 'device' does not include software functions excluded pursuant to section 520(o)" of the Federal Food, Drug, and Cosmetic Act.

[2] Throughout this guidance, when describing policies for devices that fall within enforcement policies issued during the COVID-19 public health emergency declared under section 319 of the Public Health Service Act, FDA uses the term "manufacturer" to refer to any person who designs, manufactures, fabricates, assembles, or processes a finished device. See 21 CFR 820.3(o). Other entities, including those that introduce such devices into commercial distribution, such as initial importers and certain distributors, should ensure they understand, and where applicable, they should follow, the recommendations that pertain to such devices.

[3] Throughout this guidance, FDA refers to "normal operations" as a shorthand for the circumstances when the declaration of the PHE related to COVID-19 under section 319 of the Public Health Service Act has expired and/or the relevant device emergency use declarations related to COVID-19 under section 564 of the Federal Food, Drug, and Cosmetic Act are terminated.

[4] The guidance "Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19)," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease, will be referred to as the "companion transition guidance" in the remainder of this guidance.

the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

In 2019, an outbreak of respiratory disease caused by a novel coronavirus began. The virus has been named "SARS-CoV-2," and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Secretary of Health and Human Services (HHS) issued a declaration of a PHE related to COVID-19 in accordance with section 319 of the Public Health Service (PHS Act) (hereinafter referred to as "section 319 PHE declaration") and mobilized the Operating Divisions of HHS.[5] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[6] On February 9, 2023, the HHS Secretary renewed the section 319 PHE declaration related to COVID-19, effective February 11, 2023. The section 319 PHE declaration related to COVID-19 is anticipated to expire at the end of the day on May 11, 2023.[7]

In response to the COVID-19 pandemic, the device supply chain has been stressed because the demand for certain devices has exceeded available supply. FDA recognized early in the COVID-19 pandemic the importance of maintaining the availability of certain devices. FDA's policies have helped facilitate the availability of devices intended to diagnose, treat, and prevent COVID-19 and associated conditions – including mitigating exposure to the SARS-CoV-2 virus – and to help address manufacturing limitations or supply chain issues due to disruptions caused by the COVID-19 pandemic.

FDA issued various guidance documents that describe enforcement policies for certain devices that are intended to support the emergency response to the COVID-19 pandemic.[8] These policies have helped to facilitate the availability of devices such as in vitro diagnostics, personal protective equipment intended for medical purposes, and ventilators. Additionally, FDA issued guidance to help expand the availability and remote monitoring capabilities of

[5] Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued on January 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

[6] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (March 13, 2020), available at https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/. On February 24, 2021, there was a Presidential Declaration continuing the national emergency concerning the COVID-19 pandemic beyond March 1, 2021. See Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Pandemic (86 FR 11599), available at https://www.federalregister.gov/documents/2021/02/26/2021-04173/continuation-ofthe-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic.

[7] See the HHS "Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap," (February 9, 2023), available at https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html.

[8] For links to the COVID-19-related FDA guidances, see the webpage "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders.

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certain devices, including infusion pumps and non-invasive remote patient monitoring devices, to reduce the risk of exposure for patients, healthcare providers, and other healthcare professionals to individuals diagnosed with COVID-19.

Generally, the guidances that set forth COVID-19-related enforcement policies for certain devices initially stated that they were intended to remain in effect only for the duration of the section 319 PHE declaration. As FDA announced in the Federal Register on March 13, 2023, many of these guidance documents – the guidances in List 1 (see below) – have been revised to state that they are intended to continue in effect for 180 days after the section 319 PHE declaration expires unless a different intended duration is set forth in the finalized version of this guidance.[9,10] A different intended duration is *not* being set forth in this guidance – as described in Section V., the implementation date is the date the section 319 PHE declaration expires and the guidances are intended to continue in effect for 180 days after that date. FDA recommends reviewing the cover page for the relevant List 1 guidance to help determine the transition period for your device.

Given the magnitude of the response to the COVID-19 pandemic, FDA recognizes that a phased approach may help to ensure an orderly and transparent transition from the policies and recommendations in the List 1 guidances to normal operations. Further, FDA is taking into account that the manufacture, distribution, and use of devices in the context of the COVID-19 pandemic raises unique considerations. These unique considerations include, for example, the manufacturing of devices by non-traditional manufacturers to address supply issues and the distribution and use of capital or reusable equipment (e.g., ventilators, extracorporeal membrane oxygenation systems) that fall within enforcement policies.

FDA developed this guidance to describe a phased approach, as set forth in Section V., among other things, to help avoid disruption in device supply and help facilitate compliance with applicable legal requirements after the enforcement policies are no longer in effect. This phased approach will allow FDA to better understand the landscape of devices that fall within the relevant enforcement policies, provide support to manufacturers, and assist the Agency in resource planning for marketing submission review.

[9] See Guidance Documents Related to Coronavirus Disease 2019 (COVID-19) (88 FR 15417), available at https://www.federalregister.gov/documents/2023/03/13/2023-05094/guidance-documents-related-to-coronavirus-disease-2019-covid-19. As discussed in that notice, FDA intends to further revise 4 of these COVID-19-related device guidances during the 180-day transition period after the section 319 PHE declaration expires (see Section IV., Table 3 of that notice). Also, as noted in that document, 2 COVID-19-related device guidances will no longer be in effect when the section 319 PHE declaration expires (see Section II., Table 1 of that notice).

[10] Although the duration of these guidances has been extended, we note that FDA could withdraw any of these guidances before that 180-day transition period ends if, for example, our approach for a particular guidance is no longer needed. FDA would do so consistent with our good guidance practices regulation (21 CFR 10.115).

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III. Scope

This guidance applies to devices that fall within the enforcement policies described in the guidances identified in List 1 below.[11]

List 1

- Enforcement Policy for Remote Digital Pathology Devices During the COVID-19 Public Health Emergency[12]
- Enforcement Policy for Imaging Systems During the COVID-19 Public Health Emergency[13]
- Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the COVID-19 Public Health Emergency[14]
- Enforcement Policy for Telethermographic Systems During the COVID-19 Public Health Emergency[15]
- Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the COVID-19 Public Health Emergency[16]
- Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the COVID-19 Public Health Emergency[17]

[11] This guidance does not apply to devices that fall within the enforcement policies described in the following guidances: "Policy for Coronavirus Disease-2019 Tests (Revised)," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised; "Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests (Revised)," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-evaluating-impact-viral-mutations-covid-19-tests-revised; "Enforcement Policy for the Quality Standards of the Mammography Quality Standards Act During the COVID-19 Public Health Emergency," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-quality-standards-mammography-quality-standards-act-during-covid-19-public-health; "Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the COVID-19 Public Health Emergency (Revised)," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during; "Enforcement Policy for Clinical Electronic Thermometers During the COVID-19 Public Health Emergency," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-clinical-electronic-thermometers-during-coronavirus-disease-2019-covid-19-public; and "Enforcement Policy for Face Masks and Barrier Face Coverings During the COVID-19 Public Health Emergency," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-barrier-face-coverings-during-coronavirus-disease-covid-19-public.

[12] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-digital-pathology-devices-during-coronavirus-disease-2019-covid-19-public.

[13] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-imaging-systems-during-coronavirus-disease-2019-covid-19-public-health-emergency.

[14] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-fetal-and-maternal-monitoring-devices-used-support-patient.

[15] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-telethermographic-systems-during-coronavirus-disease-2019-covid-19-public-health.

[16] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-digital-health-devices-treating-psychiatric-disorders-during-coronavirus-disease.

[17] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-extracorporeal-membrane-oxygenation-and-cardiopulmonary-bypass-devices-during.

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- Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the COVID-19 Public Health Emergency[18]
- Enforcement Policy for Infusion Pumps and Accessories During the COVID-19 Public Health Emergency[19]
- Enforcement Policy for Face Shields, Surgical Masks, and Respirators During the COVID-19 Public Health Emergency [20]
- Enforcement Policy for Gowns, Other Apparel, and Gloves During the COVID-19 Public Health Emergency[21]
- Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the COVID-19 Public Health Emergency[22]
- Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the COVID-19 Public Health Emergency[23]
- Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV Tests During the COVID-19 Public Health Emergency[24]
- Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the COVID-19 Public Health Emergency (Revised)[25]
- Enforcement Policy for Viral Transport Media During the COVID-19 Public Health Emergency (Revised)[26]

IV. Guiding Principles

In developing this guidance, and its companion transition guidance regarding devices issued EUAs related to COVID-19, several guiding principles were followed. Some derive from existing policies and are widely known, and others are key to understanding the approach set

[18]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-ophthalmic-assessment-and-monitoring-devices-during-coronavirus-disease.
[19]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-infusion-pumps-and-accessories-during-coronavirus-disease-2019-covid-19-public.
[20]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-shields-surgical-masks-and-respirators-during-coronavirus-disease-covid-19. Bifucaration of the "Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the COVID-19 Public Health Emergency (Revised)" guidance was announced in the Federal Register notice on March 13, 2023 (88 FR 15417). The guidance relating to face shields, surgical masks, and respirators is in List 1, and the guidance related to face masks and barrier face coverings, as noted in footnote 11, is outside the scope of this guidance.
[21]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health.
[22]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease.
[23]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus.
[24]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-modifications-fda-cleared-molecular-influenza-and-rsv-tests-during-coronavirus.
[25]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/coagulation-systems-measurement-viscoelastic-properties-enforcement-policy-during-coronavirus.
[26]Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-viral-transport-media-during-coronavirus-disease-2019-covid-19-public-health.

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forth in this guidance. Thus, anyone using this guidance should bear in mind the following guiding principles:

- This guidance is intended to help facilitate continued patient, consumer, and healthcare provider access to devices needed in the prevention, treatment, and diagnosis of COVID-19.
- FDA believes the policies and recommendations in this guidance will help to ensure an orderly and transparent transition for devices that fall within the scope of this guidance. FDA's policies and recommendations in this guidance are consistent with the Agency's statutory mission to both protect and promote the public health.[27]
- FDA's policies and recommendations follow, among other things, a risk-based approach with consideration of differences in the intended use and regulatory history of devices, including whether the device is life-supporting or life-sustaining,[28] capital or reusable[29] equipment, a single-use device,[30] and whether another version of the device is FDA-cleared or -approved.
- As always, FDA will make case-by-case decisions regarding the enforcement of legal requirements in response to particular circumstances and questions that arise regarding a specific device or device type. This may include requesting a firm initiate a recall (see 21 CFR 7.45),[31] or taking other actions, including an enforcement action. Moreover, FDA may revise the enforcement policies and recommendations in the guidance, as appropriate.

V. Phased Transition Plan for Devices That Fall Within COVID-19 Enforcement Policies Described in Guidances in List 1

As previously stated, FDA recognizes that it will take time for device manufacturers, device distributors, healthcare facilities, healthcare providers, patients, consumers, and the Agency to adjust from policies adopted and operations implemented during the COVID-19 PHE to normal

[27] See section 1003(b) of the FD&C Act.

[28] Life-supporting or life-sustaining devices are defined in 21 CFR 860.3. A list of life-supporting or life-sustaining devices can be found by searching FDA's product classification database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.

[29] A reusable device is intended for repeated use either on the same or different patients, with appropriate cleaning and other reprocessing between uses. For additional information see the guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling.

[30] A single-use device is a device that is intended for one use or on a single patient during a single procedure. For additional information see the guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

[31] 21 CFR 7.45(a) states that FDA "may request a firm to initiate a recall when the following determinations have been made: (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception. (2) That the firm has not initiated a recall of the product. (3) That an agency action is necessary to protect the public health and welfare."

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operations. FDA seeks to encourage and facilitate an appropriate transition period to help, among other things, avoid exacerbating product shortages and supply chain disruptions. This transition plan takes into account that the guidances in List 1 will no longer be in effect after the 180-day transition period discussed in this guidance ends. The discussion below contains recommendations regarding the preparation and submission of marketing submissions (including the timing of such submissions),[32] manufacturers' actions if they do not wish to continue distributing their product after the end of Phase 2, and the distribution of devices that fall within the scope of this guidance.

For purposes of this guidance, devices are considered to be "already distributed" if they are finished devices[33] that are labeled and are in distribution[34] in the U.S. supply chain or are in the possession of the end user. For purposes of this guidance, FDA would generally consider devices to be "in distribution" to mean those finished, labeled devices that are no longer in the manufacturer's possession that are in transit to or held in a third party's device inventory not on behalf of the manufacturer, in a federal, state, or other government stockpile, or at a location where devices are then offered for direct sale to the end user.

Given the duration of the COVID-19 pandemic and the need to safeguard the public health in a post-pandemic environment, FDA is implementing a 180-day transition period that will begin on the "implementation date" (see discussion below regarding this date). The guidances in List 1 will no longer be in effect after the 180-day transition period ends. FDA believes a phased transition over the 180 days following the implementation date as set forth in this guidance will help foster compliance with applicable legal requirements. This approach consists of three phases as described later in this section and outlined in **Table 2**.

The implementation date is the date the COVID-19 section 319 PHE declaration expires or 45 days after the finalization of this guidance, whichever comes later. Because the COVID-19 section 319 PHE declaration is anticipated to expire at least 45 days after the finalization of this guidance, or May 11, 2023, the implementation date is that date. The guidance documents identified in List 1 will no longer be in effect after the 180-day transition period ends, or after November 7, 2023.

[32] For purposes of this guidance, "marketing submission" means a premarket approval application (PMA), PMA supplement, premarket notification (510(k)) submission, humanitarian device exemption (HDE) application, or De Novo classification request (De Novo). For devices that are class I or II and exempt from premarket notification (e.g., shoe covers, face shields), no 510(k) submission is required unless the limitations of exemption are exceeded (see, e.g., 21 CFR 878.9).
[33] See 21 CFR 820.3(*l*).
[34] See 21 CFR 807.3(b) (defining "commercial distribution").

A timeline for this process is provided in Figure 1.

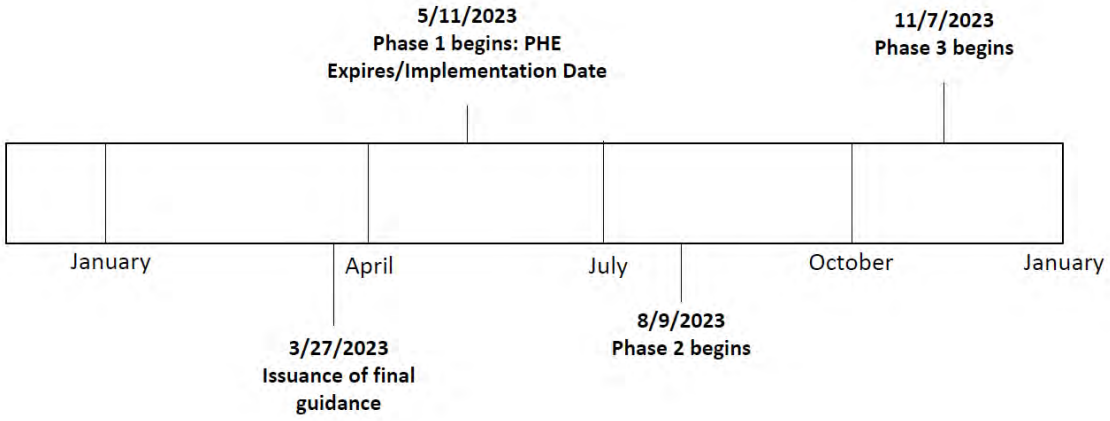

Figure 1. Transition Timeline. Implementation date occurring on the date the COVID-19 section 319 PHE declaration expires.

In the bullets below, FDA describes our transition period expectations and recommendations for all manufacturers that distributed devices as described in an enforcement policy in a guidance in List 1, both for those who do and do not pursue marketing authorization for their devices. FDA believes these expectations and recommendations will help facilitate a smooth and consistent transition to normal operations.

A summary of the three phases are as follows:

- **Phase 1**: Begins on the implementation date. If not already doing so, manufacturers should follow 21 CFR Part 803 (i.e., adverse event reporting requirements) in order to prepare for Phase 3.

- **Phase 2:** Begins 90 days after the implementation date. Before the start of Phase 2 and in order to prepare for Phase 3, if not already doing so, manufacturers should: (1) follow 21 CFR Part 806 (i.e., reports of corrections and removals requirements), and (2) if planning to continue to distribute their devices after Phase 2, should also follow 21 CFR Part 807 Subparts B-D (i.e., registration and listing requirements).

- **Phase 3:** Begins 180 days after the implementation date. After the 180-day transition period ends, the guidances in List 1 will no longer be in effect. At this time, FDA does not intend to object to continued distribution of devices within the scope of this guidance

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where a required marketing submission has been submitted and accepted[35] by FDA before the start of Phase 3 and FDA has not taken a final action[36] on the marketing submission. In addition, for these same devices, while the device is under FDA review, FDA does not intend to object to the devices not complying with certain Unique Device Identification (UDI) requirements (see 21 CFR Part 801 Subpart B) and other applicable labeling requirements (see 21 CFR Part 801) (see Section V.D.(1) of this guidance). This enforcement policy does not apply to other legal requirements (such as registration and listing, Quality System (QS), and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806, respectively).

The three phases of the transition plan, including additional considerations and recommendations related to each phase, are described in more detail below.

FDA recommends manufacturers submit a "Transition Implementation Plan" with their marketing submission that addresses the manufacturers' plans for dealing with devices already distributed in the case of a positive decision as well as in the case of a negative decision on the marketing submission (see Section V.D.(2) of this guidance). The marketing submission should be administratively complete in that it includes all of the information necessary for FDA to conduct a substantive review.[37] FDA understands there may be extenuating circumstances that make doing so difficult (e.g., ongoing clinical trial or longer term non-clinical studies). Manufacturers in such circumstances should engage with the Agency early in the transition period.[38]

FDA understands that there may be scenarios that are not specifically addressed in this guidance, but generally believes that the policies and recommendations described in **Table 2**, regardless of the specific scenario for a manufacturer, will help avoid disruptions in critical devices and allow

[35] For more information regarding FDA's acceptance policies for marketing submissions, see the guidances "Refuse to Accept Policy for 510(k)s," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks, "Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-and-filing-reviews-premarket-approval-applications-pmas, and "Acceptance Review for De Novo Classification Requests," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests.

[36] For purposes of this guidance, FDA uses the term "final action" to mean a Medical Device User Fee Amendments (MDUFA) decision, which can include positive decisions, negative decisions, and notices of withdrawals, consistent with the: 510(k) Actions/Clock guidance, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals; De Novo Actions/Clock guidance, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals; PMA Actions/Clock guidance, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-approval-applications-pmas-effect-fda-review-clock-and-goals.

[37] See footnote 35.

[38] FDA recommends that manufacturers engage with the Agency through the Q-Submission Program, including requesting Pre-Submissions, to discuss extenuating circumstances. For details on the Q-Submission Program, refer to the guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.

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FDA to best manage its resources for review of marketing submissions. To address any unique considerations or other issues not otherwise discussed in this guidance, manufacturers may wish to initiate discussions with the Agency through the Q-Submission Program, including requesting feedback in Pre-Submissions. If the manufacturer's intent is to continue to distribute its device after Phase 2, the manufacturer should promptly start preparing, and FDA intends to help facilitate acceptance of, a marketing submission before Phase 3 begins. For details on the Q-Submission Program, refer to the guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."[39]

A. Devices not distributed after Phase 2

When a manufacturer that has been distributing its device as described in an enforcement policy in a guidance in List 1 does not intend to continue to distribute its device after Phase 2, at this time, FDA does not intend to object to the disposition and use[40] of already distributed devices (i.e., FDA does not intend to request market removal[41]) as follows:

1) Single-use, non-life-supporting/non-life-sustaining devices (e.g., face masks) that were distributed before the end of Phase 2 are used by the end user prior to the product expiration date, as applicable.
2) Reusable, non-life-supporting/non-life-sustaining devices (e.g., infusion pumps) that were distributed before the end of Phase 2 are used by their end user and either:
    a. Are restored[42] by the manufacturer to an FDA-cleared or -approved version of the device,[43] or
    b. Have[44] a physical and/or electronic copy of updated labeling that accurately describes the product features and regulatory status (e.g., that the product lacks FDA clearance, approval, or authorization).
3) Reusable life-supporting/life-sustaining devices (e.g., ventilators, extracorporeal membrane oxygenation systems) that were distributed before the end of Phase 2 are restored[45] by the manufacturer to an FDA-cleared or -approved version of the device[46] so that they may be used by their end user. If not restored, a physical and/or electronic copy of updated labeling that accurately describes the product features and regulatory status

[39] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.
[40] FDA recognizes that not all uses would necessarily be violative. To the extent such use is violative, FDA generally does not intend to object as described herein.
[41] FDA uses the term "removal" consistent with the definition in 21 CFR 806.2(j).
[42] In situations where manufacturers do not believe restoration is possible or in the best interest of public health, FDA recommends additional engagement with the Agency on the appropriate disposition of a product if it is not otherwise discussed in this guidance.
[43] For example, an FDA-cleared or -approved version may include an earlier software version, component replacement, or different labeling that removes information related to the use of the device as described in an enforcement policy.
[44] The manufacturer should provide labeling to the original purchaser, and collaborate with the original purchaser to ensure that labeling is distributed to relevant stakeholders, including device distributors, healthcare facilities, healthcare providers, patients, consumers, etc.
[45] See footnote 42.
[46] See footnote 43.

(e.g., that the product lacks FDA clearance, approval, or authorization) should be provided,[47] and such devices are not to be used.[48,49] To help ensure accessibility to updated labeling, FDA recommends that stakeholders be provided an opportunity to request a physical copy of updated labeling, and after such request, be provided the requested labeling without additional cost.

Manufacturers that do not intend to distribute their devices after Phase 2 should also refer to relevant information included in other sections of this guidance (though note that recommendations in Section V.D.(1) are intended only for manufacturers that intend to distribute their device after the end of Phase 2). In addition, manufacturers should be aware of any applicable legal requirements for their device, such as adverse event reporting under 21 CFR Part 803, and are expected to comply with such requirements for the duration in which they are applicable, which may extend beyond the cessation of distribution.

Manufacturers may also voluntarily withdraw their devices from the market. For manufacturers that do not intend to continue distributing their devices and that intend to voluntarily withdraw their devices from the market, FDA recommends completing withdrawal of the devices from the market prior to the withdrawal of the guidances in List 1; otherwise, if withdrawal of the devices from the market is not completed prior to the withdrawal of the guidances in List 1, FDA recommends restoring and/or updating labeling for reusable non-life-supporting/non-life-sustaining devices and for reusable life-supporting/life-sustaining devices as outlined in the policy above prior to the withdrawal of the guidances in List 1. Manufacturers should be aware of any applicable legal requirements for their device, such as adverse event reporting under 21 CFR Part 803, and continue to comply with such requirements for the duration in which they are applicable, which may extend beyond the cessation of distribution or withdrawal. Generally, it is anticipated that, over time, legal requirements will no longer apply when the manufacturer's device withdrawal activities are completed.

FDA encourages manufacturers that do not intend to continue to distribute their devices after Phase 2 to communicate with device distributors, healthcare facilities, healthcare providers, patients, and consumers, as appropriate, regarding their product disposition to assist all stakeholders with transition planning. In addition, thinking through elements of the "Transition Implementation Plan" outlined in Section V.D.(2) of this guidance may help manufacturers and stakeholders with this process.

[47] See footnote 44.
[48] FDA recognizes that not all use would necessarily be violative.
[49] Should healthcare facilities wish to retain a device that lacks FDA clearance, approval, or authorization for use in the future, the future use of the device would be subject to the regulatory requirements of any future authorization, including marketing authorization or EUA, as applicable. For governmental stockpilers that wish to retain a device that lacks requisite FDA clearance, approval, or authorization for use in the future, FDA recommends engaging with the Agency to discuss the public health need for future deployment and/or use of the device in specific circumstances (e.g., regional natural disaster, localized disease outbreaks).

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B. Phase 1

Phase 1 starts on the implementation date, as described above. In order to prepare for Phase 3, if not already doing so, manufacturers should follow adverse event reporting requirements[50] under 21 CFR Part 803. Manufacturers should submit any adverse event reports that were stored (e.g., because of pandemic-related high employee absenteeism) and should refer to applicable FDA guidance regarding adverse event reporting during a pandemic.

During (and preferably before the start of) this phase, manufacturers that intend to continue distribution of their devices after Phase 2 should begin preparation of any required marketing submission to help avoid disruptions in critical devices and allow FDA to best manage its resources for review of marketing submissions. While preparing a marketing submission, manufacturers can use the FDA Guidance Search Tool[51] to identify relevant guidance documents that may be helpful in preparing the submission.

FDA is taking into account that the use of devices during the COVID-19 pandemic may allow manufacturers to utilize a variety of data sources in their marketing submission. As such, FDA anticipates many manufacturers may wish to reference data from related marketing authorizations and submissions, and use real-world data obtained as a result of device use during the COVID-19 pandemic.[52] FDA recommends that marketing submissions include in the cover letter a statement that the device was distributed as described in an enforcement policy, as well as submission number(s) for related premarket submissions. This information will help FDA track devices that are transitioning to the required marketing authorization,[53] facilitate review of the submission, and help ensure that the transitioning devices can be appropriately considered in light of the policy described in Section V.D.(1) of this guidance.

C. Phase 2

Phase 2 begins 90 days after the implementation date. Before the start of Phase 2 and in order to prepare for Phase 3, if not already doing so, manufacturers should follow correction and removal requirements under 21 CFR Part 806. Before the start of Phase 2, manufacturers that intend to continue to distribute their devices after Phase 2 should also register their establishments and list[54] their device(s) or update existing registration and listing (R&L) if they have not already done so. For manufacturers that register and list by the start of Phase 2, FDA recommends that manufacturers utilize the term "enforcement" (as a shorthand for "enforcement policy") in the premarket submission field if a submission number is not yet available. If the device

[50] For more information on adverse event reporting requirements under 21 CFR Part 803, see the guidance "Medical Device Reporting for Manufacturers," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-reporting-manufacturers.
[51] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/.
[52] Data derived from real-world sources may be submitted in support of a marketing submission. See the guidance titled "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices.
[53] See, e.g., sections 510(k), 513(f)(2), 515, and 520(m) of the FD&C Act.
[54] 21 CFR Part 807, Subparts B-D.

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subsequently receives marketing authorization, FDA expects manufacturers to comply with all applicable registration and listing requirements, which may require updating the listing information.

As discussed above, manufacturers that intend to continue to distribute their devices after Phase 2 should continue preparation of any required marketing submission[55] as FDA expects such manufacturers to submit a marketing submission to FDA and have it accepted before the start of Phase 3 to help avoid disruptions in critical devices and allow FDA to best manage its resources for review of marketing submissions.

In addition, FDA recommends that manufacturers of certain life-supporting or life-sustaining devices within the scope of this guidance – regardless of whether they intend to continue distribution of their devices after Phase 2 – submit a "Notification of Intent" to FDA as described in Section V.C.(1) of this guidance.

(1) "Notifications of Intent" for Certain Reusable Life-Supporting or Life-Sustaining Devices

Given the public health significance of certain reusable life-supporting or life-sustaining devices, FDA requests that manufacturers of such devices submit to FDA information about whether or not they intend to submit a marketing submission to FDA and continue distributing their product after Phase 2. This information will assist the Agency in resource planning for marketing submission review and providing support to manufacturers. This request applies to devices that fall within the scope of this guidance and that have a product code listed in Table 1:

Table 1

Product Code	Device Type	Classification Regulation
BSZ	Gas-machine, anesthesia	21 CFR 868.5160
CAW	Generator, oxygen, portable	21 CFR 868.5440
BTT	Humidifier, respiratory gas, (direct patient interface)	21 CFR 868.5450
QAV	High flow/high velocity humidified oxygen delivery device	21 CFR 868.5454
CBK	Ventilator, continuous, facility use	21 CFR 868.5895
MNT	Ventilator, continuous, minimal ventilatory support, facility use	
NOU	Continuous, ventilator, home use	
MNS	Ventilator, continuous, non-life-supporting	

[55] See, e.g., sections 510(k), 513(f)(2), 515, and 520(m) of the FD&C Act.

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Product Code	Device Type	Classification Regulation
ONZ	Mechanical ventilator	
BTL	Ventilator, emergency, powered (resuscitator)	21 CFR 868.5925

Manufacturers of the devices identified in Table 1 should submit the following information to the CDRH Document Control Center[56] before the start of Phase 2:[57]

- General information about the manufacturer, including contact information, name and place of business, and email address;
- Title of the relevant enforcement policy guidance;
- Submission number(s) for related premarket submissions;
- A list of all model numbers or other device identifying information;
- Whether the manufacturer plans to submit a marketing submission; and
- If not planning to submit a marketing submission, the manufacturer should discuss, as applicable, its plans to discontinue distribution of the device, to restore the device to an FDA-cleared or -approved version, to provide a physical copy and/or electronic copy of updated labeling, and any other efforts to address or mitigate potential risks of devices that remain distributed after Phase 2.

If another version of the device is FDA-cleared or -approved and a modified version is/was distributed as described in a policy in a guidance in List 1, the manufacturer should submit this information in a premarket notification (i.e., 510(k)) or PMA "amendment" for the cleared or approved device.[58] FDA recommends that manufacturers notate the following on the cover letter of the submission: "Attention: Notification of Intent." To the extent the Notification of Intent contains trade secret information or confidential commercial or financial information, FDA will handle that information in accordance with applicable laws, including 21 CFR 20.61.

D. Phase 3

Phase 3 begins 180 days after the implementation date. After the 180-day transition period ends, the guidances in List 1 will no longer be in effect. Before the start of Phase 3, any required

[56] The mailing address for the CDRH Document Control Center can be found in 21 CFR 807.90(a)(1) and 814.104(d)(1). FDA encourages manufacturers to submit Notifications of Intent as eCopies. Information about the eCopy program can be found in the guidance "eCopy Program for Medical Device Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions.

[57] Submitting this information as soon as possible after issuance of this guidance is encouraged because it will assist the Agency in resource planning, help to avoid any supply disruptions, and otherwise help to ensure a smooth transition for these devices after the guidances in List 1 are no longer in effect.

[58] FDA recommends that the information be submitted as an "amendment" to the 510(k) or PMA file to facilitate efficient tracking of the "Notification of Intent" submissions.

marketing submission[59] is expected to be submitted to and accepted by FDA if the manufacturer intends to continue distribution of the device after Phase 2. Where possible, FDA strongly encourages manufacturers to work to complete such submissions well in advance of the start of Phase 3 to avoid potential delays created by a large influx of new submissions and to best serve the public health.

(1) Enforcement policy for devices with a marketing submission under review by FDA

As previously stated, FDA recognizes that it may take time for device manufacturers, including non-traditional device manufacturers, to adapt and adjust from their operations during the COVID-19 PHE to normal operations. As such, at this time, FDA does not intend to object to the continued distribution of devices within the scope of this guidance after the guidances in List 1 are no longer in effect where:

- The manufacturer has submitted a marketing submission[60] to FDA and it is accepted[61] by FDA before the start of Phase 3; and
- FDA has not taken a final action[62] on the marketing submission.

For these same devices, while the device is under FDA review, FDA does not intend to object to the devices not complying with certain UDI requirements (see 21 CFR Part 801 Subpart B) or other applicable labeling requirements (see 21 CFR Part 801) where the device continues to be labeled as described in the relevant List 1 guidance.[63,64] As always, FDA will make case-by-case decisions regarding the enforcement of legal requirements in response to particular circumstances and questions that arise regarding a specific device or device type.

[59] See, e.g., sections 510(k), 513(f)(2), 515, and 520(m) of the FD&C Act. For devices that are class I or II and exempt from premarket notification (e.g., shoe covers, face shields), no 510(k) submission is required unless the limitations of exemption are exceeded (see, e.g., 21 CFR 878.9).

[60] This includes a marketing submission for the device within the scope of the guidances in List 1, or a marketing submission for a device that is a derivative of, or the next generation of, the device within the scope of the guidances in List 1.

[61] Manufacturers that do not have an accepted marketing submission before the start of Phase 3 should refer to the policy described in Section V.A. of this guidance.

[62] See footnote 36.

[63] For example, if a manufacturer made modifications to the labeling of a cleared fetal doppler as described in the "Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the COVID-19 Public Health Emergency" guidance, FDA generally does not intend to object to the manufacturer not complying with applicable labeling requirements (see 21 CFR Part 801) where the device continues to be labeled as described in that guidance while the marketing submission for the modified device is under review.

[64] Based on comments received on this draft guidance, as well as the companion transition guidance, FDA understands that updating the labeling of these devices while they are under FDA review, and then again if they are subsequently cleared, approved, or authorized, would be challenging for manufacturers. This policy takes those comments into account and is least burdensome for manufacturers and FDA. As noted elsewhere, manufacturers should engage with the Agency if they have questions specific to their device (e.g., regarding updating the device labeling to acknowledge that the device is currently under FDA review when the FDA review is expected to take an extended period of time).

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The enforcement policy in this section (Section V.D.(1)) relates to FDA marketing authorization (e.g., 510(k) clearance), and certain UDI and other applicable labeling requirements. It does not apply to other legal requirements (such as registration and listing,[65] QS, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806, respectively) that may apply.[66] Moreover, it does not apply after FDA has taken a final action on the marketing submission for a device. At that time, FDA expects manufacturers to comply with all applicable regulatory requirements for the device/manufacturer. Following the device's marketing authorization, this includes labeling updates (see 21 CFR Part 801), compliance with UDI requirements (see 21 CFR Part 801 Subpart B and Part 830), and any applicable updates to registration and listing information, including the submission number (see 21 CFR Part 807 Subparts B-D). After marketing authorization, manufacturers also should follow the steps outlined in their Transition Implementation Plan.

In addition, and as always, FDA will make case-by-case decisions regarding the enforcement of legal requirements in response to particular circumstances and questions that arise regarding a specific device or device type. This may include FDA requesting a firm initiate a recall (see 21 CFR 7.45)[67] or taking other actions, including an enforcement action. Moreover, FDA may revise the enforcement policies and recommendations in the guidance, as appropriate.

As mentioned previously, FDA recommends that marketing submissions include in the cover letter a statement that the device is/was distributed as described in an enforcement policy, and submission number(s) for related premarket submissions. This information will help FDA track devices that are transitioning to the required marketing authorization,[68] facilitate review of the submission, and help ensure that transitioning devices can be appropriately considered in light of the policy described in this section (Section V.D.(1) of this guidance). The marketing submission should be administratively complete in that it includes all of the information necessary for FDA

[65] For manufacturers that register and list by the start of Phase 2, FDA recommends that manufacturers utilize the term "enforcement" in the premarket submission field if a submission number is not yet available. If the device subsequently receives marketing authorization, FDA expects manufacturers to comply with all applicable registration and listing requirements, which may require updating the listing information.

[66] For more information regarding FDA regulatory requirements for a specific device and FDA policies related to those requirements, manufacturers can use the FDA Guidance Search Tool to identify relevant guidance documents. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/. After the start of Phase 3, FDA will look to any other applicable compliance policies and otherwise apply our general risk-based approach in making compliance and enforcement decisions. For more information, see the guidance "Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-regarding-benefit-risk-medical-device-product-availability-compliance-and.

[67] 21 CFR 7.45(a) states that FDA "may request a firm to initiate a recall when the following determinations have been made: (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception. (2) That the firm has not initiated a recall of the product. (3) That an agency action is necessary to protect the public health and welfare."

[68] See, e.g., sections 510(k), 513(f)(2), 515, and 520(m) of the FD&C Act.

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to conduct a substantive review.[69] FDA understands there may be extenuating circumstances that may make doing so difficult (e.g., ongoing clinical trial or longer term non-clinical studies). Manufacturers in such circumstances should engage with the Agency early in the transition period.[70]

In addition, during this transition period and after the start of Phase 3, FDA may receive questions from stakeholders (e.g., other Agencies, governmental stockpilers, healthcare providers) about a device's regulatory status for devices distributed as described in this section (Section V.D.(1)) while the marketing submission is under review by FDA. Typically, if a device has an EUA or conventional marketing authorization (e.g., 510(k) clearance), this information would be publicly available. The existence of a marketing submission under review is not typically disclosed unless certain circumstances apply, such as when the device is on the market.[71] As such, for devices distributed as described in this section, FDA may share that a manufacturer is distributing such device as described in the policy in this guidance, which could indirectly reveal that the manufacturer has a marketing submission under review by FDA.[72]

(2) Recommendations for "Transition Implementation Plan"

FDA anticipates that some marketing submissions will include changes or updates to the device and/or its labeling compared to the product that was distributed as described in the relevant guidance in List 1. For example, a manufacturer may have distributed fetal dopplers as described in an enforcement policy, and the manufacturer intends to submit a marketing submission for such fetal dopplers with an additional, new indication. In addition, in some cases, a manufacturer may not receive a positive decision from FDA on its marketing submission.

To help address all of these situations efficiently, FDA recommends manufacturers include in the cover letter of their marketing submissions a "Transition Implementation Plan" that addresses the manufacturers' plans for dealing with devices already distributed in the case of a positive decision as well as in the case of a negative decision on the marketing submission. To the extent the Transition Implementation Plan contains trade secret information or confidential commercial or financial information, FDA will handle that information in accordance with applicable laws, including 21 CFR 20.61.

[69] For more information regarding FDA's acceptance policies for marketing submissions, see the guidances "Refuse to Accept Policy for 510(k)s," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks, "Acceptance and Filing Reviews for Premarket Approval Applications (PMAs)," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-and-filing-reviews-premarket-approval-applications-pmas, and "Acceptance Review for De Novo Classification Requests," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests.

[70] FDA recommends that manufacturers engage with the Agency through the Q-Submission Program, including requesting Pre-Submissions, to discuss extenuating circumstances. For details on the Q-Submission Program, refer to the guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."

[71] See, e.g., 21 CFR 807.95(a)(1).

[72] To the extent the marketing submission contains trade secret information or confidential commercial or financial information, FDA will handle that information in accordance with applicable laws, including 21 CFR 20.61.

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FDA recommends the Transition Implementation Plan include the following information, as applicable:[73]

- Estimated number of devices that fall within the policies outlined in any of the guidances referenced in List 1 above that are currently in U.S. distribution;
- An explanation of the manufacturer's benefit-risk based plan for disposition of already distributed product in the event of a negative decision on the marketing submission. If the manufacturer is proposing to leave already distributed product in place, the plan should address the rationale for doing so and considerations such as the following, where relevant:[74]
  - Process for notifying patients, consumers, healthcare facilities, healthcare providers, and device distributors of the device's regulatory status;
  - Process and timeline for restoring already distributed devices to an FDA-cleared or -approved version;
  - Process and timeline for providing[75] a physical and/or electronic copy of updated labeling that accurately describes the product features and regulatory status (e.g., that the product lacks FDA clearance, approval, or authorization) for reusable devices. To help ensure accessibility to updated labeling for reusable life-supporting/life-sustaining devices, FDA recommends that stakeholders be provided an opportunity to request a physical copy of updated labeling, and after such request, be provided the requested labeling without additional cost; and
  - A description of the maintenance plan for already distributed devices.
- An explanation of the manufacturer's plans for addressing already distributed product in the event of a positive decision on the marketing submission, including considerations such as the following, where relevant:
  - Process for notifying patients, consumers, healthcare facilities, healthcare providers, and device distributors of the device's regulatory status; and
  - Process and timeline for providing to users of already distributed devices updated labeling or components for the cleared or approved device, including updated labeling or components to reflect any cleared/approved changes to the already distributed device.

[73] If the manufacturer has already submitted a Notification of Intent with some of this information, FDA still recommends that manufacturers include a Transition Implementation Plan with their marketing submission, noting any updates since the Notification of Intent was submitted to FDA.

[74] While FDA recommends the inclusion of a benefit-risk based plan for disposition of already distributed product be submitted with a marketing submission for devices within the scope of this guidance, FDA also believes such an approach is consistent with device end-of-life best practices and recommends that manufacturers consider and conduct such activities even if the manufacturer's Transition Implementation Plan is not prospectively shared with the Agency.

[75] The manufacturer should provide labeling to the original purchaser, and collaborate with the original purchaser to ensure that labeling is distributed to relevant stakeholders, including device distributors, healthcare facilities, healthcare providers, patients, consumers, etc.

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FDA encourages manufacturers to collaborate with device distributors, healthcare facilities, healthcare providers, patients, and consumers, as appropriate, regarding their Transition Implementation Plan to assist all stakeholders with transition planning.

Depending on FDA's evaluation of the marketing submission, FDA may engage with the manufacturer during the Agency's review of the submission to discuss the appropriate disposition of already distributed devices described in the Transition Implementation Plan. For marketing submissions that include changes to the device compared to the already distributed device (e.g., modifications to address a cybersecurity concern), the manufacturer should discuss possible correction or removal with FDA regarding devices already distributed to the end user, as needed. As always, FDA will make case-by-case decisions regarding the enforcement of legal requirements in response to particular circumstances and questions that arise regarding a specific device or device type (e.g., requesting a firm initiate a recall (see 21 CFR 7.45),[76] or taking other actions, including an enforcement action).

E. Discontinuing distribution of a device

FDA expects manufacturers to discontinue distribution of a device within the scope of this guidance:

1) Before the start of Phase 3, if the manufacturer has not submitted a required marketing submission[77] for its device and had it accepted by FDA before the start of Phase 3; or
2) On the date the manufacturer receives a negative decision on its marketing submission as FDA's final action, or on the date the manufacturer withdraws its submission or fails to provide a complete response to an FDA request for additional information[78] within the allotted time identified in FDA's letter.

In addition, manufacturers should be aware of any applicable legal requirements for their device, such as adverse event reporting under 21 CFR Part 803, and continue to comply with such requirements for the duration in which they are applicable, which may extend beyond the cessation of distribution.

FDA encourages manufacturers to communicate with device distributors, healthcare facilities, healthcare providers, patients, and consumers, as appropriate, regarding their product disposition to assist all stakeholders with transition planning.

[76] 21 CFR 7.45(a) states that FDA "may request a firm to initiate a recall when the following determinations have been made: (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception. (2) That the firm has not initiated a recall of the product. (3) That an agency action is necessary to protect the public health and welfare."

[77] See, e.g., sections 510(k), 513(f)(2), 515, and 520(m) of the FD&C Act.

[78] For more information on FDA requests for additional information (i.e., deficiency letters) and how to respond, see the guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-and-responding-deficiencies-accordance-least-burdensome-provisions.

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F. Quality System considerations

FDA recognizes that there may be situations that raise unique compliance considerations, particularly regarding QS requirements. For example, non-traditional device manufacturers that previously operated under different quality standards or requirements may face challenges that take more time to address in transitioning to a system that fully complies with 21 CFR Part 820. FDA intends to take such considerations into account when making case-by-case compliance and enforcement decisions. Some manufacturers who intend to continue distributing their devices beyond Phase 2 may choose to request an exemption or variance from a device QS requirement as outlined in 21 CFR 820.1(e) and section 520(f)(2) of the FD&C Act. Any such exemption or variance should be requested within 90 days of the announcement of the implementation date for this guidance to help ensure FDA considers your request in time.

VI. Examples

The following hypothetical examples are intended to illustrate the phased transition plan outlined above. To exemplify the timeline of the phased transition plan outlined in Section V. of this guidance, for purposes of the examples, FDA set the implementation date for all devices that fall within this enforcement policy as the implementation date, May 11, 2023, consistent with the timeline shown in Figure 1. The dates outlined in each example follow this example phased transition plan timeline. Note that these generalized examples do not account for every possible detail, risk, or consideration a manufacturer should evaluate or that may be relevant to FDA decisions regarding a particular device.

Example 1

A 510(k)-cleared fetal doppler was modified to add Bluetooth functionality[79] as described in the policies in the guidance, "Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the COVID-19 Public Health Emergency."[80]

a) Manufacturer who intends to continue distributing beyond Phase 2 and receives a positive decision on its marketing submission

Phase 1 (May 11, 2023): In the above-referenced guidance, FDA describes its intent not to object to modification of certain fetal dopplers in certain circumstances without marketing authorization by FDA. The enforcement policy in the guidance does not address other

[79] Manufacturers should also consult the guidance "Multiple Function Device Products: Policy and Considerations," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/multiple-function-device-products-policy-and-considerations, for more information about how such a function can affect the regulation of a device.

[80] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-fetal-and-maternal-monitoring-devices-used-support-patient.

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requirements, including adverse event reporting, reports of corrections and removals, and QS requirements. The manufacturer continues to comply with requirements under 21 CFR Parts 803, 806, and 820.

Phase 2 (August 9, 2023): As an indication of its intent to market its device beyond Phase 2, the fetal doppler manufacturer updates its existing listing under 21 CFR Part 807 Subparts B-D, as applicable. On October 1, 2023, the manufacturer submits a marketing submission to FDA, which is accepted by the Agency. Along with its marketing submission, the manufacturer includes a "Transition Implementation Plan" for already distributed fetal dopplers in the case of a positive decision as well as in the case of a negative decision on the marketing submission.

Phase 3 (November 7, 2023): The above-referenced guidance is no longer in effect after the 180-day transition period ends, and FDA has not yet taken a final action on the manufacturer's marketing submission. Under these circumstances, FDA does not intend to object to the continued distribution of the fetal doppler before FDA takes a final action on the marketing submission (see Section V.D.(1) of this guidance). The manufacturer continues to comply with all other legal requirements applicable to the device (such as registration and listing, QS, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806). Additionally, the manufacturer has kept the device labeling as described in the labeling recommendations provided in the above-referenced guidance. Under these circumstances, FDA does not intend to object to the device labeling not complying with applicable labeling requirements (see 21 CFR Part 801) where the device continues to be labeled as described in the relevant List 1 guidance while the marketing submission is under FDA review (see Section V.D.(1) of this guidance).

The manufacturer receives a positive decision on its marketing submission on December 29, 2023 (90 days after submission), although outstanding software anomalies were identified and modifications to the device were made during FDA's premarket review. Based on the Transition Implementation Plan included with the marketing submission, FDA is aware of the number of already distributed devices that may have these anomalies and engages with the manufacturer on how to address these issues with the already distributed devices and provide updated electronic labeling to the relevant stakeholders. The manufacturer initiates a correction to address the software anomalies in the fetal dopplers that were distributed prior to the positive marketing decision.

Additionally, as part of its Transition Implementation Plan, the manufacturer updates its website to add the updated device labeling. All devices distributed after receiving the positive decision will have the updated labeling.

b) Manufacturer who intends to continue distribution beyond Phase 2 and receives a negative decision on its marketing submission

Phase 1 (May 11, 2023): In the above-referenced guidance, FDA describes its intent not to object to modification of certain fetal dopplers in certain circumstances without marketing authorization by FDA. The enforcement policy in the guidance does not address other requirements, including

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adverse event reporting, reports of corrections and removals, and QS requirements. The manufacturer continues to comply with requirements under 21 CFR Parts 803, 806, and 820.

Phase 2 (August 9, 2023): As an indication of its intent to market its device beyond Phase 2, the fetal doppler manufacturer updates its existing listing under 21 CFR Part 807 Subparts B-D, as applicable. On October 15, 2023, the manufacturer submits a marketing submission to FDA, which is accepted by the Agency. Along with its marketing submission, the manufacturer includes a "Transition Implementation Plan" for already-distributed fetal dopplers in the case of a positive decision as well as in the case of a negative decision on the marketing submission.

Phase 3 (November 7, 2023): The above-referenced guidance is no longer in effect after the 180-day transition period ends, and FDA has not yet taken a final action on the manufacturer's marketing submission. Under these circumstances, FDA does not intend to object to the continued distribution of the fetal doppler before FDA takes a final action on the marketing submission (see Section V.D.(1) of this guidance). The manufacturer continues to comply with all other legal requirements applicable to the device (such as registration and listing, QS, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806). Additionally, the manufacturer has kept the device labeling as described in the labeling recommendations provided in the above-referenced guidance. Under these circumstances, FDA does not intend to object to the device labeling not complying with applicable labeling requirements (see 21 CFR Part 801) where the device continues to be labeled as described in the relevant List 1 guidance while the marketing submission is under FDA review (see Section V.D.(1) of this guidance).

The manufacturer receives a negative decision on its marketing submission on January 15, 2024 (90 days after submission), due to outstanding software anomalies that were identified and could not be addressed by the manufacturer during FDA's premarket review. As described in the Transition Implementation Plan included with the marketing submission, the manufacturer initiates a correction to restore the fetal doppler to the FDA-cleared version. In addition, the manufacturer ceases distributing the modified device.

Example 2

A FDA-cleared diagnostic x-ray system was modified to become portable and falls within the enforcement policy described in the guidance "Enforcement Policy for Imaging Systems During the COVID-19 Public Health Emergency."[81]

Phase 1 (May 11, 2023): In the above-referenced guidance, FDA describes its intent not to object to modifications to certain imaging systems in certain circumstances without marketing authorization by FDA. The enforcement policy in the guidance does not address other requirements, including requirements in 21 CFR Parts 803, 807 Subparts B-D, 806, 820, and 830. The manufacturer continues to comply with these requirements.

[81] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-imaging-systems-during-coronavirus-disease-2019-covid-19-public-health-emergency.

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Phase 2 (August 9, 2023): As an indication of its intent to market its device beyond Phase 2, the portable x-ray system manufacturer updates its existing listing, under 21 CFR Part 807 Subparts B-D, as applicable. On September 29, 2023, the manufacturer submits a marketing submission to FDA, which is accepted by the Agency. In its marketing submission, the manufacturer includes a "Transition Implementation Plan" for already-distributed portable x-ray systems in the case of a positive decision as well as in the case of a negative decision on the marketing submission.

Phase 3 (November 7, 2023): The above-referenced guidance is no longer in effect after the 180-day transition period ends, and FDA has not yet taken a final action on the manufacturer's marketing submission. Under these circumstances, FDA does not intend to object to the continued distribution of the portable x-ray system before FDA takes a final action on the marketing submission (see Section V.D.(1) of this guidance). The manufacturer continues to comply with all other legal requirements applicable to the device (such as registration and listing, QS, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806). Additionally, the manufacturer has kept the device labeling as described in the labeling recommendations provided in the above-referenced guidance. Under these circumstances, FDA does not intend to object to the device labeling not complying with applicable labeling requirements (see 21 CFR Part 801) where the device continues to be labeled as described in the relevant List 1 guidance while the marketing submission is under FDA review (see Section V.D.(1) of this guidance).

The manufacturer does not respond to a request from FDA for additional information within the specified timeframe identified in the Agency's deficiency letter. FDA issues a notice of withdrawal as the Agency's final action on the marketing submission on March 15, 2024. FDA and the manufacturer engage regarding the manufacturer's Transition Implementation Plan to address already distributed devices. The diagnostic x-ray is a reusable, non-life-supporting/non-life-sustaining device; as such, the manufacturer, following the Transition Implementation Plan, updates its website to accurately describe the product features and regulatory status of the already distributed, modified devices. FDA may request the firm initiate a recall of such devices in certain circumstances if a recall has not already been initiated (see 21 CFR 7.45). In addition, the manufacturer ceases distributing the modified device.

Example 3

A FDA-cleared ventilator was modified to make material changes to components in the gas pathway to accommodate supplier shortages and falls within the enforcement policy described in the guidance, "Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the COVID-19 Public Health Emergency."[82]

Phase 1 (May 11, 2023): In the above-referenced guidance, FDA describes its intent not to object to modifications to ventilators in certain circumstances without marketing authorization by FDA.

[82] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus.

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The enforcement policy in the guidance does not address other requirements, including requirements in 21 CFR Parts 803, 807 Subparts B-D, 806, and 820, and 830. The manufacturer continues to comply with these requirements.

Phase 2 (August 9, 2023): As an indication of its intent to market its device beyond Phase 2, the ventilator manufacturer updates its existing listing, under 21 CFR Part 807 Subparts B-D, as applicable. On October 1, 2023, the ventilator manufacturer also submits an amendment to the manufacturer's previously cleared marketing submission to the CDRH Document Control Center with "Attention: Notification of Intent" on the cover letter of the submission to describe the manufacturer's intent to submit a marketing submission. This submission amendment includes the information outlined in Section V.C.(1) of this guidance. In its marketing submission that was accepted by the Agency on December 20, the manufacturer includes a "Transition Implementation Plan" for already distributed ventilators in the case of a positive decision as well as in the case of a negative decision on the marketing submission.

Phase 3 (November 7, 2023): The above-referenced guidance is no longer in effect after the 180-day transition period ends, and FDA has not yet taken a final action on the manufacturer's marketing submission. Under these circumstances, FDA does not intend to object to the continued distribution of the ventilator before FDA takes a final action on the marketing submission (see Section V.D.(1) of this guidance). The manufacturer continues to comply with all other legal requirements applicable to the device (such as registration and listing, QS, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806). Additionally, the manufacturer has kept the device labeling as described in the labeling recommendations provided in the above-referenced guidance. Under these circumstances, FDA does not intend to object to the device labeling not complying with applicable labeling requirements (see 21 CFR Part 801) where the device continues to be labeled as described in the relevant List 1 guidance while the marketing submission is under FDA review (see Section V.D.(1) of this guidance).

The ventilator manufacturer receives a positive decision on its marketing submission on January 2, 2024. The manufacturer continues to distribute the modified ventilator with updated labeling. In addition, the manufacturer communicates with users of the modified ventilator, distributed as described in the above-referenced guidance, apprising them of the regulatory status of the device and providing updated electronic labeling.

Example 4

A new telethermographic system that has not been FDA-cleared and is intended for adjunctive diagnostic screening by providing an initial body temperature assessment for triage use, falls within the enforcement policy described in the guidance, "Enforcement Policy for Telethermographic Systems During the COVID-19 Public Health Emergency."[83]

[83] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-telethermographic-systems-during-coronavirus-disease-2019-covid-19-public-health.

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a) Manufacturer who intends to continue distribution beyond Phase 2

Phase 1 (May 11, 2023): In the guidance, FDA describes its intent not to object to the distribution and use of certain telethermographic system without submission of a 510(k), reports of corrections and removals, registration and listing, and compliance with the QS regulation and UDI, and other applicable labeling requirements in certain circumstances. The enforcement policy in the guidance does not address other requirements, including requirements in 21 CFR Part 803. The manufacturer continues to comply with 21 CFR Part 803.

Phase 2 (August 9, 2023): As an indication of its intent to market its device beyond Phase 2, the telethermographic system manufacturer registers and lists, consistent with 21 CFR Part 807 Subparts B-D, as applicable. On October 5, 2023, the manufacturer submits a marketing submission to FDA, which is accepted by the Agency. In its marketing submission, the manufacturer includes a "Transition Implementation Plan" for already distributed telethermographic systems in the case of a positive decision as well as in the case of a negative decision on the marketing submission.

Phase 3 (November 7, 2023): The above-referenced guidance is no longer in effect after the 180-day transition period ends, and FDA has not yet taken a final action on the manufacturer's marketing submission. Under these circumstances, FDA does not intend to object to the continued distribution of the telethermographic system before FDA takes a final action on the marketing submission (see Section V.D.(1) of this guidance). The manufacturer complies with all other legal requirements applicable to the device (such as registration and listing, QS, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806). Additionally, the manufacturer has kept the device labeling as described in the labeling recommendations provided in the above-referenced guidance. Under these circumstances, FDA does not intend to object to the device labeling not complying with applicable labeling requirements (see 21 CFR Part 801) where the device continues to be labeled as described in the relevant List 1 guidance while the marketing submission is under FDA review (see Section V.D.(1) of this guidance).

The manufacturer receives a "not substantially equivalent" decision on January 3, 2024, after FDA's review of the manufacturer's marketing submission. The manufacturer ceases distributing the telethermographic system. FDA and the manufacturer engage regarding the manufacturer's Transition Implementation Plan to address already distributed devices. FDA may request the firm initiate a recall of such devices in certain circumstances if a recall has not already been initiated (see 21 CFR 7.45).

b) Manufacturer who does not intend to continue distribution beyond Phase 2

A new telethermographic system that has not been FDA-cleared and is intended for adjunctive diagnostic screening by providing an initial body temperature assessment for triage use was

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distributed under the enforcement policy described in the guidance, "Enforcement Policy for Telethermographic Systems During the COVID-19 Public Health Emergency."[84]

Phase 1 (May 11, 2023): In the above-referenced guidance, FDA describes its intent not to object to the distribution and use of a certain telethermographic system without submission of a 510(k), reports of corrections and removals, registration and listing, and compliance with the QS regulation, UDI, and other applicable labeling requirements in certain circumstances. The enforcement policy in the guidance does not address other requirements, including 21 CFR Part 803. The manufacturer continues to comply with 21 CFR Part 803.

Phase 2 (August 9, 2023): The manufacturer decides that it does not want to continue to market and distribute the device beyond Phase 2. The manufacturer ceases distributing the device on November 1, 2023. The telethermographic system is a reusable, non-life-supporting/non-life-sustaining device. Devices that were distributed before the end of Phase 2 remain distributed. In addition, the manufacturer continues to report adverse events that it becomes aware of, even after the manufacturer has ceased distributing the telethermographic system.

Phase 3 (November 7, 2023): The above-referenced guidance is no longer in effect after the 180-day transition period ends. Prior to the start of Phase 3, the manufacturer provides updated electronic labeling for the telethermographic system, and such labeling accurately describes all product features and notes that the product is not FDA-cleared, -approved, or -authorized for marketing. The manufacturer leaves already distributed telethermographic systems in the field. The manufacturer continues to engage in adverse event reporting to FDA concerning the device.

[84] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-telethermographic-systems-during-coronavirus-disease-2019-covid-19-public-health.

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Table 2 . Summary of Recommendations for a Phased Transition			
PHASE	**1**	**2**	**3**
STARTING TIME	**0 days** (implementation date – May 11, 2023)	**90 days** after the implementation date – August 9. 2023	**180 days** after the implementation date – November 7, 2023
ACTIONS	Manufacturers should, if not already doing so, follow adverse event reporting requirements under 21 CFR Part 803. Manufacturers should submit any stored adverse event reports and should refer to applicable FDA guidance regarding adverse event reporting during a pandemic. Manufacturers that intend to continue distribution of their devices after Phase 2 should begin to prepare their required marketing submissions.	Before the start of Phase 2, manufacturers that intend to continue to continue to distribute their devices after Phase 2 should register their establishments and list their device(s), or update their existing registration and listing, under 21 CFR Part 807 Subparts B-D, as applicable. Before the start of Phase 2, if not already doing so, manufacturers should submit reports of corrections and removals consistent with 21 CFR Part 806 (regardless of whether they intend to continue distribution of their devices after Phase 2). Manufacturers of devices under the product codes listed in Table 1 of this guidance should send a Notification of Intent to FDA (regardless of whether they intend to continue distribution of their devices after Phase 2). Manufacturers that intend to distribute their devices after Phase 2 should continue to prepare to submit a marketing submission to FDA and have it accepted by FDA before the start of Phase 3.	After the 180-day transition period ends, the List 1 guidances containing COVID-19 related enforcement policies will no longer be in effect. Before the start of Phase 3, if manufacturers submit a marketing submission(s), and that submission is accepted by FDA, at this time, FDA does not intend to object to the continued distribution of the device after Phase 2 as described in Section V.D.(1) of this guidance. With the marketing submission, the manufacturer should include a "Transition Implementation Plan" that addresses the manufacturer's plans for devices already in distribution in the case of a positive decision or a negative decision on the marketing submission. FDA recommends that the Transition Implementation Plan include the information in Section V.D.(2) of this guidance, as applicable. Moreover, for devices for which FDA has accepted a marketing submission prior to the start of Phase 3, FDA does not intend at this time to object to the devices not complying with certain UDI and other applicable labeling requirements where they are labeled as described in the relevant List 1 guidance. This enforcement policy does not apply to other applicable legal requirements (such as registration and listing, QS, and reports of corrections and removals requirements under 21 CFR Parts 807, 820, and 806, respectively).

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Opternative, Inc. v. S.C. Board of Medical Examiners, et al.
(Civil Action No. 2016-CP-40-06276)

AFFIDAVIT OF CHRISTOPHER O'BRIEN, M.D., M.B.A., M.P.H. (APP 72-APP 104)

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IN THE COURT OF COMMON PLEAS FOR THE FIFTH JUDICIAL CIRCUIT

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND Opternative, Inc., Plaintiff, v. South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation, Defendants, South Carolina Optometric Physicians Association, Defendant-Intervenor.	Civil Action No. 2016-CP-40-06276

AFFIDAVIT OF CHRISTOPHER O'BRIEN, M.D., M.B.A., M.P.H.

I, Christopher O'Brien, M.D., M.B.A., M.P.H., submit the following testimony under oath:

1. I am a citizen of the United States over eighteen years of age. I am of sound mind and fully competent to make this affidavit, which I make knowingly and based on my personal knowledge.

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2. I am a licensed, board-certified ophthalmologist with over a decade of clinical practice experience. My academic, clinical, and professional experience are set forth in Exhibit 1, which is a true and correct copy of my CV. Besides my personal knowledge, the following testimony is also based on my expertise in the field of ophthalmology as set forth in my CV.

3. Ophthalmologists are medical doctors specializing in total eye and vision care, who are qualified to (among other things) conduct eye exams and vision tests, diagnose and treat eye diseases, perform eye surgeries, and prescribe corrective lenses (including glasses and contact lenses).

4. Ophthalmologists are qualified to determine whether a patient requires corrective lenses and, if so, which lenses to prescribe.

5. One piece of information that ophthalmologists use in order to determine whether a patient requires corrective lenses and, if so, which lenses to prescribe, is the patient's visual acuity.

6. A common way that ophthalmologists test a patient's visual acuity is by asking the patient to report their subjective responses to images on a chart or screen.

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7. Until recently, these vision tests could only be conducted in-person: Patients had to physically travel to a doctor's office, sit in a chair, and report their subjective responses to images on a chart or screen.

8. This sort of vision test is sometimes conducted by the doctor himself, but it can also be conducted by a clinical assistant (i.e., a trained staff person) with the doctor making the final determination about an appropriate prescription. In my clinical practice, I have at times used clinical assistants to gather certain kinds of information I needed to write prescriptions.

9. The brick-and-mortar system described above disfavors patients in rural areas, patients with lower incomes who work long hours or have multiple jobs, handicapped patients, and patients with children, who are often unable or unwilling to travel to a doctor's office just to take a vision test.

10. Moreover, the brick-and-mortar system has drawbacks for contact lens wearers. In my experience, the most common health problem associated with contact lenses is that patients wear them too long, which causes irritation or damage to the eye. In my experience, the most common reason that patients wear contact lenses for too long is that they either do not have time, or cannot afford, to visit a brick-and-mortar eye doctor to renew their lens prescription.

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11. Telemedicine—the use of online technologies to connect doctors with patients, whether via synchronous or asynchronous means—is a valuable tool for expanding access to care that ophthalmologists can and commonly do safely use in their practices.

12. Ophthalmologists are just as qualified as medical doctors in other specialties to incorporate telemedical tools into their practices safely, responsibly, and consistent with the applicable standard of care.

13. I am aware of zero evidence that ophthalmologists are in any way less capable than other medical specialists of incorporating telemedical tools into their practices safely, responsibly, and consistent with the applicable standard of care.

14. The key to safely using telemedicine in any medical practice, including an ophthalmological practice, is to evaluate each patient on a case-by-case basis and to ensure that using telemedicine meets the relevant standard of care.

15. A company called Visibly offers an online vision test that has been cleared by the U.S. Food and Drug Administration (FDA) for marketing to adults aged 22–40. Attached as Exhibit 2 is a true and correct copy of an August 12, 2022

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letter from the FDA to Visibly confirming the same. I have read, and am familiar with, the parameters of the FDA-approved version of Visibly's online vision test as reflected in Exhibit 2.

16. In 2014, when Visibly was still called Opternative, I heard about the company's online vision testing software and reached out the company of my own accord to learn more. Inspired by the company's vision of using technology to expand access to care, and confident that the technology was safe to use, I began partnering with the company to review individual patient information sent by the software (patients' vision test results and health survey information) and—if medically appropriate—to issue prescriptions for corrective lenses to patients who needed them.

17. Since I began partnering with Visibly (then Opternative) in 2014, I have written thousands of corrective lens prescriptions based on individual patient information sent by the company's software. By the same token, based on my medical judgment, I have also rejected thousands of lens prescriptions based on individual patient information sent by the company's software.

18. I am not aware of any patient ever having been harmed or suffering adverse health effects from a prescription that I wrote based on information sent

by Visibly's or Opternative's software. To the contrary, my professional opinion is that those patients benefitted from increased access to vision care—especially the patients who would not otherwise have visited a brick-and-mortar doctor's office at all because doing so was either too expensive or inconvenient.

19. It is both common and consistent with the standard of care for ophthalmologists to allow clinical assistants to test a patient's visual acuity and record the patient's responses when the ophthalmologist is not in the same room.

20. It is both common and consistent with the standard of care for ophthalmologists to write corrective lens prescriptions based on the results of visual acuity tests performed by clinical assistants when the ophthalmologist is not in the same room.

21. It is both common and consistent with the standard of care for ophthalmologists—in certain cases—to assess a patient's visual acuity and prescribe corrective lenses without also conducting a comprehensive eye health exam. Indeed, I have done so in my clinical practice. This is because comprehensive eye health exams are not always medically necessary for otherwise-healthy patients.

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22. There is no significant medical difference between renewing a corrective lens prescription using Visibly's software and renewing a corrective lens prescription based on a visual acuity test performed by a clinical assistant.

23. The American Academy of Ophthalmology (AAO), which helps set the standard of care for ophthalmologists nationwide, recommends:

> Adults with no signs or risk factors for eye disease should receive a comprehensive medical eye evaluation at age 40 if they have not previously had one. Before the onset of presbyopia (at approximately age 40), the majority of American adults experience no changing refractive error or significant ocular disease and routine eye examinations are not indicated. For asymptomatic individuals or individuals without risk factors, who are 40 to 54 years old, and who have had a comprehensive eye examination, the recommended interval for evaluations is 2 to 4 years. For individuals aged 55 to 64 years old, the recommended interval for evaluations is 1 to 3 years. For individuals 65 years old or older, the American Academy of Ophthalmology recommends an examination every 1 to 2 years, even in the absence of symptoms.

Attached as Exhibit 3 is a true and correct copy of the AAO policy document that contains the recommendation quoted above.

24. Accordingly, an ophthalmologist can safely rely on the information collected by Visibly's software to evaluate a patient's visual acuity and renew that patient's prior lens prescription as long as the ophthalmologist (a) evaluates the patient's information individually, (b) determines that the information is

sufficient to renew the patient's prior lens prescription, and (c) determines that the patient had a comprehensive eye health exam recently enough to fall within the AAO's recommended frequency for that patient. Again, I have done so thousands of times.

25. In other words, as long as an ophthalmologist complies with the ordinary professional standards that would govern the use of telemedical tools in any context, it is safe for a patient to take Visibly's online vision test and for an ophthalmologist to renew a patient's corrective lens prescription based on information sent by Visibly's software.

26. There are, of course, circumstances under which ophthalmologists will not issue prescriptions using Visibly's software. On the front end, Visibly's software will not even send a patient's information to an ophthalmologist if that patient's responses to Visibly's health survey or vision test results indicate that they are too old/young, that they have health conditions or are taking drugs that may affect their eyes/vision, or that their vision has changed. On the back end, ophthalmologists can and do refuse to write prescriptions if they conclude that it would be improper under the circumstances for that individual patient. Again, I have personally done so.

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27. I am aware that Visibly is not currently operating in South Carolina due to the Eye Care Consumer Protection Law (ECCPL), S.C. Code Ann. §§ 40-24-10 & 40-24-20, and that Visibly is challenging that law's constitutionality in this case.

28. Based on my experience with Visibly's software, and given the benefits of Visibly's online vision testing software to patients and the fact that ophthalmologists are already using Visibly's software in dozens of states, I am confident that South Carolina licensed ophthalmologists would resume using Visibly's software to expand access to vision care should the ECCPL be struck down in court.

29. This testimony is true and correct to the best of my knowledge.

FURTHER AFFIANT SAYETH NOT.

Christopher O'Brien, M.D., M.B.A., M.P.H.

SWORN to and subscribed before me:

Nahil Mishu

This the 12 day of May, 2023

Notary public for the State of Tenn

My commission expires My Commission Expires 10-31-2026

NAHIL N. MISHU
STATE OF TENNESSEE NOTARY PUBLIC
KNOX COUNTY

P00480

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EXHIBIT 1

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Christopher P. O'Brien M.D., M.B.A., M.P.H.

CLINICAL EXPERIENCE

Founder and Pediatric Ophthalmologist 2016 – Present
- *Bright Eye Consultants PC,* Knoxville, TN

Telemedicine Physician Reviewer 2016 – Present
- *Hill-Rom RetinaVue Network*

Comprehensive Ophthalmologist On-Call (locum tenens) 2016
- *St. Joseph Health System,* Santa Rosa, CA

Google Telemedicine Crowd Computing Diabetic Eye Project 2015 – 2016
- *Physician Reviewer, over 50,000 images interpreted*

Telemedicine Physician Reviewer 2015 – 2021
- *Optimized Eye Care,* Chicago, IL

Comprehensive & Pediatric Ophthalmologist 2014 – 2016
- *Center For Sight PC*, Knoxville, TN

Pediatric Ophthalmologist 2013 – 2014
- *Office of Veronique Jotterand MD,* Long Beach, CA

Comprehensive Ophthalmologist 2013 – 2014
- *Lakewood Eye Physicians and Surgeons,* Orange County, CA

Comprehensive & Pediatric Ophthalmologist 2012 – 2013
- *Southern California Kaiser Permanente Group*, Orange County, CA

CONSULTING AND COLLABORATION

President 2021 – Present
- *Optimized Eye Care of California*

Board of Governors 2019 – Present
- *Childrens West Surgery Center,* Knoxville, TN

Consultant: Vision Screening and Telemedicine 2018 – Present
- *Welch Allyn for Hillrom,* Skaneateles Falls, NY

Consultant: Physician Advisory Board 2016 – Present
- *Visibly,* Chicago, IL

AAO Young Ophthalmologists National Committee 2014 – 2016

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TRAINING

Fellowship – Pediatric Ophthalmology and Strabismus 2012
- *Univ. of California, San Diego: Abraham Ratner Children's Eye Center at Shiley Eye Center*, San Diego, CA
- *Naval Medical Center,* San Diego, CA

Residency – Ophthalmology 2011
- *New York Medical College / Jamaica Hosp.*, Queens, NY

Internship – Transitional Medicine 2008
- *Univ. of Tennessee Hosp.*, Knoxville, TN

Doctor of Medicine 2007
- *Tulane Univ. School of Medicine*, New Orleans, LA

Master of Business Administration 2007
- *Tulane Univ., A.B. Freeman School of Business*, New Orleans, LA
- Core Curriculum completed at *The Wharton School, Univ. of Pennsylvania*, Philadelphia, PA

Master of Public Health 2007
- *Tulane Univ. School of Public Health and Tropical Medicine*, New Orleans, LA

Bachelor of Arts with Honors – Economics 2002
- *Washington Univ. in St. Louis,* St. Louis, MO

LICENSURE / CERTIFICATION

Illinois Medical License	2021 – Present
New York Medical License	2020 – Present
South Dakota Medical License	2016 – Present
Delaware Medical License	2016 – Present
North Dakota Medical License	2016 – Present
Maine Medical License	2016 – 2019
New Hampshire Medical License	2016 – Present
Vermont Medical License	2016 – 2020
Montana Medical License	2015 – Present
Rhode Island Medical License	2015 – Present
American Board of Ophthalmology	2014 – Present
Fellow, American Academy of Ophthalmology	2014 – Present
Tennessee Medical License	2013 – Present
California Medical License	2011 – Present
Certified Microsoft Office Specialist, Microsoft Office 2003 Excel	2006

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PUBLICATIONS / RESEARCH

5 Pearls For Conducting A Pediatric Exam 2015

- AAO YO (young ophthalmologists) Contributing Author
- http://www.aao.org/young-ophthalmologists/yo-info/article/5-pearls-conducting-better-pediatric-exam

4 Pearls For A Better Pediatric Exam: How To Prepare 2015

- AAO YO (young ophthalmologists) Contributing Author
- http://www.aao.org/young-ophthalmologists/yo-info/article/4-pearls-better-pediatric-exam-how-to-prepare

Tchoupitoulas to Terpsichore: 2013 YO Program + Lagniappe 2013

- AAO YO (young ophthalmologists) Contributing Author
- http://www.aao.org/yo/newsletter/201312/article04.cfm

The Wiggle Suture, *a novel approach to the non-filtering bleb* 2011

- Presented to New York Academy of Medicine Ophth. Residents' Night

Chart Review Study 2010

- Incidence of cystoid macular edema following secondary intraocular lens placement using the McCannel iris fixation technique
- Primary Investigator: Kenneth Wald, M.D., *The New York Eye and Ear Infirmary*

Hyperspectral Imaging and Retinal Oxygen Saturation 2006 – 2007

- Primary Researcher: Bahram Khoobehi, PhD., *Louisiana State Univ.*
- In-Vivo experiment with cynomolgus monkeys

Retinopathy of Prematurity in Louisiana 1999 – 2003 2007

- Louisiana Department of Health and Hospitals Publishing, 2007

LECTURES

Uveitis in the Pediatric Age Group 2012
Pediatric Vitreous and Retinal Diseases and Disorders 2012
Optic Disc Abnormalities 2012
Pediatric Cataract 2012
Craniofacial Malformations 2012

PEDIG Amblyopia Trials 2011
Juvenile Idiopathic Uveitis 2011
A Resident-to-Resident Guide for the Fellowship Match 2011
Posterior Segment Manifestations of Trauma 2010
Non-Physiologic Visual Loss 2010

Retinal Vascular Occlusive Events 2009
Retinal Prostheses and Artificial Vision 2009
Toxoplasmosis Retinitis 2009
Visual Field Perimetry: Hippocrates to Humphrey 2008
Evidence For and Against Supported Discharge 2008

Autologous Eye Drops 2008

Dohlman-Doane Type 1 Keratoprosthesis 2006
Terson's Syndrome 2006
HMG Co-A Reductase Inhibitor Financial Assistance 2005

PROFESSIONAL ORGANIZATIONS

American Association for Pediatric Ophthalmology and Strabismus 2015 – Present
American Academy of Ophthalmology 2008 – Present
California Academy of Eye Physicians & Surgeons 2013 – 2014

ADDITIONAL ACADEMIC COURSES

Agarwal Eye Hospital Advanced Cataract Course, *Chennai, India* 2014
Wills Eye Board Review for ophthalmologists, *Wills Eye Institute* 2011
Cataract Course for 2nd Year Residents, *Massachusetts Eye and Ear Infirmary* 2010
Board and OKAP Review, *The New York Eye and Ear Infirmary* 2010
Care of the Deaf-Blind Rotation, *Helen Keller National Center for Deaf-Blind* 2010
Greater New York Ophth. Lecture Series, *Manhattan Eye, Ear, & Throat Hosp.* 2009
Ophthalmic Pathology for Ophthalmologists, *Armed Forces Institute of Pathology* 2009

OTHER EMPLOYMENT / VOLUNTEER EXPERIENCE

Consultant, *Fort Defiance Industries, Inc*, Loudon, TN 2012
Volunteer, *Ozanam Inn Homeless Shelter*, New Orleans, LA 2002 – 2003
Captain, Plant Propagation Biology Teaching Team,*Washington Univ.* 2000 – 2002
Certified Nurses Aide 2000 – 2001
Programmer and Graphics Coordinator, *Univ. of TN Calculus I – II* 1998

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EXHIBIT 2

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September 30, 2022

Visibly, Inc.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K220090
Trade/Device Name: Visibly Digital Acuity Product
Regulation Number: 21 CFR 886.1150
Regulation Name: Visual Acuity Chart
Regulatory Class: Class I
Product Code: QTO

Dear Janice Hogan:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 12, 2022. Specifically, FDA is updating this SE Letter as an administrative correction because of a typo in the Indications for Use form.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Elvin Ng, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 240-402-4662, Elvin.Ng@fda.hhs.gov.

Sincerely,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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August 12, 2022

Visibly, Inc.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K220090
Trade/Device Name: Visibly Digital Acuity Product
Regulation Number: 21 CFR 886.1150
Regulation Name: Visual Acuity Chart
Regulatory Class: Class I
Product Code: QTO
Dated: January 11, 2022
Received: January 11, 2022

Dear Janice Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tieuvi H. Nguyen -S

for Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page

510(k) Number *(if known)*

K220090

Device Name

Visibly Digital Acuity Product

Indications for Use *(Describe)*

The Visibly Digital Acuity Product (VDAP) is a web-based, self-guided software application intended for use by adults, ages 22 to 40, who have the capability to perform a self-test at home, to aid in the evaluation of visual acuity with or without correction. The software allows users to view and respond to displayed optotypes and uses the responses to categorize a patient's visual acuity into one of two categories, with an individual output for each eye:

- TRUE - visual acuity that is consistent with normal vision
- FALSE - visual acuity that is not consistent with normal vision

The Visibly Digital Acuity Product recommendations are intended to be supportive recommendations that will be used by an eye care provider, along with the patient's medical history and profile, prior corrective eyewear prescriptions, and subjective vision data. The Visibly Digital Acuity Product does not provide screening or diagnosis of eye health or other disease, nor is it intended to replace an in-person eye exam.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

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510(k) SUMMARY
Visibly, Inc.'s Visibly Digital Acuity Product
K220090

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Visibly, Inc.
207 E Ohio Street, #233
Chicago, IL 60611
Phone: 217-971-4852
Contact Person: Paul Foley CFO/COO

Date Prepared: August 11, 2022

Name of Device

Visibly Digital Acuity Product

Classification Name

Visual Acuity Chart (21 CFR 886.1150, Class I, Product Code QTO)

Predicate Devices

Predicate Device:

Vimetrics, LLC Central Vision Analyzer (CVA-1000)

Reference Devices:

SoloHealth, Inc. SoloHealth Station (K113402)

Vital Art and Science, Inc. MyVisionTrack Model 005 (K143211)

Intended Use / Indications for Use

The Visibly Digital Acuity Product (VDAP) is a web-based, self-guided software application intended for use by adults, ages 22 to 40, who have the capability to perform a self-test at home, to aid in the evaluation of visual acuity with or without correction. The software allows users to view and respond to displayed optotypes and uses the responses to categorize a patient's visual acuity into one of two categories, with an individual output for each eye:

- TRUE - visual acuity that is consistent with normal vision
- FALSE - visual acuity that is not consistent with normal vision

The Visibly Digital Acuity Product recommendations are intended to be supportive recommendations that will be used by an eye care provider, along with the patient's medical history and profile, prior corrective eyewear prescriptions, and subjective vision data. The Visibly Digital Acuity Product does not provide screening or diagnosis of eye health or other disease, nor is it intended to replace an in-person eye exam.

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Technological Characteristics

The Visibly Digital Acuity Product is a web-based, software application intended for use by adults, at home, to aid in the evaluation of visual acuity with or without correction. The standalone software application allows the user to interface with the software via a web browser on two internet-enabled devices:

- A computer screen (the Display) which displays optotypes.
- A touchscreen mobile device (the Remote) which operates as a remote control and interface for the user to respond to prompts related to the optotypes appearing on the Display while standing 10 feet away.

The software allows users to view and respond to displayed optotypes and uses the responses to categorize a user's vision acuity into one of two buckets: (1) TRUE - visual acuity that is consistent with normal vision (2) FALSE - visual acuity that is not consistent with normal vision.

A table comparing the key features of the subject, predicate, and reference devices is provided below.

	Visibly Digital Acuity Product (subject)	**Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)**	**SoloHealth Station (reference)**	**MyVisionTrack Model 0005 (reference)**
510(k)	K220090	K100095	K113402	K143211
Product Code	QTO	HOX, Chart, Visual Acuity	DXN, Automated Blood Pressure Monitor HOX, Chart, Visual Acuity	HOQ, Amsler grid
Indications for Use	The Visibly Digital Acuity Product (VDAP) is a web-based, self-guided software application intended for use by adults, ages 22 to 40, who have the capability to perform a self-test at home, to aid in the evaluation of visual acuity with or without correction. The software allows users to view and respond to	The CVA-1000 is intended for use under the direct supervision of an ophthalmologist or optometrist in the measurement of vision at fixation in one or both eyes, with or without optical correction.	The SoloHealth Station is intended to be used by the general public so that a user can measure his/her own blood pressure and pulse rate and his/her own weight. Additionally, the SoloHealth Station is intended to screen adults for clarity of central vision. SoloHealth Station does not provide a general	The myVisionTrack® Model 0005 is intended for the detection and characterization of central 3 degrees metamorphopsia (visual distortion) in patients with maculopathy, including age-related macular degeneration and diabetic retinopathy, and as an aid in monitoring

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	Visibly Digital Acuity Product (subject)	**Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)**	**SoloHealth Station (reference)**	**MyVisionTrack Model 0005 (reference)**
	displayed optotypes and uses the responses to categorize a patient's visual acuity into one of two categories, with an individual output for each eye: ● TRUE - visual acuity that is consistent with normal vision ● FALSE - visual acuity that is not consistent with normal vision The Visibly Digital Acuity Product recommendations are intended to be supportive recommendations that will be used by an eye care provider, along with the patient's medical history and profile, prior corrective eyewear prescriptions, and subjective vision data. The Visibly Digital Acuity Product does not provide screening or diagnosis of eye health or other disease, nor is it intended to replace an in-person eye exam.		screening of visual function and does not provide a diagnosis of eye health or other disease. The SoloHealth Station only screens clarity of central vision. Users should consult their personal physicians if they have concerns regarding their eyesight.	progression of disease factors causing metamorphopsia. It is intended to be used by patients who have the capability to regularly perform a simple self-test at home. The myVisionTrack® Model 0005 is not intended to diagnose; diagnosis is the responsibility of the prescribing eye-care professional.

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	Visibly Digital Acuity Product (subject)	**Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)**	**SoloHealth Station (reference)**	**MyVisionTrack Model 0005 (reference)**
Intended Population	Adults, ages 22 to 40	General Public	General Public	Patients at high risk or already diagnosed with maculopathy
Prescription or OTC	OTC	Prescription	OTC	Prescription home use by patients
Device Type	Web-based software application	Device with electronic display	Device with electronic display	Downloadable application to cell phone or tablet
Hardware Platform	Display: Computer, laptop or tablet Remote: Touchscreen smartphone or mobile device	Display: Computer, 2 LCD computer monitors, keyboard, mouse	Display: LCD computer monitor, Interactive Central Vision Panel	Display: User supplied cell phone or tablet
Software Design	Interactive software platform with audio and visual prompts	Interactive software platform with audio and visual prompts. It has two panels: Interactive Central Vision Panel and Chart Panel	Interactive software platform with audio and visual prompts	Interactive software platform with visual prompts
Target Presentation	Landolt C optotypes with crowding bars, facing 4 different directions (openings at 180, 270, 0, and 90 degrees) Optotypes are presented singly	Multiple and Individual optotypes (depending on the panel selected)	Multiple optotypes as well as sentences and paragraphs	Distorted and undistorted shapes
How/Where Used	At home	Clinical environments	Non-clinical environments	At home
Test Administration	Self-administration	Setup and Testing Method is selected by HCP	Self-administration	Self-administration

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	Visibly Digital Acuity Product (subject)	Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)	SoloHealth Station (reference)	MyVisionTrack Model 0005 (reference)
		Testing process is completed via self-administration		
Test Procedure Summary	Based on optotypes presented on the Display, the user will select what object they see on their Remote. The following outputs are generated for Eye Care Provider (ECP) review: (1) user-inputted data confirmed during Qualification; (2) Visual Acuity output by eye classifying the individual eye's vision into one of the following buckets: • TRUE - visual acuity that is consistent with normal vision • FALSE - visual acuity that is not consistent with normal vision	Chart Panel: A monitor, viewed by the patient, presents traditional symbol charts with progressive 0.1 logMAR gradations of symbol size, each of which may be presented in the following Michelson contrasts of black letters presented against a white background in a range of progressively reduced contrasts. The examiner may view on the physician monitor what is presented to the patient on the patient monitor so he can mark the letters that are correctly identified, allowing either line-by-line or letter-by-letter scoring. The total letters read correctly are recorded as well as the smallest line read correctly in which the traditional method of scoring is utilized. Interactive Central Vision Panel: A monitor is viewed by	Near distance screening is simulated at 17 inches through a series of prompts on the computer monitor where patients are asked to view the clarity of sentences and letters at different sizes. Far distance screening is simulated at 11 feet through a view finder on the device. Patients are asked to determine the clarity of a set of letters.	The myVisionTrack® Model 0005 implements a shape discrimination hyperacuity (SDH) vision test. The distorted shape is created by modulating the radius of the circle with a sinusoid. The user is shown four circles and asked to identify the distorted circle.

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	Visibly Digital Acuity Product (subject)	Vimetrics Central Vision Analyzer 1000 (CVA-1000) (predicate)	SoloHealth Station (reference)	MyVisionTrack Model 0005 (reference)
		the patient in which automated measurements are conducted by an interactive computer program at logMAR 0.05 gradations of symbol size. The patient sits in a chair in the darkened examination room with or without optical correction (spectacles, contact lenses, or trial lenses) and with one eye or both eyes exposed, he/she views in a mirror at the end of the room an LCD monitor (patient monitor) mounted on the wall next to the examiner's desk (total distance entered into the computer program at the time of installation). The examiner selects the method of operation and contrasts to be tested by keyboard and mouse interaction and with information presented on the physician's working monitor.		

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Performance Data

The following testing is provided to support the safety and performance of the VDAP:

- Luminance Testing was completed to demonstrate that the luminance of the Display hardware is above the minimum threshold for luminance (80 cd/m^2) in accordance with: (1) ANSI Z80.21-2010(R2015). American National Standard for Ophthalmics - Instruments - General-Purpose Clinical Visual Acuity Charts; (2) ISO 8596:2017. Ophthalmic optics - Visual acuity testing - Standard and clinical optotypes and their presentation and (3) International Council of Ophthalmology (1984) Visual Acuity Measurement Standard.

- Optotype Sizing Testing was conducted to validate each optotype size rendered during the VDAP test. For each of the 22 optotypes presented by the visual acuity test, the arc length of optotype gap and the optotype diameter were measured using manufacturer-calibrated Mitutoyo Digital Calipers. All measurements of arc length and optotype diameter were ±5% of the pre-specified size equivalent for each LogMar Size.

- Human Factors testing to confirm that the VDAP can be used safely and effectively by the intended users in the intended use environment – i.e., adults aged 22 to 40 years old in a home environment (n=18). This testing established that the overall residual risk of use errors with the VDAP have been mitigated to an acceptable level. Therefore, VDAP can be used without use errors or problems that could result in an inaccurate visual acuity assessment.

- The controlling software for the VDAP presents a “moderate” level of concern as defined in FDA’s “Guidance for the Content of Premarket Submission for Software Contained in Medical Devices” (May 2005). The appropriate supportive software documentation was provided, including a hazard analysis. Verification and validation activities demonstrated that VDAP functioned as intended. In addition, since the VDAP is sent to a medical device data system (MDDS) that is necessary for viewing by clinicians, Visibly provided software documentation consistent with a minor level of concern for the MDDS per the FDA Guidance "Multiple Function Device Products: Policy and Considerations" (July 2020).

- Potential cybersecurity risks were addressed by providing the documentation requested in the FDA Guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” (October 2014). The software mitigates or prevents the unauthorized access, modification, misuse and unauthorized use of information that is stored, accessed or transferred.

A prospective, multi-center clinical study was also completed (n=329) to evaluate the safety and effectiveness of the VDAP compared to an ETDRS Visual Acuity (VA) Lane Test. This study evaluated the agreement of the VDAP with the ETDRS VA Lane Test as well as the reproducibility of the VDAP. The primary agreement endpoints were the PPV, defined as the proportion of study eyes with VA of 20/25 or better for which ETDRS VA was also 20/25 or better, and the NPV, defined as the proportion of study eyes with VDAP VA worse than 20/25 for which ETDRS VA was also worse than 20/25. Supportive analyses included a subgroup analysis for performance stratified by the actual, measured viewing distance from which the subjects took the VDAP test.

Selection of the study eye occurred after subjects exited the study following the completion of VDAP and ETDRS assessments of each eye. The study eye was selected based upon the

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subject's first VDAP VA assessment. If one of the subject's eyes had "20/25 of Better" VDAP VA and the other eye had "Worse than 20/25" VDAP VA, the eye with the "Worse than 20/25" was selected as the study eye. If both eyes had the same VDAP VA, the study eye was selected randomly.

The observed PPV, NPV, sensitivity, and specificity for study eyes were as follows: (97.3%, 95% CI: 95.2% - 99.4%), (48.1%, 95% CI: 38.6% - 57.6%), 79.7% (95% CI: 74.9% - 84.5%) and 89.5% (95% CI: 81.5% - 97.4%). The observed PPV, NPV, sensitivity, and specificity for non-study eyes were as follows: (94.5%, 95% CI: 91.9% - 97.2%), (50.9%, 95% CI: 37.5% - 64.4%), 90.9% (95% CI: 87.6% - 94.2%) and 64.3% (95% CI: 49.8% - 78.8%).

Observed agreement performance in sensitivity and specificity diverged between the Study Eye and Non-Study Eye cohorts due to the study eye selection methodology discussed above. As a result, a pooled analysis combining Study Eye and Non-Study Eyes was completed.
The observed PPV, NPV, sensitivity, and specificity for the pooled Study Eye and Non-Study Eye cohort were as follows: (95.8%, 95% CI: 93.6% - 97.6%), (49.1%, 95% CI: 40.0% - 58.1%), 85.5% (95% CI: 81.9% - 88.9%) and 78.8% (95% CI: 69.1% - 87.6%).

PPV and NPV in the pooled cohort are similar to what was observed in Study Eye and Non-Study Eye Cohorts. Sensitivity and Specificity for the pooled cohort reflect true device performance for these metrics as they are not impacted by the study eye selection methodology in the way the Study Eye and Non-Study Eye Cohorts were.
The secondary agreement endpoint was subject level agreement, defined as the proportion of subjects with matching VDAP and ETDRS classifications (20/25 or Better vs. Worse than 20/25) for both eyes (study eye and non-study eye). The secondary reproducibility endpoint was subject level reproducibility, defined as the proportion of subjects with matching VDAP VA Classifications for the two VDAP tests for both eyes.

The subject level agreement was as follows: 75.9% (95% CI: 71.3% - 80.5%). The subject level reproducibility was as follows: 82.8% (95% CI: 78.7% - 86.9%).

The primary reproducibility endpoint was the proportion of study eyes with matching VDAP VA classifications for the two VDAP tests. The observed reproducibility for Study Eyes (89.3%, 95% CI: 85.9% - 92.6%) was statistically significantly greater than the performance goal of 75% (p-value < 0.0001). There were no safety concerns found with VDAP assessments throughout the study. Furthermore, the reproducibility of the VDAP was confirmed in this study, and the PPV and NPV results of VDAP demonstrate that the selected cut off point of 20/25 Snellen is appropriate. Therefore, the device performance was adequate to support an indication for use as an aid in the assessment of visual acuity.

Conclusion

The VDAP is as safe and effective as the predicate device. The VDAP also shares similar technological characteristics as the reference devices. The VDAP has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the VDAP and its predicate devices raise no new issues of safety or effectiveness. Furthermore, performance data demonstrate that the VDAP is as safe and effective as the predicate device. Therefore, the VDAP is substantially equivalent.

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EXHIBIT 3

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AMERICAN ACADEMY® OF OPHTHALMOLOGY
The Eye M.D. Association

POLICY STATEMENT

Frequency of Ocular Examinations

Policy

The frequency of ocular examinations should be based on the presence of visual abnormalities and the probability of visual abnormalities developing. Individuals who have ocular symptoms require prompt examinations. Individuals who do not have symptoms but who are at high risk of developing ocular abnormalities related to systemic diseases, such as diabetes mellitus and hypertension or who have a family history of eye disease, require periodic comprehensive eye examinations to prevent or minimize visual loss. The frequency of examinations depends on an individual's age, specific condition, and the likelihood of finding abnormalities on examination. Adults who have no symptoms, and who are at low risk, should receive an initial comprehensive eye examination by an ophthalmologist and follow a schedule of periodic assessment designed to detect ocular disease.

Background

There are several times in an individual's lifetime when an ocular examination is extremely important. Certain infectious, congenital, and hereditary eye diseases may be manifest at birth, and since they create a risk to vision if undetected, a screening in the newborn is justified. Infants who have detected abnormalities as well as infants with risk factors, such as systemic diseases or a family history of certain conditions, should be referred for a comprehensive eye examination by an ophthalmologist.

Children should receive age-appropriate eye health and vision screenings throughout childhood because different childhood eye problems may be detected at each visit and new problems can arise. The goal is to identify and treat preventable visual impairment at the earliest feasible age. The elements of vision screening vary depending on the age and level of cooperation of the child. Instrument-based screening is first recommended between 6–12 months of age and until a child is able to cooperate for subjective visual acuity testing as stated in the Academy's Pediatric Eye Evaluation, Preferred Practice Pattern® guidelines. The ophthalmologist should be aware there is a trade-off in terms of false positives and false negatives with instrument-based technology as data are analyzed on the basis of preset refractive error criteria to determine whether a child passes or fails.[1] Amblyopia is estimated to occur at a rate of 1–3% in children aged 6–72 months,[2, 3] and may lead to functional blindness if undetected by autorefractors or photoscreening. Therefore any child with an abnormal subjective visual acuity assessment, or one who has not been successfully tested by age 3,[1] should be referred for a comprehensive eye examination by an ophthalmologist.

The major abnormality among school-age children is the unrecognized development and progression of myopic refractive error, and individuals in this age group should be examined during primary health care visits. Myopia can develop in individuals in their 20s, and it can progress in those whose refractive error did not stabilize in the teenage years. In the young adult the rate of development of other significant eye disease is low, but it increases steadily after the age of 40.

Evaluation

Adults with no signs or risk factors for eye disease should receive a comprehensive medical eye evaluation at age 40 if they have not previously received one.[4] Before the onset of

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presbyopia (at approximately age 40), the majority of American adults experience no changing refractive error or significant ocular disease and routine eye examinations are not indicated. For asymptomatic individuals or individuals without risk factors, who are 40 to 54 years old, and who have had a comprehensive eye examination, the recommended interval for evaluations is 2 to 4 years. For individuals aged 55 to 64 years old, the recommended interval for evaluations is 1 to 3 years. For individuals 65 years old or older, the American Academy of Ophthalmology recommends an examination every 1 to 2 years, even in the absence of symptoms.[5]

Note that an eye examination is warranted if ocular symptoms, visual changes, or injury are involved. Also, for individuals at higher risk for certain diseases, such as African-Americans and Hispanics who are at higher risk for glaucoma, comprehensive eye examinations should be considered every 2 to 4 years for those under age 40, every 1 to 3 years for those aged 40 to 54, and every 1 to 2 years for those aged 55 to 64, even in the absence of visual or ocular symptoms.[4, 6, 7, 8, 9, 10, 11]

Recommendations

1. Infants at high risk, such as those with the potential for retinopathy of prematurity and those with a family history of retinoblastoma, childhood cataracts, childhood glaucoma, or metabolic and genetic disease, should have a comprehensive examination by an ophthalmologist as soon as medically feasible.

2. Children should have an assessment for eye problems in the newborn period and then at all subsequent routine health supervision visits. The elements of the assessment vary with the age of the child. Abnormalities present at birth, such as opacities of the ocular media (e.g., congenital cataract) or ptosis, may have profound effects on normal vision development in an infant. By age 3 to 3 1/2 years, the child will generally cooperate enough for fairly accurate assessment of visual acuity and ocular alignment.[1] He or she should have these assessed by a pediatrician or other medical practitioner.[12] Any abnormalities or the inability to test are criteria for referral to an ophthalmologist.

3. School-age children should be evaluated regularly for visual acuity and ocular alignment (approximately every 1 to 2 years) during primary health care visits, in schools, or at public screenings. Note the choice and arrangement of optotypes (letters, numbers, symbols) on an eye chart can significantly affect the visual acuity score obtained. Preferred optoypes are standardized and validated.[1]

4. Individuals who develop diabetes mellitus type 1 should be examined by an ophthalmologist 5 years after disease onset and at least yearly thereafter.[13, 14] Individuals who develop diabetes mellitus type 2 should be examined at the time of diagnosis and at least yearly thereafter.[15] Women with type 1 or type 2 diabetes should receive a comprehensive eye examination before conception and then early in the first trimester of pregnancy. Recommended intervals for subsequent examinations depend upon the level of retinopathy.[16-18]

5. Adults with no signs or risk factors for eye disease should receive a baseline comprehensive eye evaluation at age 40.[4] Individuals without risk factors aged 40 to 54 should be examined by an ophthalmologist every 2 to 4 years. Individuals without risk factors aged 55 to 64 should be examined by an ophthalmologist every 1 to 3 years.[4, 5]

6. Individuals without risk factors 65 years old or older should have an examination performed by an ophthalmologist every 1 to 2 years as the incidence of unrecognized

ocular disease increases with age.[4, 5]

7. The frequency of ocular examinations in the presence of acute or chronic disease will vary widely with intervals ranging from hours to several months, depending on the risks involved, response to treatment, and potential for the disease to progress.

8. Any individual at higher risk for developing disease, based on ocular and medical history, family history, age, or race should have periodic examinations determined by the particular risks, even if no symptoms are present.

9. A routine comprehensive annual adult eye examination in individuals under the age of 40 unnecessarily escalates the cost of eye care and is not indicated except as described above.

Summary

In summary, the frequency of ocular examinations should depend on the individual's age, race, past ocular history, medical history, family history of eye disease, and the types of symptoms or ocular findings encountered. If significant ocular disease is detected, the frequency of examination will depend on the severity of the condition, the response to therapy or surgery, and the potential for detecting progression of the abnormality.

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Approvals
American Academy of Ophthalmology, Board of Directors, February 1983

Revised and Approved by:

American Academy of Ophthalmology, Board of Directors; September 1990, February 2000, February 2005, November 2009, February 2015

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(Second) Affidavit of Joshua Windham (and Exhibits)

Originally attached to Plaintiff's (Second) Motion for Summary Judgment and can be found in the Record on Appeal at pages 676-935

(All exhibits that were attached to this Affidavit were also attached to the Affidavit submitted with Plaintiffs' Response to SCOPA's Motion for Summary Judgment)

Affidavit of Daniel Bodde (and Exhibits)

Originally attached to Plaintiff's (First) Motion for Summary Judgment and can be found in the Record on Appeal at pages 170-176

Affidavit of Edward Chaum (and Exhibits)

Originally attached to Plaintiff's (First) Motion for Summary Judgment and can be found in the Record on Appeal at pages 177-179

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STATE OF SOUTH CAROLINA COUNTY OF RICHLAND Opternative, Inc., Plaintiff, v. South Carolina Board of Medical Examiners and the South Carolina Department of Labor, Licensing & Regulation, Defendants. and South Carolina Optometric Physicians Association, Defendant-Intervenor.	IN THE COURT OF COMMON PLEAS FIFTH JUDICIAL CIRCUIT C/A No.: 2016-CP-40-06276 **RESPONSE TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT OF DEFENDANTS SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS AND THE SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING & REGULATION**

Defendants South Carolina Board of Medical Examiners (the "Board") and the South Carolina Department of Labor, Licensing & Regulation ("LLR") (collectively the "Defendants"), by and through undersigned counsel, hereby respond to the Motion for Summary Judgment of Plaintiff Opternative, Inc. ("Plaintiff" or "Opternative" or "Visibly")[1] under Rule 56, SCRCP, and respectfully request that this Court deny Plaintiff's motion and dismiss its lawsuit.

Plaintiff has brought a declaratory judgment action to challenge the constitutionality of South Carolina's Eye Care Consumer Protection Law ("ECCPL"), S.C. Code Ann. § 40-24-10 *et seq*., arguing that the ECCPL is "protectionist" legislation and unconstitutional on grounds of (1)

[1] Plaintiff states that it changed its name from "Opternative" to "Visibly" in 2018. In this Response, these names are used interchangeably.

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due process and (2) equal protection. (Plaintiff's Amended Complaint, ¶¶ 80-100).

For the reasons set forth below, the Defendants respectfully request that this Court deny Plaintiff's motion and dismiss its lawsuit because the ECCPL is constitutional.

PLAINTIFF'S LAWSUIT

Plaintiff is a private foreign corporation that has developed an online technology designed to conduct eye examinations and produce prescriptions for corrective lens. (Plaintiff's Amended Complaint, ¶ 1).[2] In bringing this declaratory judgment action, Plaintiff argues that the ECCPL is "protectionist" legislation and unconstitutional on grounds of (1) due process and (2) equal protection. Specifically, Plaintiff has argued that:

- Article I, Section 3 of the South Carolina Constitution "protects Visibly's right to pursue its chosen business free from legal restrictions that do not reasonably further a legitimate government interest." (Plaintiff's Amended Complaint, ¶ 82). Plaintiff argues that the ECCPL does not further any valid public health or safety purpose, and for that reason, it has no legitimate basis under the South Carolina Constitution. For that reason, the ECCPL allegedly violates the "due process" rights of Plaintiff. (Plaintiff's Amended Complaint, ¶¶ 80-89).

- Article I, Section 3 of the South Carolina Constitution provides for "equal protection of the laws." (Plaintiff's Amended Complaint, ¶ 91). Plaintiff argues that the ECCPL violates Plaintiff's equal protection rights by creating a "legal classification between doctors who want to use telemedicine to prescribe corrective-lens consistent with the standard of care, and doctors who want to use telemedicine to prescribe almost anything else under South Carolina's telemedicine law. See S.C. Code § 40-47-37(A), (C)(6)." (Plaintiff's Amended Complaint, ¶ 93).

- Regarding both grounds, Plaintiff alleged the "[u]nless Defendants are enjoined from enforcing the ECCPL, Visibly will suffer continuing and irreparable harm." (Plaintiff's Amended Complaint, ¶¶ 89, 100).

[2] Plaintiff has filed a request to submit an Amended Complaint, to which the Defendants have no objection.

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THE ECCPL

The ECCPL has two parts. The first part establishes the definitions of terms that it uses, and the second establishes the substance of the act.

Importantly, the first part of the act defines "provider" as "an individual licensed by the South Carolina Board of Examiners in Optometry or the South Carolina Board of Medical Examiners." S.C. Code Ann. § 40-24-10(7). The second part of the ECCPL provides as follows:

> **SECTION 40-24-20.** Valid prescription required to dispense spectacles or contact lenses; penalties.
>
> (A) A person in this State may not dispense spectacles or contact lenses to a patient without a valid prescription from a provider.
>
> (B) To be valid, a prescription must contain an expiration date on spectacles or contact lenses of one year from the date of examination by the provider or a statement of the reasons why a shorter time is appropriate based on the medical needs of the patient. The prescription must take into consideration medical findings made and refractive error discovered during the eye examination. If a provider determines a patient is a suitable candidate for a prescription for contact lenses or spectacles, a provider may not thereafter refuse to issue a prescription for spectacles or contact lenses to a patient.
>
> (C) A prescription for spectacles or contact lenses may not be based solely on the refractive eye error of the human eye or be generated by a kiosk.
>
> (D) Violation of this section constitutes misconduct as provided for in Sections 40-37-110 and 40-47-110. A provider who violates this section is subject to the penalties authorized in Chapter 37, Title 40 or Chapter 47, Title 40, as applicable.[3]

When requested to identify the public health or safety purpose advanced by the ECCPL, and how the ECCPL is tailored to achieve that purpose, Defendant-Intervenor South Carolina Optometric Physician's Association ("SCOPA") has noted that the ECCPL "protects patients of ophthalmologists and optometrists from unwittingly putting their eye health at risk by obtaining a

[3] Chapter 37, Title 40 applies to optometrists. Chapter 47, Title 40 applies, among other physicians, to ophthalmologists.

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prescription for corrective lenses without a comprehensive eye examination. Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination." (Answer of SCOPA to Plaintiff's First Set of Interrogatories, p. 2). SCOPA further asserts that this assertion derives from the collective training and clinical experience of SCOPA's members. (Answer of SCOPA to Plaintiff's First Set of Interrogatories, p. 3).

THE BOARD AND LLR

The Board is the professional licensing board in South Carolina that regulates physician practice and conduct. S.C. Code Ann. § 40-47-5 *et seq*. **Notably, it does not regulate Plaintiff, as Plaintiff is not a physician licensed in the State of South Carolina**. S.C. Code Ann. § 40-1-70; S.C. Code Ann. § 40-47-10(I).

The LLR administers the Board. S.C. Code Ann. § 40-1-40(B). Like the Board, **LLR does not regulate Plaintiff, as Plaintiff is not licensed by a Board that LLR administers.** Rather, LLR merely "is responsible for all administrative, fiscal, investigative, inspectional, clerical, secretarial, and license renewal operation and activities" of the Board, and in fact does make such support available to the Board. S.C. Code Ann. § 40-1-50(A).

LEGAL ARGUMENT

I. UNDER SOUTH CAROLINA LAW, STATUTES ARE PRESUMED TO BE CONSTITUTIONAL.

The provisions of the South Carolina Constitution are not a grant but a limitation on legislative power, so that the Legislature may enact any law not expressly prohibited, or by clear implication prohibited, by the state or federal constitution. *Segars-Andrews v. Judicial Merit Selection Comm'n*, 387 S.C. 109, 118, 691 S.E.2d 453, 458 (2010).

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Moreover, when the constitutionality of a statute is challenged, every presumption will be made in favor of its validity. A statute will not be declared unconstitutional unless its invalidity appears so clearly as to leave no doubt that it violates some provision of the constitution. *Id.* A "legislative act will not be declared unconstitutional unless its repugnance to the constitution is clear and beyond a reasonable doubt." *Joytime Distribs. and Amusement Co. v. State,* 338 S.C. 634, 640, 528 S.E.2d 647, 650 (1999). The challenging party bears the burden of proving the statute unconstitutional. *Home Health Serv., Inc. v. South Carolina Tax Comm'n,* 312 S.C. 324, 440 S.E.2d 375 (1994); *In re Treatment & Care of Luckabaugh*, 351 S.C. 122, 135, 568 S.E.2d 338, 344 (2002).

II. PLAINTIFF CANNOT SHOW THAT THE ECCPL LACKS A "RATIONAL BASIS," AND FOR THAT REASON, ITS DUE PROCESS AND EQUAL PROTECTION CLAIMS MUST BE DISMISSED.

Plaintiff's constitutional attack on the ECCPL is based on both "due process" and "equal protection" grounds. Plaintiff's due process claim is based on its allegation that the ECCPL is protectionist legislation that does not further any valid public health or safety purpose. In this regard, the claim is presumably a "substantive due process" claim.[4] Plaintiff's equal protection claim is based on an imagined "classification" of physicians that Plaintiff posits are created by the ECCPL between (1) doctors who want to use telemedicine to prescribe corrective-lens consistent with the standard of care, and (2) doctors who want to use telemedicine to prescribe almost anything else under South Carolina's telemedicine law. (Plaintiff's Amended Complaint, ¶ 93).

[4] Plaintiff's Amended Complaint contains no discernable allegations that it has been denied "procedural" due process. Plaintiff bases its due process claim on its allegations that the ECCPL is protectionist legislation, and that the ECCPL "serves only to protect brick-and-mortar optometrists from economic competition, which is not a legitimate governmental interest." (Plaintiff's Amended Complaint, ¶ 86).

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However, each of these arguments fails because the ECCPL is supported by a "rational basis."

A. Equal Protection.

In ruling on an equal protection challenge to a statute, if a classification does not implicate a suspect class[5] or abridge a fundamental right,[6] courts employ the "rational basis" test. *Denene, Inc.*, 359 S.C. at 91, 596 S.E.2d at 920. In such a case, Plaintiff bears the burden "to negate every conceivable basis which might support" the legislation. *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 364, 93 S.Ct. 1001, 35 L.Ed.2d 351 (1973); *Mitchell v. Comm'r of the Soc. Sec. Admin.*, 182 F.3d 272, 274 (4th Cir. 1999).

As set forth above, Defendant-Intervenor SCOPA noted that the ECCPL "protects patients of ophthalmologists and optometrists from unwittingly putting their eye health at risk by obtaining a prescription for corrective lenses without a comprehensive eye examination. Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination." (Answer of SCOPA to Plaintiff's First Set of Interrogatories, p. 2). SCOPA further asserts that this assertion derives from the collective training and clinical experience of SCOPA's members. (Answer of SCOPA to Plaintiff's First Set of Interrogatories, p. 3).

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[5] A suspect class, as defined by numerous court opinions, is a discrete and insular minority that is unable to shake or rise above the bonds and stigma of its minority status. Courts have been unwilling to extend suspect class status to any classification other than race, alienage and national origin. *Eldridge v. Bouchard*, 645 F. Supp. 749, 752 (W.D. Va. 1986), *aff'd*, 823 F.2d 546 (4th Cir. 1987). Plaintiff does not appear to argue that "ophthalmologists" are a suspect class.

[6] There is also no fundamental right for a physician to use Visibly's technology in violation of the ECCPL. *In re Evans*, 413 B.R. 315, 322 (Bankr. E.D. Va. 2009) (no "fundamental right" under the equal protection clause to pursue a calling as a bankruptcy petition preparer).

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Whatever Opternative's substantive objection to the ECCPL, and however it may disagree with the underlying reason articulated as its "rational basis," it cannot dispute that the state has a legitimate interest in supporting good eye health, that undiagnosed diseases of the eye are a legitimate public health concern, and that legislation encouraging an in-person comprehensive eye examination in order to increase the chance of detecting these diseases is reasonably related to the statute's purpose.

Plaintiff's reliance on *Joseph v. S.C. Dep't of Labor, Licensing & Regulation*, 417 S.C. 436, 790 S.E.2d 763 (2016), to support its equal protection argument is particularly misplaced. *Joseph* involved a physical therapist (PT) and two orthopedic surgeons challenging a 2011 position statement from the South Carolina Board of Physical Therapy that – unlike other licensed healthcare professionals – forbade PTs from providing treatment while in the direct employ of physicians. The Court found that 2011 position statement violated the equal protection clause because the classification at issue – preventing PTs but not other health professionals from working directly for physicians – had no rational relationship to the legislative purpose of the statute, which was "to protect consumers and government-sponsored health care programs from conflicts of interest and potential misuse of medical services." 417 S.C. at 452, 790 S.E.2d at 771. More specifically, the Court found that:

> Although, under *Sloan*, physicians may employ other healthcare professionals such as occupational therapists, speech pathologists, and nurse practitioners, they may not employ PTs. Neither the *Sloan* opinion nor Appellants have articulated any plausible reason as to why PTs are so different from other health care professionals that they must be singled out and provided disparate treatment for self-referral purposes. Accordingly, the Court's interpretation in *Sloan* constitutes an equal protection violation.

Id. (emphasis added).

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There are notable distinctions between *Joseph* and the instant case. *Joseph* concerns a purpose that broadly applies to any type of health care professional, namely, protecting "consumers and government-sponsored health care programs from conflicts of interest and potential misuse of medical services." More narrowly, the ECCPL's legislative purpose is related specifically to those health care professionals – such as optometrists and ophthalmologists – who routinely conduct comprehensive eye examinations.

In that light, Plaintiff's "classification" argument makes no sense. By analogy, using Plaintiff's logic, a statute seeking to regulate use-of-force by a certified law enforcement officer would be unconstitutional, because it would apply only to law enforcement officers. In any event, the Court may be assured that, to the extent that other health care professionals other than optometrists and ophthalmologists attempt to prescribe corrective lens in violation of the ECCPL, the statute would apply to them as well.

For these reasons, Plaintiff's equal protection argument must fail.

B. Due Process.

In order to show that the ECCPL violates Plaintiff's substantive due process rights, Plaintiff must show that it was arbitrarily and capriciously deprived of a cognizable property interest rooted in state law. *Sunset Cay, LLC v. City of Folly Beach,* 357 S.C. 414, 430, 593 S.E.2d 462, 470 (2004). The standard for reviewing all substantive due process challenges to state statutes or municipal ordinances, including economic and social welfare legislation, is whether the statute or ordinance bears a reasonable relationship to any legitimate interest of government. *Id.* at 430, 593 S.E.2d at 470; *Denene, Inc. v. City of Charleston*, 359 S.C. 85, 96, 596 S.E.2d 917, 923 (2004).

"No one has an unfettered right to pursue a business detrimental to the public health, safety, and welfare." *Denene, Inc.*, 359 S.C. at 97, 596 S.E.2d at 923 (citing *Greenville County v.*

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Kenwood Enterprises, Inc., 353 S.C. 157, 170-71, 577 S.E.2d 428, 435 (2003) (county ordinance requiring a 1,500-foot setback for sexually oriented businesses based on the rationale of combating secondary effects of those businesses was constitutional)); *Curtis v. State,* 345 S.C. 557, 573, 549 S.E.2d 591, 599 (2001) (statute making it unlawful to defraud a drug test furthers the public purpose of ensuring a drug-free workplace, which is a legitimate exercise of the State's police powers in regulating public safety and welfare, and outweighs any legitimate interest of the business).

Plaintiff has essentially argued that, because the ECCPL does not explicitly order all patients to undergo a comprehensive eye examination from a physician when seeking a prescription for corrective lens, it is not "rationally related" to the ECCPL's goal of encouraging patients to undergo such an examination in order to detect hidden eye diseases. This argument is without merit.

As with its equal protection argument, Plaintiff cannot find support from the Court's opinion in *Joseph* for its due process argument. In *Joseph*, the Court found:

> In addition, the interpretation violates the substantive due process rights of physical therapists by imposing an arbitrary restriction upon physical therapists while preserving those employment relationships for all other health care providers and allied health professionals.

Joseph, 417 S.C. at 452, 790 S.E.2d at 771. Unlike that finding, the ECCPL does not create an "arbitrary restriction" that is unrelated to public health. Indeed, even Plaintiff's own website acknowledges that comprehensive eye examinations are critical to good public health. In explaining why it does not offer its remote vision tests to persons over 55 years old, Plaintiff acknowledges that "[o]nce we reach the age of 55, there is an increasing likelihood of eye and health conditions, and our eye needs go beyond just how well we are seeing. Because we want to ensure that our patients' health is at its best, we recommend that those over 55 see a doctor in-

person to ensure that any of these health conditions that we acquire as we get older are not missed." https://visiblysupport.zendesk.com/hc/en-us/articles/1500007024862-Why-do-I-have-to-be-between-18-55-years-old-to-take-the-vision-test- (***Attached as Exhibit "A"***).

In light of the standards applicable to Plaintiff's due process claim, it appears beyond reasonable doubt that (1) improving the chances of detecting undiagnosed diseases of the eye are a legitimate health concern of the state, and (2) encouraging patients to seek an in-person comprehensive eye examination may increase the chance of detecting these diseases. Therefore, the statute in question bears a reasonable relationship to a legitimate interest of government.[7]

For these reasons, Plaintiff's due process claim must fail.

CONCLUSION

As set forth above, Plaintiff has failed to satisfy the exacting standard that a statute will not be declared unconstitutional unless its invalidity appears so clearly as to leave no doubt that it violates some provision of the Constitution.

For these reasons, the Board and LLR respectfully request that this lawsuit be dismissed, and that the Court grant any other such relief as it deems just and proper.

Dated this the 2nd day of August, 2023.

RICHARDSON PLOWDEN & ROBINSON, P.A.

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[7] Furthermore, nothing prevents South Carolina-licensed ophthalmologists from deciding for themselves whether to use – or not use – Visibly's on-line technology to assist them in their provision of lawful corrective-lens prescriptions to their patients. That decision does not rest with the Board or with LLR.

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COUNSEL FOR DEFENDANTS SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS AND THE SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING & REGULATION

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visibly

Why do I have to be between 18-55 years old to take the vision test?

Permanently deleted user
2 years ago · Updated

Follow

Throughout our whole life, the health of our eyes and health is very important. To ensure our users' safety, we enforce an age window of 18-55 for all participants of our online vision test.

For those under 18, we want to ensure that parental consent is given when taking the vision test so to protect our customers, we require that the minimum age of our participants is 18 years old.

Once we reach the age of 55, there is an increasing likelihood of eye and health conditions, and our eye needs go beyond just how well we are seeing. Because we want to ensure that our patients' health is at its best, we recommend that those over 55 see a doctor in-person to ensure that any of these health conditions that we acquire as we get older are not missed.

We are exploring ways to expand to the 55+ population and we will be sure to announce if we expand our capabilities to a wider age range!

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STATE OF SOUTH CAROLINA)	IN THE COURT OF COMMON PLEAS
)	FOR THE FIFTH JUDICIAL CIRCUIT
COUNTY OF RICHLAND)	
)	Civil Action No. 2016-CP-40-06276
Visibly, Inc.,)	
Plaintiff,)	
v.)	**DEFENDANT-INTERVENOR'S MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM OF LAW IN SUPPORT**
)	
South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation,)	
)	
Defendants,)	
and)	
)	
South Carolina Optometric Physicians Association,)	
)	
Defendant-Intervenor.)	

TO: MILES E. COLEMAN, JOSHUA WINDHAM, ATTORNEYS FOR PLAINTIFF:

PLEASE TAKE NOTICE that Defendant-Intervenor South Carolina Optometric Physicians Association ("SCOPA"), by and through its undersigned counsel, will move ten (10) days hence, or as soon as counsel may be heard, for an order pursuant to Rule 56, of the *South Carolina Rules of Civil Procedure*, granting it summary judgment as to all causes of action set forth in the pleadings in this case and denying the Motion for Summary Judgment filed by Plaintiff Visibly, Inc. f/k/a Opternative, Inc. ("Plaintiff" or "Visibly") on June 15, 2023.

This motion is supported by the affidavits of Dr. Mark E. Robinson and Dr. Melvin D. Shipp, attached hereto as Exhibits 1 and 2, respectively, the transcript from Plaintiff's 30(b)(6) deposition, attached hereto as Exhibit 3, and the following memorandum of law. For the reasons set forth below, SCOPA respectfully requests that this Court deny Plaintiff's Motion for Summary Judgment and grant judgment in favor of Defendants.

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SUMMARY OF ARGUMENTS

The Eye Care Consumer Protection Law, S.C. Code Ann. §§ 40-24-10, et seq. ("ECCPL") was enacted on May 11, 2016 with overwhelming support from the South Carolina General Assembly and from practicing optometrists and ophthalmologists at large. The purpose of the ECCPL is to protect the public from receiving inadequate eye care by establishing minimum parameters for issuing prescriptions for corrective lenses in South Carolina.

Visibly, a telehealth company that employs an online vision test to gather a user's data for use in writing corrective lens prescriptions, has challenged the ECCPL under equal protection and due process grounds. In reality, Visibly's present lawsuit is an attempt to bypass the legislative process entirely so that it can deploy a technology for vision tests in South Carolina that is demonstrably less accurate, less effective, and less safe than that of in-person eye examinations.

The South Carolina Constitution grants the General Assembly the authority to legislate for the protection of the public health and welfare. The ECCPL accomplishes this goal by preventing citizens from unwittingly putting their eye health at risk by obtaining a prescription for corrective lenses without a comprehensive eye examination. There is no dispute that certain diseases of the eye and body may go undiagnosed if patients forego an in-person comprehensive eye examination. Eye care professionals in South Carolina are required to use their medical judgment to determine whether their patients' symptoms are indicators of systemic diseases. It also cannot seriously be disputed that Visibly's online vision test is no substitute for the efficacy, safety and accuracy of a comprehensive in-person eye exam – notwithstanding Visibly's attempts to represent it as such.

In short, the ECCPL addresses an identifiable risk to the public's eye care and is reasonably necessary to protect and uphold the applicable standard of care for South Carolina-licensed optometrists and ophthalmologists. The ECCPL is therefore a lawful exercise of the General

Assembly's constitutionally-mandated duty to protect the health and welfare of the citizens of South Carolina and should be upheld.

FACTS

I. The Parties

Founded in 2012 by Aaron Dallek and Steven Lee, O.D., Visibly is a Chicago-based telehealth company that developed a technology through which individuals can use a computer or smartphone to determine the refractive error of their eyesight without having an ophthalmologist or optometrist in the room ("Technology"). (Visibly Depo. 12:17 – 14:2; Shipp Aff., ¶ 7; Robinson Aff., ¶ 5). Visibly currently offers its Technology in approximately 35 states and, in addition to its remote vision tests, sells contact lenses through its subsidiary, Next Day Contacts, LLC, an online contact lens retailer. (Visibly Depo. 15:23 – 16:17; 21:14-22).

SCOPA is an association of optometric physicians practicing in South Carolina. Optometrists are independent primary health care professionals for the eye that examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures as well as identify related systemic conditions affecting the eye. (Shipp Aff., ¶ 6). Ophthalmologists are medical doctors specializing in eye and vision care, who by study and training are qualified to diagnose and treat ocular diseases, perform eye exams and surgeries and prescribe lenses to correct vision problems. Ophthalmologists who practice in South Carolina are licensed and regulated by the South Carolina Board of Medical Examiners ("BME"), within the Department of Labor, Licensing & Regulation ("LLR"). (Robinson Aff. ¶¶ 3-4).

II. Visibly's Technology and In-Person Eye Examinations

Users can access Visibly's Technology through Visibly's website or, alternatively, they may be routed to Visibly's vision test through any one of its dozens of affiliated third-party corrective

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lenses retailers. (Visibly Depo. 22:6-13). Visibly's Technology then collects the user's information by soliciting responses to questions and visual stimuli through a computer interface. (Visibly Depo. 34:10 – 35:16). Visibly uses the responses to generate a dataset about the user and his or her ocular refractive error, which – after receiving a fee from the user – it will then send to Optimized Eye Care, Inc. ("Optimized"), a separate corporation that contracts with optometrists and ophthalmologists to review the results and write prescriptions. (Visibly Depo. 25:7-15; 28:2-8). Once a prescription is generated, Optimized will send it via Visibly back to the original user, who can use the prescription to purchase contacts. (Visibly Depo. 25:7-15; 29:22 – 30:18). Visibly's Technology does not measure objective data about the user's eyes or eye health, it cannot detect or aid in diagnosing diseases of the eye or systemic diseases, nor does it perform a corneal examination and evaluation. (Robinson Aff., ¶ 13).

Conducting comprehensive eye examinations is within the scope of practice of both optometrists and ophthalmologists. Comprehensive eye examinations consist of, but are not limited to, the following: a review of the patient's health history; measuring visual acuity, both aided and unaided; performing an examination with a slit lamp of the anterior segments of the eyes and eyelids; performing an internal ophthalmoscopic examination through a dilated pupil, including evaluation of the optic nerve head, macular and peripheral retina; performing a subjective refraction; performing tonometry; evaluating pupils; assessing ocular motility and eye alignment; performing confrontation visual field or similar screening field; performing other tests and procedures as indicated by the patient's chief complaint, case history or objective signs and symptoms discovered during the course of the eye examination; making a diagnosis and formulating a treatment plan; seeking consultation and/or making referrals for assessment/treatment to other health providers as appropriate. (Shipp Aff., ¶ 21; Robinson Aff., ¶ 10).

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Optometrists and ophthalmologists are under an affirmative obligation to look after the health and safety of their patients, which requires them to use their judgment to determine whether their patients' complaints or symptoms pertaining to their eyesight or eye health are indicators of systemic or body-wide disease processes or pathologies. They are likewise obliged to make such determinations even when the disease processes or pathologies are asymptomatic. (Shipp Aff., ¶ 22; Robinson Aff., ¶ 14). It undisputed that optometrists and ophthalmologists are best able to make those necessary determinations through in-person comprehensive eye examinations. (Robinson Aff., ¶ 16; Shipp Depo. (Visibly Ex. 4) 91:22 – 92:25).

Both optometrists and ophthalmologists are authorized to issue prescriptions for corrective lenses, including spectacles and contact lenses. A contact lens evaluation is a set of diagnostic tests and procedures performed in addition to a comprehensive eye examination. These tests and procedures include a measurement of the corneal curvature (keratometry or corneal topography) and an evaluation of the anterior segment and tear layer of the eye in relation to the contact lens fit. A poorly fit contact lens can cause irritation to the eyes, and the prolonged use of irritating contact lenses can cause pain, scarring, and vision loss even when a patient does not exhibit any symptoms. Such consequences of a poorly fit contact lens can only be detected by a corneal evaluation. (Shipp Aff., ¶ 14; Robinson Aff., ¶ 12). Typically, a prescriber will not prescribe contact lenses they have not seen on their patient's eyes and will factor in a trial period to evaluate how the lenses are fitting and whether the lenses are causing vision problems. (Shipp Depo. 41:3-12; 53:8 – 54:12).

Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination. There is also a risk that individuals may mistakenly believe that they have received a comprehensive eye examination after receiving a prescription for spectacles or

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contact lenses from an ophthalmologist who only relies upon Visibly's Technology. (Shipp Aff., ¶ 15; Robinson Aff., ¶ 15). To that point, a 2023 investigation brought by the Attorney General of Illinois, along with ten other states in which Visibly operates, "raised concerns about unsubstantiated claims made by Visibly regarding the accuracy and safety of its online test, including that it was as accurate as an in-person exam."[1] The investigation ultimately resulted in a settlement between Visibly and participating states that required Visibly to pay $500,000 and, among other things, "disclose that its online vision test is not a substitute for an in-person comprehensive eye examination, and urge consumers to seek such exams to determine overall eye health."

In addition to assessing eye and vision problems, an eye examination may be the first opportunity to detect diabetes and other health conditions. Examples include high blood pressure, hypercholesterolemia, and certain inflammatory diseases. (Shipp Aff., ¶ 16; Robinson Aff., ¶ 16). Diabetes is currently the nation's seventh leading cause of death in the United States. Diabetes is also a risk factor for heart disease and stroke, and a leading cause of kidney disease and blindness in adults. Early detection can allow early treatment and management of both systemic and eye-related diabetic changes. (Shipp Aff., ¶ 17). One of the more debilitating eye-related outcomes associated with type 2 diabetes in adults is vision impairment, including blindness. Diabetes-related eye conditions include, but are not limited to, refractive changes, cataracts, diabetic retinopathy, and glaucoma. Diabetic retinopathy is among the leading causes of preventable blindness in the United States. (Shipp Aff., ¶ 18). Most symptoms associated with diabetic eye disease progress slowly, and unnoticeably; therefore, comprehensive dilated eye examinations are necessary to diagnose, prevent and manage

[1] "Attorney General Raoul Accounted Settlement with Telehealth Company, Visibly," April 14, 2023, Press Release Office of the Illinois Attorney General, last accessed 8/4/2023: https://illinoisattorneygeneral.gov/news/story/attorney-general-raoul-announces-settlement-with-telehealth-company-visibly?fbclid=IwAR13kr6hC_QDxAOnyskGWcvED7Z5bely36_8LvWH2U4QPWx7f5MvlGfkYCU&mibextid=Zxz2cZ

these conditions. (Shipp Aff., ¶ 19). Importantly, diabetic eye disease can be detected and diagnosed during a routine comprehensive dilated eye examination. (Shipp Aff., ¶ 20).

III. The Eye Care Consumer Protection Law

The General Assembly passed the ECCPL on April 29, 2016, with overwhelming support from both the House of Representatives and Senate. Governor Nikki Haley vetoed the ECCPL on May 16, 2016, but on May 19, 2016, the General Assembly overrode the Governor's veto by a vote of 98 to 1 in the House of Representatives and by a vote of 39 to 3 in the Senate. The ECCPL is now codified at S.C. Code Ann. §§ 40-24-10 and 40-24-20.

The ECCPL contains two parts: the first part establishes the relevant definitions, while the second part contains the substance of the Act. Part one of the ECCPL defines a "provider" as "an individual licensed by the South Carolina Board of Examiners in Optometry or the South Carolina Board of Medical Examiners," meaning both optometrists and ophthalmologists are governed by the Act. S.C. Code Ann. § 40-24-10(7). Part two of the ECCPL provides as follows:

> **SECTION 40-24-20.** Valid prescription required to dispense spectacles or contact lenses; penalties.
>
> (A) A person in this State may not dispense spectacles or contact lenses to a patient without a valid prescription from a provider.
>
> (B) To be valid, a prescription must contain an expiration date on spectacles or contact lenses of one year from the date of examination by the provider or a statement of the reasons why a shorter time is appropriate based on the medical needs of the patient. The prescription must take into consideration medical findings made and refractive error discovered during the eye examination. If a provider determines a patient is a suitable candidate for a prescription for contact lenses or spectacles, a provider may not thereafter refuse to issue a prescription for spectacles or contact lenses to a patient.
>
> (C) A prescription for spectacles or contact lenses may not be based solely on the refractive eye error of the human eye or be generated by a kiosk.
>
> (D) Violation of this section constitutes misconduct as provided for in Sections 40-37-110 and 40-47-110. A provider who violates this section is subject to the penalties

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authorized in Chapter 37, Title 40 or Chapter 47, Title 40, as applicable.[2]

S.C. Code Ann. § 40-24-20.

It is undisputed that SCOPA lobbied in favor of – and worked with legislators to enact – the ECCPL. In doing so, SCOPA relied on the collective training and clinical experience of its members to help pass a law that "protects patients of ophthalmologists and optometrists from unwittingly putting their eye health at risk by obtaining a prescription for corrective lenses without a comprehensive eye examination." (SCOPA Answers to Plaintiff's First Set of Interrogatories No. 3 (Visibly's Exhibit 4)). In sum, the ECCPL establishes a baseline in the standard of care for corrective lens prescriptions such that they must be based upon more than just refractive error measurements generated by a computer or smart phone.

IV. Procedural History

Visibly[3] initiated this action against Defendants South Carolina Board of Medical Examiners and South Carolina Department of Labor, Licensing and Regulation on October 20, 2016, seeking a declaratory judgment that portions of the ECCPL are unconstitutional because they result in both a denial of equal protection and substantive due process. Specifically, Visibly challenges sections 40-24-20(C) and (D) of the ECCPL, alleging these provisions violate Article I, Section 3 of the South Carolina Constitution. It also challenges Section 40-24-10(9) of the ECCPL, which provides that vision assessments:

> may not be based solely on objective refractive data or information generated by an automated testing device, including an auto refractor or other electronic refractive-only testing device, to provide a medical diagnosis or to establish a refractive error for a patient as part of an eye examination.

[2] Chapter 37, Title 40 applies to optometrists. Chapter 47, Title 40 applies to ophthalmologists, among other physicians.

[3] Visibly was called Opternative at the time the action was commenced but changed its name in 2018. (Visibly Depo. 16:21-24).

S.C. Code Ann. 40-24-10(9).

The Court granted SCOPA's motion to intervene on February 22, 2017. Following a brief discovery period, on July 12, 2017, Defendants moved for summary judgment on the basis that (1) Plaintiff lacked standing to challenge the constitutionality of the ECCPL and (2) even if Plaintiff possessed standing, the ECCPL passes constitutional muster because it bears a reasonable relationship to its legislative purpose that is supported by rational basis. Plaintiff responded with its own motion for summary judgment on September 6, 2017, arguing the ECCPL amounted to "naked economic protectionism" that served no purpose except protecting the financial interests of brick-and-mortar optometrists "all while doing literally nothing to protect the public health or safety." (Plaintiff MSJ pp. 1-2). On October 3, 2017, SCOPA filed a brief in support of Defendant's motion and opposing Plaintiff's.

The circuit court granted Defendants' motion for summary judgment and dismissed Plaintiff's Complaint with prejudice on January 26, 2018, finding Plaintiff failed to demonstrate that it had standing to bring its Complaint. (Order p. 8). In light of this conclusion, the court expressly declined to address the parties' equal protection and due process arguments regarding the constitutionality of the ECCPL. (Order p. 8).

On February 23, 2018, Plaintiff filed a Notice of Appeal from the court's order granting summary judgment to the Defendants. On February 9, 2023, the Court of Appeals reversed the circuit court's order, finding Plaintiff had satisfied the requirements for constitutional standing. *Opternative, Inc. v. S.C. Bd. of Med. Examiners*, 433 S.C. 405, 418, 859 S.E.2d 263, 270 (Ct. App. 2021). The South Carolina Supreme Court affirmed the decision of the Court of Appeals on August 24, 2022. *Opternative, Inc. v. S.C. Bd. of Med. Examiners*, 437 S.C. 258, 878 S.E.2d 861 (2022).

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APPLICABLE LEGAL STANDARD

I. Summary Judgment

Summary judgment shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Rule 56(c), SCRCP. "In determining whether any triable issue of fact exists, the evidence and all inferences which can reasonably be drawn therefrom must be viewed in the light most favorable to the nonmoving party." *Quail Hill, LLC v. County of Richland*, 387 S.C. 223, 235, 692 S.E.2d 499, 505 (2010). Even when the evidentiary facts are not disputed, if the conclusions to be drawn from them are, summary judgment should be denied. Summary judgment is not appropriate when further inquiry into the facts is desirable to clarify the application of law. *Coker v. Cummings*, 381 S.C. 45, 49, 671 S.E.2d 383, 385 (2008).

II. Statutes Presumed Constitutional

Statutes are presumed constitutional, and a law that neither creates a suspect class nor abridges a fundamental right is given only minimal equal protection scrutiny. *Faircloth v. Finesod*, 938 F.2d 513 (4th Cir. 1991). A statute is presumed constitutional and will not be declared unconstitutional unless its repugnance to the constitution is clear and beyond a reasonable doubt. *Sojourner v. Town of St. George*, 383 S.C. 171, 679 S.E.2d 182 (2009). Constitutional constructions of statutes are not only judicially preferred, they are mandated. *State v. McGrier*, 378 S.C. 320, 663 S.E.2d 15 (2008).

When the constitutionality of a statute is at issue, "every presumption will be made in favor of its validity and no statute will be declared unconstitutional unless its invalidity appears so clearly as to leave no doubt that it conflicts with the constitution." *South Carolina Dept. of Social Servs. v. Sarah W.*, 402 S.C. 324, 334, 741 S.E.2d 739, 745 (2013); *Dunes West Golf Club, LLC v. Town of*

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Mount Pleasant, 401 S.C. 280, 737 S.E.2d 601 (2013); *McMaster v. Columbia Bd. Of Zoning Appeals*, 395 S.C. 499, 719 S.E.2d 663 (2011). Accordingly, the burden is on the challenging party to prove the unconstitutionality of the statute. *Home Health Serv. v. S.C. Tax Comm'n*, 312 S.C. 324, 327, 440 S.E.2d 375, 377 (1994); citing *Gold v. South Carolina Board of Chiropractic Examiners*, 271 S.C. 74, 245 S.E.2d 117 (1978) (emphasis added).

Similarly, those attacking the rationality of a legislative classification have the burden to negative every conceivable basis which might support it. *FCC v. Beach Communications*, 508 U.S. 307 (1993); *accord McLeod v. Starnes*, 396 S.C. 647, 723 S.E.2d 198 (2012) (a classification is presumed reasonable and will remain valid unless and until the party making an equal protection challenge proves beyond a reasonable doubt that there is no admissible hypothesis upon which it can be justified).

ARGUMENT

Visibly challenges the ECCPL on grounds of equal protection and due process, and decries the law as mere economic protectionist legislation that violates the South Carolina Constitution. In particular, Visibly first claims that the ECCPL denies it equal protection of the law because it treats doctors who prescribe contact lenses differently than all other doctors who use telemedicine. (Visibly MSJ pp. 17). Visibly further claims that the ECCPL violates South Carolina's due process clause because it does not rationally protect patient health and only serves to insulate brick-and-mortar optometrists from online competition. (Visibly MSJ pp. 20-24).

I. The ECCPL does not violate South Carolina's equal protection clause.

(A) Rational basis is the applicable standard.

The Parties do not dispute that the determination of whether the ECCPL violates the Equal Protection Clause turns upon the application of the rational basis test. (Plaintiff's Motion for

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Summary Judgment, p. 16). Courts generally analyze equal protection challenges under one of three standards: (1) rational basis, (2) intermediate scrutiny, or (3) strict scrutiny. If the classification does not implicate a suspect class or abridge a fundamental right, the rational basis test is used. *Denene, Inc. v. City of Charleston*, 359 S.C. 85, 596 S.E.2d 917 (2004). South Carolina's equal protection jurisprudence reveals no discernable difference between its application of the rational basis test to questions of equal protection under the South Carolina Constitution and the federal courts' use of the standard to measure equal protection under the United States Constitution.

Under the rational basis test, the requirements of equal protection are satisfied when: (1) the classification bears a reasonable relation to the legislative purpose sought to be affected; (2) the members of the class are treated alike under similar circumstances and conditions; and (3) the classification rests on some reasonable basis. *Denene*, 359 S.C. at 85; *Bodman v. State*, 403 S.C. 60, 742 S.E.2d 363 (2013); *Harleysville Mut. Ins. Co. v. State*, 401 S.C. 15, 736 S.E.2d 651 (2012); *Sunset Cay, LLC v. City of Folly Beach*, 357 S.C. 414, 593 S.E.2d 462 (2004); *Fraternal Order of Police v. South Carolina Dep't of Rev.*, 352 S.C. 420, 430, 574 S.E.2d 717, 722 (2002); *Gary Concrete Prods., Inc. v. Riley*, 285 S.C. 498, 504, 331 S.E.2d 335, 339 (1985).

(B) Visibly cannot prove beyond a reasonable doubt that the ECCPL violates the Equal Protection Clause.

(i) SCOPA's efforts to lobby for the ECCPL have no bearing upon the issues before the Court.

Visibly expends much of its brief to this Court recounting the efforts made by SCOPA and its affiliates to develop and lobby for the passage of legislation that eventually became the ECCPL. SCOPA does not hide from the exercise of its constitutional rights to participate in the legislative process by urging members of the South Carolina General Assembly to pass laws that protect the health and safety of its members' patients, as it is incumbent upon its members to look after their

patients' well-being. (Shipp Aff., ¶ 22, Robinson Aff., ¶ 14). SCOPA is justifiably proud of the campaign it pursued to enact the ECCPL, which was overwhelmingly embraced by both the House of Representatives and Senate, even despite Governor Haley's veto.

Regardless of how SCOPA and its members feel about the ECCPL, the resolution of the issues before the Court does not depend, and is not aided in any respect, by examining their involvement in the legislative process. Visibly's inclusion of this history in its Motion is a tellingly obvious attempt to divert the Court's attention away from the only real issue before it—whether the ECCPL bears some reasonable relationship to a salutary public purpose. It most certainly does.

(ii) The ECCPL is reasonably related to its legislative purpose.

The ECCPL protects the public health and welfare because it upholds the standard of care for eye care professionals in South Carolina and prevents citizens from unwittingly putting their eye health at risk by obtaining a prescription for corrective lenses without a comprehensive eye examination. (Shipp Aff., ¶ 15; Robinson Aff., ¶ 15). The applicable standard of care for eye care professionals in South Carolina requires them to use their medical judgment to determine whether their patients' complaints or symptoms pertaining to their eyesight or eye health are indicators of systemic or body-wide disease processes or pathologies. As Visibly acknowledges, certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination. (Shipp Aff., ¶ 15; Robinson Aff., ¶ 15; Visibly Depo. 88:11-18). Corrective lens wearers may therefore incur health risks if they forego regular eye exams that would allow the optometrist or ophthalmologist to spot emerging health problems in their early stages.

Visibly argues that the ECCPL does nothing to protect the public health and safety, ignoring the evidence in the record to the contrary. For instance, it fails to acknowledge that one year

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prescriptions for corrective lenses are consistent with national optometric standards, and with extant South Carolina and federal law concerning contact lenses. *See*, *e.g.*, Shipp. Aff., ¶ 25; S.C. Code Ann. § 37-25-10 *et seq.* (Rev. ed. 2015, as amended); 15 U.S.C. ch. 102 *et seq*.; 16 C.F.R. § 315.1. It likewise glosses over the fundamental requirement of the ECCPL—that corrective lens prescriptions must be based on more than just a refractive examination. *See* S.C. Code Ann. § 40-24-20 (Supp. 2016); (Shipp Depo. 91:22 – 92:3 ("A refractive correction is a prescription. And just like any other prescription you receive for a pharmacology-type intervention, health intervention, you don't write that prescription pro forma or on the basis of the fact that you have an approximation of what you think the problem is without assessing it.").

Instead, Visibly argues that the ECCPL does not serve its stated purposes because it does not *require* eye-health exams, nor does it *require* eye doctors to check for emerging health problems. (Visibly MSJ p. 21). Again, this ignores that optometrists and ophthalmologists are already under an affirmative obligation as part of their standard of care to look after the health and safety of their patients, including using their judgment to determine whether their patients' complaints or symptoms are indicative of a latent disease or other issue. The ECCPL need not spell out what particular steps an optometrist or ophthalmologist needs to take during a comprehensive eye examination for it to survive rational basis scrutiny. Both the General Assembly and the common law have long recognized that the standard of care for professionals across a wide range of disciplines is too nuanced and fact-specific to be established by legislative act. *See, e.g.*, S.C. Code Ann. § 15-36-100 (Supp. 2016) (expert witness must attest to standard of care and its breach as a prerequisite to bringing a claim for professional negligence); *Dawkins v. Union Hosp. Dist.*, 408 S.C. 171, 758 S.E.2d 501 (2014) (expert testimony required in medical malpractice action). What the ECCPL does is establishes a baseline for corrective lens prescriptions, just as other laws and regulations establish minimum

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requirements in the healthcare context and otherwise. *See, e.g.*, S.C. Code Ann. § 40-33-32 (outlining minimum standards for licensure as a nurse); S.C. Code Ann. § 40-57-135 (establishing minimum standards for real estate brokers-in-charge management agreements); S.C. Code Ann. § 37-15-30 (setting minimum standards for using a contest as a ruse to promote the sale of goods, property or services).

To that end, Visibly acknowledges in its disclaimer to potential consumers that its Technology is not available to individuals over the age of 55, stating: "Because we want to ensure that our patients' health is at its best, we recommend that those over 55 see a doctor in person to ensure that any of these health conditions that we acquire as we get older are not missed." (Visibly Depo. 87: 7-15; 88:7-18). Clearly then, Visibly has instituted its own minimum baseline for the appropriate standard of care regarding the need for in-person eye exams for those over a certain age. Just because the General Assembly has instituted a higher baseline than Visibly does not mean the ECCPL is not reasonably related to its legislative purpose.

In short, the South Carolina Constitution grants the General Assembly the authority to legislate for the protection of the public health and welfare, and the ECCPL does just that by protecting the public from receiving inadequate eye care. Because there is an identifiable risk that the law addresses, Visibly cannot meet its evidentiary burden to overcome the presumption of constitutionality and this Court should leave the ECCPL intact.

(iii) The ECCPL treats all ophthalmologists and optometrists alike under similar circumstances and conditions.

Unquestionably, the ECCPL creates a bright line rule for *all* ophthalmologists and optometrists to follow. This is not a case in which some ophthalmologists or optometrists are treated differently than others. *Compare Daniel v. Cruz*, 268 S.C. 11, 231 S.E.2d 293 (1977) (no reason to treat fortune tellers in one county differently from those in another). Nor are ophthalmologists and

optometrists being treated differently from other health care providers, as the ECCPL only applies to conduct that falls within ophthalmologists and optometrists' scope of practice. *Compare Joseph v. S.C. Dep't of Labor, Licensing &* Regulation, 417 S.C. 436, 790 S.E.2d 763 (2016) (physical therapists treated differently than other healthcare providers); *Broome v. Truluck*, 270 S.C. 227, 241 S.E.2d 739 (1978) (different statutes of limitations for different professionals involved in making improvements to real property).

Visibly argues the ECCPL singles out ophthalmologists from other types of physicians because "dermatologists, cardiologists, endocrinologists, psychiatrists, family doctors, and all other doctors are allowed to prescribe using telemedicine." (Visibly MSJ p. 19). This comparison is inapposite. None of these other types of doctors are allowed to prescribe contact lenses, while eye doctors can. Eye doctors – like other types of doctors – may still prescribe whatever type of drugs that South Carolina law and their standard of care allows via telemedicine. But eye doctors – like other types of doctors – cannot base a prescription for corrective lenses based solely off the refractive error measured by a kiosk or computer. In other words, the standard for prescribing corrective lenses is applied uniformly, just like eye doctors, or any other type of doctor, cannot prescribe "drugs to individuals the licensee has never personally examined based solely on answers to a set of questions." S.C. Code Ann. § 40-47-113.

Furthermore, there is nothing in the ECCPL that makes it illegal for ophthalmologists to rely upon Visibly's Technology in the course of treating a patient; it merely proscribes writing prescriptions for patients based *solely* upon the refractive error that the Technology measures. Visibly acknowledges that it is possible for eye doctors to use its Technology in conjunction with an in-person eye exam, although it has not attempted to market it for use in that manner because that is not where the "demand" lies. (Visibly Depo. 30:19-25; 33:15-23; 34:6-9). Regardless, South Carolina is not

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unique in determining it is necessary to protect consumers in this fashion while acknowledging a place for telemedicine. *See e.g.,* Ga. Code Ann. § 31-12-12(a)(5) and (b)(1)(C) (mandating that "[n]o person in this state shall write a prescription for contact lenses or spectacles unless an eye examination is conducted," and defining "eye examination" as a "real-time examination, which includes the use of telemedicine, in accordance with the applicable standard of care of the prescriber, of the ocular health and visual status of an individual that does not consist solely of objective refractive data or information generated by an automated testing device, including an autorefractor or kiosk, in order to establish a medical diagnosis or refractive diagnosis for the establishment of refractive error, conducted with the patient and prescriber in the same physical location or via telemedicine.").

The ECCPL bears a reasonable relationship to the State's legitimate interest in protecting the eye and systemic health of South Carolina citizens. The ECCPL's utility in tackling traditional police power concerns easily survives rational basis scrutiny for the reasons outlined above in Section B(ii), *supra*. The distinction between ophthalmologists who write prescriptions for corrective lenses based solely upon Visibly's Technology and the ophthalmologists who write prescriptions based upon a comprehensive eye examination is not arbitrary or capricious at all. It reflects the General Assembly's determination as to what constitutes appropriate patient care in the realm of eye health. This Court is not empowered to pass judgment upon that determination, except to acknowledge the legislative prerogative to make it.

(iv) The classification in the ECCPL has a reasonable basis.

Visibly relies heavily upon *Joseph v. SC Dep't of Labor, Licensing & Regulation*, 417 S.C. 436, 790 S.E.2d 763 (2016) to argue the ECCPL has no rational basis. In *Joseph*, the Supreme Court held that the statute at issue "deprives physicians of the right to practice medicine in the best interest of their patients" by not being able to hire physical therapists. Visibly draws a parallel with that case,

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claiming the ECCPL deprives ophthalmologists of their right to practice medicine in the best interest of their patients. The comparison fails, because the ECCPL addresses a particular public health risk (*see* Shipp and Robinson Affs.), whereas it was impossible to find any such risk to the public health and welfare that the statute in *Joseph* was allegedly designed to mitigate.

The text of the ECCPL in no way prevents ophthalmologists from using their medical judgment to write corrective lens prescriptions. If anything, it prevents Visibly, and other similar healthcare technology providers, from fulfilling a market desire for convenience, *to the detriment of ophthalmologists' patients*. *See Dene, Inc.*, 359 S.C. at 97, 596 S.E.2d at 923 ("No one has an unfettered right to pursue a business detrimental to the public health, safety, and welfare.") Unlike in *Joseph*, the ECCPL does not prevent ophthalmologists and optometrists from practicing medicine in best interest of their patients. To the contrary, the ECCPL prevents corrective lens prescriptions from being issued without an examination that takes into consideration a patient's overall health. (*see* Shipp Depo. 90:17-20 ("[Y]ou can have the best pair of glasses you want, but if you died of something preventable, that's not protecting the public health.")). Addressing that risk is clearly within the General Assembly's constitutional prerogative.

II. Substantive Due Process

The test for a substantive due process claim is "[w]hether [a statute] bears a reasonable relationship to any legitimate interest of government." *R.L. Jordan Co. v. Boardman Petroleum, Inc.*, 338 S.C. 475, 478, 527 S.E.2d 763, 765 (2000). "In order to prove a denial of substantive due process, a party must show that he was arbitrarily and capriciously deprived of a cognizable property interest rooted in state law." *Harbit v. City of Charleston*, 382 S.C. 383, 394, 675 S.E.2d 776, 782 (Ct. App. 2009) (citing *Sunset Cay, LLC v. City of Folly Beach*, 357 S.C. 414, 430, 593 S.E.2d 462, 470 (2004)).

"The State's deprivation of the property interest must fall so far beyond the outer boundaries of legitimate governmental authority that no process could remedy the deficiency." *Id.*

(A) Visibly cannot prove beyond a reasonable doubt that the ECCPL violates its right to substantive due process.

Although the analysis of Visibly's due process claim is largely identical to its equal protection claim, it is nonetheless clear that the ECCPL bears a reasonable relationship to the State's legitimate interest in protecting the eye and systemic health of South Carolina citizens. Whether couched in terms of "legitimacy" or "reasonableness," it cannot be disputed that the state has an interest in supporting good eye health.

The undisputed facts before the Court reveal that the ECCPL's legislative purpose is to protect the public from receiving inadequate eye care. The ECCPL protects the public health and welfare because it prevents citizens from unwittingly putting their eye health at risk by obtaining a prescription for corrective lenses without a comprehensive eye examination. There is no dispute that that undiagnosed diseases of the eye are a public concern, and that certain diseases of the eye or of the body may go undiagnosed if patients forego an in-person comprehensive eye examination. The provisions of the ECCPL are reasonably necessary to protect and uphold the applicable standard of care for eye care professionals in South Carolina, which requires them to use their medical judgment to determine whether their patients' symptoms are indicators of systemic diseases.

Accordingly, because the South Carolina Constitution grants the General Assembly the authority to legislate for the protection of the public health and welfare, and because the ECCPL does just that, the ECCPL is constitutional. Furthermore, because there is an identifiable risk that the law addresses, Visibly cannot meet its evidentiary burden to overcome the presumption of constitutionality beyond a reasonable doubt.

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CONCLUSION

For the above-stated reasons, SCOPA respectfully requests that this Court grant its motion for summary judgment and deny Visibly's Motion for Summary Judgment.

Respectfully submitted,

s/ Kirby D. Shealy III
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Attorneys for Defendant-Intervenor SCOPA

August 4, 2023.

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Exhibit 1 - Affidavit of Mark E. Robinson (and Exhibits)

Originally attached to SCOPA's Response to the Parties' Motions for Summary Judgment and can be found in the Record on Appeal at pages 240-244

Exhibit 2 - Affidavit of Dr. Melvin Shipp (and Exhibits)

Originally attached to SCOPA's Response to the Parties' Motions for Summary Judgment and can be found in the Record on Appeal at pages 245-251

EXHIBIT 3

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ROUGH DRAFT - NOT EDITED - NOT PROOFREAD

CASE NAME: Opternative vs. SCBE & SCLLR, et. al.

DATE: Monday, August 1, 2023

WITNESS: Joel Stonedale - 30(b)(6) Opternative

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- - -

JOEL STONEDALE, after having been first duly sworn, was examined and testified as follows:

- - -

EXAMINATION

- - -

BY MR. SHEALY:

Q. Okay. Mr. Stonedale, can you hear me okay?

A. Yes, sir.

Q. Okay. My name is Kirby Shealy. I'm a lawyer in Columbia, South Carolina, and I represent the South Carolina Optometric Physicians Association which is an intervenor in this lawsuit that has given rise to this deposition. And you, I understand, have been designated to testify on behalf of Visibly. Is that your understanding?

A. Yes, sir.

Q. All right. We issued a deposition notice that contains certain topics. Do you recall seeing a list of topics?

A. Yes, sir.

Q. Okay. I'm going to show my screen to you, and I think this is the right one. All right. Can you see -- can you see that now?

A. Yes, I can.

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Q. And the document I'm showing you is captioned South Carolina Optometric Physicians Association's Notice of Taking 30(B)(6) Deposition of Opternative, Incorporated.

And, first, let me make sure that the record is clear. Is -- the company now known as Visibly, was it formally known as Opternative, Inc.?

A. Yes.

Q. Okay. And the -- this deposition notice contains a set of topics, and let me ask you. Have you seen the deposition notice before?

A. Yes.

Q. You have. Okay.

And have you seen the list of topics that numbers 15?

A. Yes, sir.

Q. Okay. And do you believe that you are the person most knowledgeable to testify on Visibly formerly known as Opternative's behalf as to these 15 topics?

A. Yes, sir.

MR. SHEALY: Okay. All right. Madam Court Reporter, I'm going to ask you to mark this deposition notice as Exhibit 1 to today's deposition.

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THE STENOGRAPHER: Yes, sir.

- - -

(Notice of Deposition marked Defendants' Exhibit Number 1 for identification.)

- - -

BY MR. SHEALY:

Q. Okay. And I'll stop sharing.

All right. Mr. Stonedale, have you given a deposition before?

A. No.

Q. All right. So I'm sure Visibly's lawyers have -- have gone over some of this with you, but I'm required by the Rules of Civil Procedure in South Carolina to mention certain things to you. So bear with me for a moment.

So a deposition is just an opportunity for the lawyers in a case that's pending in court to put a witness under oath and ask them questions to sort of develop their testimony before trial. It is a way -- it's part of what we lawyers call the discovery process, and that process is aptly named a process of trying to figure out, to discover, what documents, witnesses, evidence, each side has in the case so that we're prepared, so that we're not surprised when we go to trial. So I'm going to ask

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you a few questions, first, to get to know you and -- and a little bit about your history with Visibly, and then we'll dive into questions related to these topics on Exhibit 1.

If at any point today I ask you a question that you find to be vague or confusing or if I use words that you don't know or use words that you do know in a way that you do not understand, please tell me. Please let me know that. It's not my intention today to try to confuse you in any way. And I will tell you that I will ask you a poor question from time to time. But if you answer a question that I pose to you, I will assume that you understood the question. Is that fair?

A. Yes, sir.

Q. Okay. And as you just did, if you'll provide your answers both verbally, in other words, yes, no, yellow, 1946, whatever the answer happens to be, in a sufficient volume for our court reporter to take down your answer, that will make for a clean record.

Our court reporter, Ms. Osborne, is typing everything that we say while we are on the record. And she will produce a little booklet, and it'll have every question that I pose to you and every answer

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that you -- that you give. And we want that record to be as clear as possible.

And we all communicate in -- in non-verbal ways more than we realize. We nod our head, as you're doing from time to time. We say uh-huh or huh-uh. We respond with other gestures, and we communicate in ways that we don't even realize non-verbally with our facial expressions and whatnot. If you give a non-verbal response, I may prompt you to convert whatever your response is into a verbal response.

Everything does that. It's not that you have failed in some way if you give a non-verbal response. It's just that -- the prompting is just so that we make sure that that record is clear. And if you will do me the courtesy of waiting until I have finished forming my question before you begin providing your response, I'll give you the return courtesy of waiting until you have finished answering before I pose another question to you.

When we talk over each other, it makes it difficult on our court reporter, and this format of using Zoom is something we've become accustomed to over the last three years or so, but -- and it's great, but it -- it has a tendency to -- for there to

be a little bit of a delay in the transmission sometimes, and it makes it a little easier for us to talk over each other than if we were in the same room, so we just got to be careful about that. Okay?

A. Yes. Understood.

Q. Okay. Now, the other thing that I need to tell you is that I'm going to move through what I have in mind to ask you as expeditiously as I possibly can, but if at any point during the deposition you want to take a break, feel free to say can we take a break. This is not an endurance contest, and I don't expect that this is going to take more than a couple hours, but -- but, nonetheless, if you need to take a break for any reason, feel free to do that.

What I'm required by our rules to tell you is that if during any break you discuss the substance of your testimony being given in this deposition with anybody, including Visibly's lawyers, I'm allowed under our rules to inquire into the substance of that communication, and I'm required also to give you that warning to let you know that -- that if you have that kind of a communication within the -- the context of the deposition, I'm allowed to discover what that is about.

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I have no intention today of -- to ask you about communications you've had with Visibly's lawyers at any point prior to the start of the deposition. Don't want to know that and will not ask you any questions about that. But if any communication occurs during the deposition, the rules allow me to inquire into -- into that.

Okay. So any questions about the procedure before we get started?

A. No, sir.

Q. Okay. Are you under the influence of any medication, drug or other substance that would impair your ability to think or understand my questions or to provide truthful testimony today?

A. No, sir.

Q. All right. So if you would, start by just stating your full name for the record.

A. My name is Joel Stonedale.

Q. And, Mr. Stonedale, have you ever been known by any other name?

A. No.

Q. And where do you live?

A. Live in -- outside Smithville, Texas.

Q. And is that where you're from originally?

A. I grew up in Arlington, Texas, spent a lot

of time in Austin, Texas, and then moved here a couple years ago.

Q. Okay. How far did you go in school?

A. Law school.

Q. All right. So you -- are you a licensed lawyer?

A. Yes, sir.

Q. All right. And are you -- what -- what position do you hold, if any, at Visibly?

A. I'm Visibly's general counsel.

Q. All right. Okay. So -- and how long have you held that position?

A. Three years. A little under three years. I started in January of 2021.

Q. All right. Have you -- when were you first licensed to practice law?

A. 2011. Summer of 2011.

Q. And were you in private practice for any time before joining Visibly?

A. Yes, sir. After graduating law school, I clerked for a year. I then did three years or a little under three years at a large law firm doing mostly patent litigation. Then worked for a year at the Texas Public Policy Foundation doing public interest litigation, then moved to the Texas Attorney

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General's Office, also doing public interest litigation. I then went back to patent litigation for I think a little over three years and then from there went to Visibly.

Q. All right. Have you had an occasion to take a deposition before?

A. Yes, sir.

Q. Okay. Well, forgive me for going through all of that in such basic terms. I did not realize that you were a licensed lawyer.

But have you ever litigated any cases in South Carolina?

A. No, sir.

Q. Are you licensed to practice law in any states other than Texas?

A. No, sir.

Q. Have you ever been licensed in any states other than Texas?

A. No.

Q. Has your license to practice law ever been suspended or have you ever been disciplined in any fashion by the Texas bar association?

A. No.

Q. Okay. And you said you were in private practice with a larger firm. What firm were you

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with?

A. McKool Smith.

Q. And -- but since you've been with Visibly, that -- that has been a -- your full-time job is being -- being Visibly's general counsel, correct?

A. Yes, sir.

Q. Have you ever lived or worked in South Carolina?

A. No, sir.

Q. All right. So your area of practice you mentioned was -- it sounds like mostly patent litigation or intellectual property. Have you ever practiced in any other areas?

A. Oh, I have -- that -- I think it's accurate to say most of my work has been in patent litigation, but I have done various other forms of commercial litigation, regulatory, dealing with various regulatory schemes. The clean air act, endangered species act, some of the -- affordable care act. And then, of course, since Visibly -- since joining Visibly, I've been dealing with a great deal of healthcare litigation with the FDA.

Q. Okay. And where did you go to law school?

A. Did you say where or when?

Q. Where?

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A. University of Chicago.

Q. And you -- and from -- over what period of time?

A. 2008 to 2011.

Q. And where did you get your undergraduate degree?

A. University of Texas in Austin.

Q. All right. Well, so let's talk about Visibly. I may go back and ask you some of those background questions at -- as they occur to me, but let's talk about Visibly, the history of Visibly as you understand it. The company is incorporated where?

A. Delaware.

Q. And in what states does it currently operate?

A. Well, it depends on what you mean by "operate." The employees are scattered across probably 15 states. The base is primarily in Illinois. I would say that's a -- we -- we had a physical office in Chicago until 2019 or thereabouts, and then since then, it's been a fully online company, so doesn't have a physical base of operations.

Q. Okay. So there isn't -- there really isn't

a principal place of business as -- as we're talking to each other.

A. Not a physical location. To the extent there's a concentration of employees in business, it would be Chicago, Illinois.

Q. All right. And -- but you -- do you work out of your home?

A. Yes, sir.

Q. And before the office in -- in Illinois was shut down, had the -- had the office always been in the state of Illinois?

A. I believe the company was founded in Illinois and that was where it had been until that point.

Q. Okay. And you said this earlier. What year did you begin with the company?

A. January of 2021.

Q. And what year did the -- did -- was the company founded?

A. Founded. I would think it's either 2012 or 2013 in terms of the initial incorporation, that sort of thing.

Q. Okay.

A. Yeah.

Q. And do you know who the -- who the founder

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or founders were?

A. Aaron Dallek and Steve Lee.

Q. Okay. Are those two people still affiliated with the company?

A. No, sir.

Q. And do you know when -- when they left?

A. Not precisely. I could give you a ballpark range. So I can -- I can tell you with some precision that Steve Lee left in the latter half of 2019.

Q. Okay.

A. Aaron Dallek was before that. I want to say 2017, but my confidence in that is not particularly high.

Q. Okay. Okay. Well, I appreciate at least giving me the ballpark.

Do you know what -- under what circumstances either of them left? Were they bought out? Did they -- did they resign? Were they fired? What -- do you know what the circumstances were?

A. I could not tell you about Aaron Dallek. I know that Steve Lee was suspended initially, and then I don't know if he -- after that resigned or was fired, but I know he was initially suspended.

Q. Okay. And do you know why he was suspended?

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A. I believe there was dissatisfaction with his -- with his managing of the FDA process the first time around.

Q. Okay. And the company is governed -- does it have a board of directors?

A. Yes, sir.

Q. Okay. And so the decision to suspend Mr. Lee, was that a board decision?

A. I believe so. I would -- I would expect so, but --

Q. Okay.

A. Yeah. I think that's very likely.

Q. And Aaron Dallek, I mean, you don't know anything about what -- what the circumstances of his leaving were.

A. No.

Q. All right. We'll talk about the -- the managing the FDA process here shortly. So what -- all right. What -- what is the corporate structure of the -- of the company? Does it -- does it -- does it have any subsidiaries, or is it just one entity? How -- what's the structure like look?

A. There's just one subsidiary. So Visibly, Incorporated has one wholly owned subsidiary which is Next Day Contacts, LLC. That's the extent of it.

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Q. And is -- was that -- is that subsidiary established by way of some sort of acquisition or a merger of some kind?

A. Yeah. I believe it was an asset purchase acquisition.

Q. And when did that occur?

A. Approximately 2020.

Q. And say the name of the subsidiary again.

A. Next, N-e-x-t, Day Contacts.

Q. Okay. Does that business operate in -- as some -- under some other name, or is -- is that the name that it is known by in the public sphere?

A. It's known as Next Day Contacts in the -- in the public sphere, yes.

Q. Okay. And I assume that's some kind of contact lens supplier.

A. Contact lens retailer.

Q. Okay. And was that company operating as Next Day Contacts prior to the asset purchase?

A. I believe so.

Q. Has -- well -- and let me go back. When -- when did Visibly -- when did Optternative change its name to Visibly?

A. It was late 2018 or early 2019.

Q. And do you know the circumstances giving

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rise to the decision to change the name?

A. Yes. It was thought that Opternative conveyed a -- a notion that Visibly wanted to be an alternative to optometry, and that was not the message we wanted to send. Visibly wanted to work with optometrists, be an adjunct they use in their office, for example, when they can't get a patient to come in, things of that nature. And so it was looking to make it easier to partner with optometrists, and having a name like Opternative hinted that it was an alternative to optometry which was not the message they wanted to send.

Q. Okay. So it was really a marketing decision that gave rise to the name change.

A. I don't know if I would characterize that as marketing. I think it was more about clear communication to the potential partners.

Q. Okay. And that was just accomplished by virtue of a name change filing with the Delaware Secretary of State?

A. I can't tell you the precise mechanism, but I could tell you that it is not much more complicated than that, if it was any more complicated than that. It did -- there was no re-organization or anything of that nature.

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Q. Okay. Okay. So today how many employees does Visibly have?
A. 35.
Q. And who is -- does it have a chief executive officer?
A. Yes.
Q. Who is that?
A. Brent Rasmussen.
Q. Okay. And how long has Mr. Rasmussen been with the company?
A. Can I answer that question shortly? I wanted to point out: When I said 35, I should have said approximately 35.
Q. Okay.
A. I'm not entirely certain of what the head count is today.
Q. Yeah.
A. Brent Rasmussen, he has been with the company, I believe, since 20 -- 2017 to 2018. He may have started in 2018, but definitely by 2018.
Q. All right. Who are the other officers of the company day?
A. Paul Foley is the chef operating officer and might still be the chief financial officer. Then there's -- Brian Ambers is the head of finance. I

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don't know if he's the CFO or not technically, but Paul and me both work on finance aspects. Sam Shanley is the head of Next Day Contacts operations. And then Simran Chatrik -- that's S-i-m-r-a-n. I'm attempting to spell this right, and I'm not sure I am.

Q. Okay.

A. C-h-a-t-r-i-k. She is the -- someone with a name that's spelled approximately like that is the head of business development. And let's see. Pann -- it's another difficult name. Pichetsurnthorn. His first name is P-a-n-n. His last name is approximately P-r-i-t-c-h-e-n-t-h-o-r-n. He is the head of product. And, oh, yes. Brandon Varilone. I'm sorry with these names. I just call them by their first names.

Q. Understood.

A. He is our chief technology officer.

Q. Okay. And is Visibly privately held?

A. Yes.

Q. All right. Do you know who the -- who the owner or owners of the stock are?

A. I know some of them. There are a lot. It's -- there are a lot of owners. There's probably over 100.

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Q. Okay.
A. Quite a diffuse ownership.
Q. Is there -- okay. Is there anyone with a controlling interest?
A. No.
Q. Okay. So no -- no one has greater than 50 percent of the shares?
A. No.
Q. How many people serve on Visibly's board?
A. I believe there are -- so there are seven seats, five of which are currently occupied. So there's only five boards, and there's two seats that are vacant right now.
Q. Okay. Are the folks that serve on the board actively managing the company, or are they outside -- outside folks just serving on the board?
A. A mix of the two. There are three outside people that are fully outside, and then two of the people on the board are Paul Foley who is our chief operations officer and Brent Rasmussen who is the CEO.
Q. Okay. Who are the -- who are the outside people?
A. It changed recently to David Ting who is at Zenni, and then a -- I'm blanking on his name.

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Another man who works for Johnson & Johnson in his day job. And I'm trying -- I can't remember his name at the moment. And then Peter Carroll who works for Jump Capital.

Q. Okay. I want to ask you about the next day contact operation just briefly and then -- and then get back to Visibly's core business. Next Day Contacts, is that a -- is that some sort of an online contacts real -- retailer?

A. Yes, sir.

Q. Okay. And does -- does Next Day Contacts or Visibly manufacture any contact lenses?

A. No.

Q. Okay. So its -- it purchases contact lenses manufactured by others and then sells them via an online platform to the public; is that correct?

A. Correct.

Q. Okay. And had -- to your knowledge, has that been the business model for Next Day Contacts from its inception?

A. As far as I know, it has always been a contact lens retailer, never a manufacturer.

Q. Okay. Now -- and does -- other than selling contact lenses via an online platform, is there any other service or product that Next Day Contacts

offers to the public?

A. It links to Visibly's vision test, but it doesn't actually offer the vision test, but you -- if you go to the Next Day Contacts site, you can take Visibly's vision test on that site.

Q. Okay. Does Visibly have any relationships with any other contact lens retailers other than -- than its -- its own subsidiary, Next Day Contacts?

A. Yes. Many. I would say a couple dozen at least, maybe -- maybe 50. There are -- there are quite a few. They're -- they put a link to Visibly's vision test on Visibly's -- or on their -- on their contact lens retail site.

Q. Okay. And so that's sort of the -- that's sort of the typical way that a customer of one of those companies gets to Visibly's site, by way of a -- a link on those retailers' websites.

A. Yes.

Q. Okay. Now, Visibly, can you describe what Visibly's business operations are? I mean, what -- what product or service does it offer to the public?

A. Visibly makes vision testing software.

Q. Okay. And so it offers a service, a vision testing service, to the public, and that's how it generates its revenue?

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A. Well, it makes the software that's then used by others to test vision.

Q. Okay. When you say it's used by others, explain to me how that works.

A. A -- a eye care provider, such an optometrist or an ophthalmologist might use Visibly's software to test the vision of one of their patients, for example.

Q. Okay. And so is the software licensed to the optometrist or ophthalmologist?

A. Yes. The software runs on Visibly's servers, but the -- the optometrist or ophthalmologist has access to a portal to the software where they can see the results of the vision test.

Q. Okay. And what I'm -- what I'm trying to understand is the way that Visibly generates revenue through that -- that sort of operating model. Is it that -- is there a fee for access to the portal that Visibly charges an eye care professional?

A. Yes.

Q. Okay. Now, is -- is that the only way by which Visibly generates revenue?

A. No. We also -- well, Visibly gets revenue through Next Day Contacts as well.

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Q. Okay.
A. Contact lens sales.
Q. Okay. Does Visibly allow or does it provide a service to laypeople that -- to allow them to access its software?
A. Sort of. So it is possible to go to Visibly's -- so, yes. Laypeople can on their own access Visibly's software. One way they can do that is to go to Visibly's website and click take a test and take a vision test.
Q. Okay. And do -- so do they have to pay a fee up front to take the -- take the test?
A. I believe they pay the fee -- when do they pay the fee? At some point they pay the fee. I think it's at the end of the test.
Q. Okay. But so that's another way that Visibly generates revenue, is just by -- by laypeople going on Visibly's website and taking the test. Correct?
A. Right.
Q. Okay. So -- so a layperson could go to Visibly's website, pay a fee, take the test and then, with the results, purchase contact lenses from Next Day Contacts, and -- and -- and Visibly would generate revenue from the fee for taking the test and

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from to the sale of the contacts as well, correct?

MR. MCNAMARA: Objection.

THE WITNESS: Well, no, I don't think so. That's -- I think I oversimplified somewhat.

BY MR. SHEALY:

Q. Okay.

A. If someone were to go to Visibly's website and -- and take the test, they would -- the -- the payment for that would go to Optimized Eye Care, which is a professional corporation that employs optometrists and ophthalmologists. Then -- and Optimized Eye Care via Visibly would send the prescription back to the user, and they could then use that prescription to purchase contacts from wherever they wanted.

Q. Okay. So -- all right. So let me make sure I understand how the -- the payment stream works. Okay. So the layperson takes the test, pays the fee via Visibly's website, but the fee goes to another company, Optimize...

A. Optimized Eye Care.

Q. Optimized Eye Care.

And does -- does Visibly have any interest in that company?

A. No. Visibly has a -- Visibly provides

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management services to that company, administrative services --

Q. Okay.

A. -- but that company is owned by a doctor by the name of David Hillman.

Q. All right. So -- all right. So -- okay. So Visibly when it provides management services to that company, does it -- does it charge the -- that company for providing those management services?

A. Yes.

Q. Okay. Does -- is there some sort of contractual arrangement by which the fee that is -- that goes to optimized -- what did you say? It was optimized?

A. Optimized Eye Care.

Q. Eye care. Where Visibly receives a portion of that fee?

A. No. Visibly's paid on a standard yearly fee for its services.

Q. Okay. Okay. So there's just an arrangement where Optimized Eye Care pays Visibly for both the management services and -- and for having this portal that sends the eye test results to Optimized Eye Care, correct?

A. No. They -- Optimized Eye Care pays for the

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management fee. There's a -- management services and for -- for billing and for the software license for the vision test.

Q. Okay. All right. So have we talked about all of the ways that Visibly generates revenue?

A. Certainly the vast majority of it. I mean, basically all the revenue Visibly gets is from the vision test one way or another, the origins of -- for licensing the vision test one way or another and -- and for the sale of contact lenses.

Q. Okay. And Optimized Eye Care, where is that company located?

A. Illinois.

Q. It's incorporated in Illinois?

A. It is an Illinois professional corporation.

Q. Okay. And to your knowledge, does it -- it employs optometrists or ophthalmologists to review the vision test results generated by Visibly's software?

A. Some of both.

Q. Okay. It has both optometrists and ophthalmologists --

A. Yes.

Q. -- on its staff? Okay.

A. Yes, sir.

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Q. And do the --
A. I should be clear. I don't believe it employs them. I believe they have a contractual relationship.
Q. Okay.
A. I think you said employ, but it -- both -- it has contractual relationships with doctors that are both optometrists and ophthalmologists.
Q. Okay. Now, so is -- if the -- if -- if an optometrist or an ophthalmologist reviews a particular patient's vision test results, is there some mechanism by which a doctor that is licensed in the same state where the patient is performs that review or do you know how that works?
A. Can you repeat the question?
Q. Yeah. What I'm trying to figure out is does Optimized Eye Care direct a vision test to a doctor that is licensed in the state where the patient is that took the test to perform the review?
A. Yes.
Q. Okay. And that -- and as you understood it then, if -- if in that medical professional's opinion it's appropriate, they issue a prescription to that patient based on the -- that test result.
A. Yes.

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Q. And -- and is there any -- there any personal interaction between the patient and that medical professional during the process we've just been talking about?

A. What do you mean by personal interaction?

Q. Is there any -- does -- does the doctor have any kind of an interview with or any kind of a face-to-face interaction with the patient?

A. Depends on who's using Visibly's software and how and when. And they -- when Optimized Eye Care uses Visibly's software, as opposed to an independent ECP, one of the other independent ECPs that use it --

Q. And when you -- let me -- I didn't -- sorry to stop you, but just so our record's clear, when you say ECP, you mean eye care professional.

A. Or eye care provider. I mean typically optometrists or ophthalmologists.

Q. Okay.

A. I'll try to use those words.

Q. Okay.

A. So I guess there's two -- two main scenarios how the software is used. One is where someone comes online through one of our retail partners or through Visibly, through Visibly's website directly, and --

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and they, you know, take the vision test. The information is sent to Optimized Eye Care remotely, and then the doctor at Optimized Eye Care then reviews the information from the vision test, determines whether to send the prescription. Typically there's no face-to-face interaction there. Certainly not through the Visibly software there isn't.

There's another situation where let's say a local optometrist has a patient that -- he, you know, can't come into the office for some reason or doesn't want to. For whatever reason, they would prefer not to come into the office, and they -- so they might use the software in that case to remotely assess someone's vision or gather information about the vision remotely, and then that person might later call them in or might not, depending on the results of the test.

Q. Okay. Is there -- are you aware of any eye care provider that uses Visibly's software to perform an eye -- a vision test inside that eye care provider's office?

A. I'm not aware of a specific individual. Though I suspect some people do that, I couldn't name someone who does that, but I -- I guess I don't know.

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Q. Okay. Are you involved in the -- in Visibly entering into a contractual relationships with eye care providers?

A. Yes.

Q. Okay. So you're generally aware of who Visibly has contractual relationships with in various places in the country?

A. I'm aware of many of them. I typically don't see a contract unless it has edits that are, you know, interesting enough to send to me. If someone -- someone on our sales team gives a contract to an eye care provider and they just sign it, I'm not going to see that contract.

Q. Okay. But to what extent were you involved in the drafting of sort of your standard contract with an eye care provider?

A. I have edited our standard template. I'm familiar with it.

Q. Okay. And has that template evolved over time during the life of -- during Visibly's life?

A. Yes.

Q. Is that a "yes"?

A. It has changed, you know, year to year. It changes.

Q. Okay. Does Visibly currently have any

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contractual relationships with any eye care providers within the state of South Carolina?

A. Visibly does not have any contractual -- well, it's possible that there are still contracts with South Carolina doctors who are not using the test anymore because it's no longer legal to do so. There were South Carolina doctors using it beforehand. Now, whether those contracts are still running, I guess I don't know. It would have -- this all happened before I came to Visibly. But I can't say for certain that there are no South Carolina licensed doctors that Visibly does not have a contract with, though I can say for certain that if you tried to use the software and you said you're in South Carolina, it would kick you out. It wouldn't -- you know, it wouldn't let you.

Q. So when you said that it's illegal for a South Carolina eye care provider to use the software, to your knowledge is there anything stopping a South Carolina eye care provider from using the software in conjunction with a comprehensive eye examination?

A. I would have to look more closely at the law to form an opinion on that.

Q. Okay. But you have not to this point formed an opinion about that, correct?

A. If someone could use it in their office?
Q. Yes.
A. No, I have not looked at that.
Q. Okay. Visibly just made the decision that the software would not be made available to eye care providers if the patient was in South Carolina; is that correct?
A. Visibly understood that at least in most use cases that it would run afoul of the -- the law from 2016 in South Carolina and as a result told the system that if someone is in South Carolina that it should not -- they shouldn't use the test or at least shouldn't send the information to any doctor for review.
Q. Okay. But -- and -- but Visibly has not looked at the possibility of entering into contracts with South Carolina eye care providers that would require that if the software was used, it was used in conjunction with a comprehensive eye examination?
A. I don't know what our sales team -- if they've -- if they've felt out if there's much interest in that or not.
Q. Okay.
A. I -- you -- the typical use case is not in office. The -- a major advantage of Visibly's

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software is that somebody doesn't have to come to the office. So some -- some -- some people do use it locally, say, within the same county or town or whatever, to have a patient who can't make it into the office be able to get his vision tested by his optometrist or ophthalmologist, but I -- my impression is that there is less demand, if there's any, for having someone be tested in the office with an optometrist by the -- by a doctor.

Q. Okay. And the -- the -- just if you would, kind of walk me through what the -- what the interface is with a patient. Is -- does -- can the patient do the test via a desktop computer?

A. Yes.

Q. Can the patient do the test using a cell phone, a smartphone?

A. Yes.

Q. Okay. And does the test rely on the patient to provide feedback about what he or she is able to see or not see?

A. Yes. And I -- I should clarify something. We have two different versions of -- of vision tests. One that uses a computer screen as the -- the eye chart analog, and then one that uses a cell phone as a eye chart analog. The one that uses the computer

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screen, the cell phone -- the person also uses their cell phone as a remote. They sync their cell phone with their computer screen, and they enter the answers to the vision test. You know, it says -- asks them -- shows a Landolt C, and that's the optotype, and the optotype is facing one of four directions, and they select up, down, left or right on their cell phone.

There's another version of the test that shows the optotype on the cell phone, and they use their voice to control it from across the room, and they say -- they say up, down, left or right vocally, and -- from -- from a distance, and it based on that feedback assesses -- or provides the information to, you know -- about their visual acuity from a distance.

Q. Okay. And is -- are they -- is the patient required to stand or situate themselves at a certain distance away from whatever screen they're using, where it's their cell phone or whether it's a desktop computer?

A. Yes.

Q. What's -- what is that distance?

A. It's most commonly 10 feet. I don't know if there are any instances where it tells people to move

forward. I don't think it does. So, I mean, the starting distance is 10 feet. I know that for sure, and I think it's always 10 feet, but I -- I wonder if there's some iteration when it might ask you to move closer, but I don't -- sorry. I'm trying to -- I've taken the test a bunch of times, but it's never asked me to move closer, but maybe it's because I'm -- I think it's always at 10 feet.

Q. Okay. Does the software have some means of verifying that the person -- the patient is far enough away for -- for there to be a valid result?

A. The software -- there's two ways it gets to the right distance. It says either you can get a tape measure and measure out 10 feet and then, you know, stand there, or it walks you through a -- if you don't have a tape measure, it walks you through a series of instructions using the size of your foot and taking heel-to-toe steps to get the same distance away.

Q. Okay. All right. And to your knowledge is this sort of -- the two forms of interface that you've just described, has that always been the way a patient has interacted with Visibly's software?

A. I think the explicit instruction to use a tape measure or having that being an explicit option

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is relatively new. Maybe it was added in the last two years or something like that.

Q. Okay.

A. Of course, everyone always knew that they needed to get 10 feet away, so they could always use a tape measure, but I want to say about two years ago, we made that an explicit suggestion, whereas before it said get 10 feet away. Here's how you can do it with your heel-to-toe steps.

Q. Okay.

A. And before my time I honestly couldn't say. I couldn't speak to how they were doing it before three years ago. I first took the test three years ago.

Q. And I note that you're wearing eyeglasses today. Have you used Visibly's test to renew a prescription for -- for eye glasses?

A. I have taken the test many times, but I've never actually submitted it to get a renewed prescription.

Q. Okay. What -- for what purpose did you take the test?

A. Just to understand it.

Q. Okay. All right. I want to switch gears for a minute. I many ask you more questions about --

about the mechanics of the test. But I do want to ask you about whether Visibly has been involved in any lawsuits concerning its business operations. Has it been involved in lawsuits?

A. Yes.

Q. How -- how many other than the one we're talking about here today?

A. Let's see. I can walk you through it if that's easier.

Q. Yeah. That would be fine.

A. You can tell me which ones you care about and don't want to hear more about.

Q. Okay.

A. So we are currently in a patent lawsuit against -- against a competitor, Easee. We're suing them for patent infringement in Germany. It's actually utility model infringement. Utility model is a German thing that's a lot like a patent.

Q. Okay.

A. I imagine you don't care about that, but happy to tell you more if you --

Q. I don't need to know any more details about that, but thank you.

A. We had a lawsuit where Steve Lee, the founder of Visibly, sued Visibly for defamation, and

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that settled about a month ago. Not a month ago. About a year ago.

Q. Okay. And what -- was the settlement confidential?

A. Probably. I can't remember specifically now --

Q. Okay.

A. -- but they typically are.

Q. Where -- where was that lawsuit brought?

A. In Cook County, Chicago.

Q. Okay. And what were the allegations of -- that gave rise to this -- to a defamation claim?

A. With a high level -- you could probably find the complaint online. At a high level, it was that -- so when Visibly suspended Steve Lee, it published a letter, and that letter said that Steve Lee had messed up the FDA process because he didn't -- didn't respond to the feedback offered by the FDA. The FDA said you need to do A, B, and C, and he didn't adequately do A, B, and C.

Q. Okay. When you say you published a letter, to whom?

A. Oh, sent a letter to the board or, I guess, specifically Brent Rasmussen, the CEO of Visibly, and Visibly's lawyer by the name of Lisa -- Lisa Conmy,

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who were also named in the lawsuit.

Q. Okay.

A. The two of them were -- they -- the allegation is they published the letter, and by "published" I think he means sent. But for defamation, you got to call it "published."

Q. I understand.

A. Sent the letter to the board saying that Steve Lee had -- had messed up the FDA process by not following the FDA's feedback.

Q. Was there any allegation that the letter had been published outside of the company?

A. I don't know if there was an allegation. I'm pretty sure there was no evidence of that. But I'm -- I don't recall there being an allegation. There's definitely an allegation that it was published to the board --

Q. Okay.

A. -- that resulted in his suspension or firing or whatever it was. I don't recall specifically if he was ever actually fired. But -- and then there were other allegations of more verbal -- they were a little more nebulous, and I can't remember them with specificity but something along the lines of, you know, people in the company after he was suspended

had bad mouthed him, you know, saying --

Q. Out in the world?

A. Say again.

Q. Out in the world in some way or --

A. I think -- well, at least some of the allegations were that it was within the company, you know, that people within the company had said bad things about him to -- within the company and maybe there was some allegations about out in the world. I can't remember the specific details --

Q. Okay.

A. -- but that was the gist of.

Q. Okay. All right. So that -- that's now resolved.

A. (Witness nodding head.)

Q. Is that a "yes"?

A. Yes. Sorry.

Q. All right. What other litigation are you aware of?

A. Let's see. There was the lawsuit filed against Warby Parker. This is another IP suit where Visibly sued Warby Parker for the breach of an NDA.

Q. Of a non-disclosure agreement?

A. Yes, non-disclosure.

The basic allegations -- this is, again,

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before my time so forgive me on the details. Basic allegation was Visibly had shown Warby Parker certain things about his vision test as part of, you know, looking into some sort of partnership agreement, and then Warby Parker developed its own vision test and the allegation, something along the lines of that process used some of Visibly's confidential information in violation of the non-disclosure agreement.

Q. Okay. Is that lawsuit still pending?

A. No. That was 2017 or 2018.

Q. And do you know how the lawsuit was resolved?

A. Eventually there was a settlement agreement.

Q. Okay.

A. I don't know much of the details about how -- how it went down. I know there was a -- it went on for a while, I think.

Q. Okay. All right. And what else?

A. I think that's it for litigation.

Q. Okay. So are -- other than the lawsuit that we're currently involved in -- or is -- is Visibly involved in any other litigation? I guess -- I guess the -- the patent suit in Germany is still pending. But is there any other lawsuit pending either against

Visibly or where Visibly is the plaintiff in the United States at present?

A. No.

Q. Okay.

A. I am not certain that my recollection of the historical litigation is complete, but I am certain that I know about all the current litigation.

Q. Okay. Okay. All right. I understand that the Illinois Attorney General opened an investigation that -- against Visibly that -- that ended with some sort of settlement. Are you aware of that situation?

A. Yes.

Q. And that settlement agreement was reached in April of this year?

A. That sounds approximately correct.

Q. Okay. Were there any sort of formal proceedings initiated by the attorney general?

A. It depends on what you mean by "formal proceedings." There was a civil investigative demand which I understand to be more along the lines of a subpoena almost.

Q. Okay.

A. I wouldn't consider it litigation, but it -- you know, they -- they ask you for documents, and I believe you have to give it to them without, you

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know -- or maybe you can challenge it like a subpoena. That part happened before my time. The actual civil investigative demand. I was involved in settling it but not the initial process.

Q. Okay. And the -- were there -- did the settlements impose certain requirements on Visibly?

A. Yes. But the requirements were largely redundant with -- with the law.

Q. What do you --

A. But, yeah, the --

Q. I'm not sure I understand.

A. Yeah. The requirements -- so for context, the -- the states alleged that Visibly was -- was misleading consumers because among other things, they had -- we had listed the device as FDA registered, and that was true. It was FDA registered. But the states considered that to be misleading because someone might confuse FDA registered with FDA approved or FDA cleared or something like that, and that according to the states violated consumer protection laws that say you can't say misleading things, and so Visibly committed to not saying misleading things, but I wouldn't -- it -- essentially the agreement was parallel to what the legal requirements were anyway, so it was not an

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especially groundbreaking agreement.

Q. So you say "the states." Did other attorneys general join with the attorney general of the state of Illinois in this civil investigation?

A. Yes, sir. Eleven states.

Q. Okay. Who -- do you remember what states they were?

A. Illinois, Nebraska, Texas, Washington, Kentucky and some more. I'm going to start reaching the ends of my memory and get speculative if I go further.

Q. Well, let me see if I can help you because I have a statement up on my other screen issued by the attorney general of the state of Illinois about the settlement. He indicates that Illinois joined with attorney -- or the states of Kentucky, Mississippi, Nebraska, Nevada, Pennsylvania, South Dakota, Texas, Vermont, Washington and Wisconsin in participating in the settlement. Does that comport with your memory?

A. Yes.

Q. Okay. It also indicates that Visibly agreed to pay $500,000 to the participating states. Is that correct?

A. Yes.

Q. All right. It says that Visibly agreed not

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to market or sell any product to consumers unless it could be legally marketed or sold in accordance with the Food, Drug and Cosmetic Act or other FDA authority.

Is that part of the settlement to your knowledge?

A. Yes.

Q. It also indicates that Visibly could not make any representations comparing the safety or effectiveness of any Visibly product to products or services provided in person by medical professionals without possessing competent and reliable scientific evidence substantiated the representation.

Is that a correct recitation of an element of the settlement agreement?

A. I don't have a specific recollection if that's precisely correct, but I think it's at least approximately correct --

Q. Okay.

A. -- in their characterization. I couldn't -- I don't specifically recall that.

Q. Okay. And as I -- as I'm reading that, my own interpretation is that there's -- there's some proscription against making a comparative statement about the relative effectiveness of Visibly's

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software with other means of testing a patient's vision. Does that sound like approximately what the settlement agreement touched on?

A. I think what it was going for is there's an FDA rule that when you make a comparison along those lines that you have to have a certain level of evidence, and I think the -- the FDA term of art for that is competent and -- and -- competent and reliable or -- I'm not sure of the exact wording, but there's -- there's a term of art that they have for the level of evidence that you need to make a claim of just about any kind, and so I -- I think what that's getting at is that -- another way of saying we have to adhere by the FDA rule on that subject.

Q. Okay. Today, as we're talking to each other, does Visibly have evidence that meets that standard?

A. Yes. We -- FDA cleared the vision test based on the -- I don't know if finding is the right word. FDA came to the conclusion, broadly speaking, that the vision test is as safe and reliable as, you know, the process of testing vision with a ETDRS chart or the -- I'm not sure if that's even the exact right one. An eye chart that was standard in the market beforehand. So in order to get pre-clearance

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what Visibly had to do was convince the FDA that we are -- that our device -- and it defines the device as the -- the vision test. That that vision test is substantially equivalent to something else in the market before 1976. That thing is some version of an eye chart. I think we actually used a couple versions of an eye chart.

Q. Okay.

A. So we ran clinical studies, and the FDA agreed with us that it was -- that our vision test was approximately as accurate or, you know, did -- I can't remember. They have a specific -- they have specific FDA term of art they use for this, but they -- they concluded that it was comparable enough, I'll put it that way, or as safe and effective or something like that to the ETDRS eye chart, and I would think that satisfies the competent evidence.

And I'm probably -- I am getting to where I need to take a break.

MR. SHEALY: Yeah. That's -- and so am I. So why don't we --

THE WITNESS: Yeah.

MR. SHEALY: We'll do that right now, and we'll come back in, say -- why don't we just come back in 10 minutes?

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THE WITNESS: Sounds great.

MR. SHEALY: That work?

MR. MCNAMARA: Okay.

MR. SHEALY: Okay. Thank you.

- - -

(There was a recess from 11:12 to 11:24.)

- - -

BY MR. SHEALY:

Q. Okay. Mr. Stonedale, during the break, did you have any communication with any -- anyone else about the substance of your testimony?

A. No.

Q. Okay. All right. I was asking you about the terms of the settlement reached that the attorney generals of some eleven states in April of this year. And -- and you were telling me that the FDA had -- had given clearance to Visibly. Do I understand correctly that that clearance came in August of 2022?

A. That's correct.

Q. Okay. And was that clearance in the form of -- I think it's called a 510(k) letter?

A. It was a 510(k) clearance.

Q. 510(k) clearance. Okay.

Let me show you my screen and ask is this the -- can you see that?

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A. Yes.

Q. This is a -- it looks like an 8-page document. Is this the 510(k) clearance from the FDA?

A. It is the -- it's called the 510(k) summary. It's something that's issued along with the 510(k) clearance.

Q. Okay. All right. So this is the -- this is the 510(k) summary that -- that Visibly received from the FDA in -- it looks like on or about August 11 of 2022?

A. Thereabouts.

Q. Okay. All right. I'll mark this as Exhibit 2 to your deposition.

- - -

(FDA 510(K) Summary Letter marked Defendants' Exhibit Number 2 for identification.)

- - -

BY MR. SHEALY:

Q. And then let me see -- I think -- all right. And did that -- did that come along with a letter of some kind which indicated that Visibly had received the clearance?

A. I think so. I'm not certain.

Q. Okay. Let me -- let me see if I can find -- just hold on one second. Okay. All right. I'm

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showing you a -- I think it's two -- two letters. One issued in -- yeah, August 12, 2022. And then a sort of follow-up letter of September 30, 2022.

And are these the communications by which Visibly learned that it had received FDA clearance?

A. I'm not certain that's when we learned it. But those were communications, I guess, formally -- well, I don't know if that's what formally grants it or not, now that I think about it. I guess is -- is your question how we learned?

Q. No. I just --

A. Or is your question just to authenticate these documents?

Q. I was trying to authenticate these documents.

A. Oh. Yes, they looked authentic to me. I haven't --

Q. Okay.

A. Yeah.

Q. As I -- well -- and as I'm looking at them myself, I see that the August 12 letter looks like I don't have all of the pages of that letter in this -- in what I had hoped to be an exhibit. The August -- I mean, the September 30 letter is one page. It just -- and it looks like that has been issued

because of the typo in the August letter. Correct?

A. I think so.

Q. Okay. All right. I'll -- I will -- when we -- we'll take a break again. I'll get a complete copy of the August letter, and we'll -- we'll have these two together marked as Exhibit 3 to your deposition.

So talk to me, if you will, about this whole FDA process because you've mentioned earlier, again, a big dust up with Stephen Lee about not handling that appropriately. Can you sort of tell me what your understanding is about what -- what steps Opternative took to -- to be able to market and license its software to the public?

A. And so when you say "Opternative," to me that hints you want me to talk about the first attempt at FDA.

Q. Yeah. I kind of want to walk through the whole -- the whole history.

A. The whole history. Okay.

With the caveat that my recollection is much better on the more recent attempt because I was around --

Q. Right.

A. -- I will -- I'll tell you what I know about

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the original. So the -- we attempted to do the De Novo process which as -- that is more involved than the 510(k) clearance process.

Q. Okay.

A. And it is the -- De Novo process has a different role. The 510(k) clearance was the appropriate process for what we were trying to do. Why we chose to do the De Novo process is not entirely clear. It was not the right decision.

The -- so the 510(k) -- the 510(k) clearance is easier to understand. It's trying to establish the fact that the device you would like to market is functionally equivalent within some standard range in terms of safety and effectiveness as some device that was marketed before 1976, I believe it is. Sometime in the '70s. In any event. Now, that is a -- that took us years and millions of dollars. It is a very involved process, and that's considered the relatively simple one.

The De Novo process which I have not had to go through is even more involved because instead of trying to show that -- like in our case that the -- the vision test is functionally similar, equivalent to a -- to an eye chart, we're trying to create a whole new device category of things that other things

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can then be in the future equivalent to. So effectively, yeah, it -- then, you know -- huh? Yeah. I don't -- I don't actually know that's true. Scratch that.

So what is very clear is it's a lot more involved. So we chose the more involved route and --

Q. Do you know when -- when you -- when -- and I guess it was Opternative then when it initiated that -- that -- the -- its first attempt through the De Novo process.

A. I believe it started in 2016.

Q. Okay.

A. So to give you the full time line, before 2016 we were operating under the notion -- because we had gotten an email from the FDA saying, "Your device is classified as an eye chart. Eye charts are 510(k), pre-market notification exempt. You don't have to go through a process to market it. You just have to register the device, and you can go on."

Then sometime in 2016, we had a meeting with the FDA where we learned that they had effectively changed their mind, and they no longer -- they did still consider it HOX code. HOX is -- so they did still consider it an eye chart, but they considered it the sort of eye chart that needs to go through a

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510(k) clearance anyway, and most eye charts are not required to go through any sort of clearance.

So we were kind of under this exception because -- basically because it worked differently than a normal eye chart. Normal eye chart is a -- just a piece of paper or even a computer screen that you read the lines, whereas we showed the optotypes one at a time, and, you know, there were differences that the FDA later decided were significant enough that we needed to go through the clearance process.

And then we started going through the De Novo process. And there was a lot of back-and-forth. You know, the whole -- the whole process with the FDA, I know from experience in the simpler 510(k) process, is very involved. They give you feedback at every step of the way. You know, you need to -- so before you even say, "This is the clinical trial we're going to do," you say, "This is the sort of clinical trial I'm thinking about doing."

And they say, "Oh, okay. I would actually do it like this. That would be better."

And then you say, "Okay. So here's the plan based on what you said."

And then they say, "Well, I would tweak these five things."

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And then, you know, it's back and forth. Many, many submissions.

Q. And did -- and it looks like -- did Hogan Lovells handle this whole process for -- for Opternative, or did it get involved later with the 510(k) process?

A. I -- so I'm certain that Hogan Lovells was the main firm involved in the 510(k) process, and I think they may have come in and lent a hand at the very end of the De Novo process, but I'm not certain of that --

Q. Okay.

A. But they were -- they were in charge of the 510(k) process, the main lawyers.

And so there's lots of back-and-forth where the FDA gives you a great deal of feedback on how to design the appropriate clinical trials to -- to demonstrate what they want demonstrated. And the main problem with our attempt at the De Novo process is we didn't take the feedback into account sufficiently. We tried to do things -- we kind of stuck to the original plan despite the feedback telling us that wasn't -- that wasn't the right plan.

You know, they -- so, for example, they said you're going to need more eyes, more -- more study

participants, I shouldn't say. We always refer to it as eyes, but you're going to need more individuals in your study, and you're going to need them to have this age distribution, this ethnic distribution, this geographical distribution, and, you know, we didn't meet those requirements. That's one of the simpler things that they wanted for statistical purposes to have the right kind of sample size.

And then there are a lot of details about changes in labeling and so forth that -- so that process didn't go right because we didn't listen enough, I think, and ultimately as it -- so -- okay. So we started that in 2016.

Then in 2017, we got this letter, it's a warning letter, saying, you know, you need to be -- you need to have 510(k) cleaning or De Novo clearance or some sort of official clearance from the FDA or approval, rather, and -- and -- or clearance or approval, I should say, actually.

And then we called the FDA and said, "Hey, you know, we were operating under the understanding that we could continue in the market while we're going through this process."

And they said, "Yes, you can."

There's a disconnect between the people

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doing enforcement and the people doing device classification. So we continued operating as we continued to go through the De Novo process over, I guess, three -- three to four years. It was a while. So from 2016 to 2019. And then in the spring or summer of 2019, the -- you know, the process I guess had gone so slowly or for whatever they -- I don't know if they lost their patience with us or for some reason. I can't read the FDA's mind.

For some reason, the FDA changed its position and said, "Just take it off the market. We -- you know, you -- we are giving up on enforcement discretion to allow you to keep using the software while you go through the De Novo process."

Q. All right.

A. So then --

Q. So this is in -- you think 2019 is when you were given a directive to take the service off the -- off the market?

A. Right.

Q. And -- okay. And did you -- did -- was -- was -- was it still Opternative in 2019?

A. By then, it was Visibly.

Q. Okay. Did Visibly comply with that directive?

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A. Yes, sir.
Q. And how long was the service off the market?
A. From approximately the summer, the spring or summer, of 2019 until COVID. When the pandemic started, the FDA changed its mind again, said, "We do not -- you don't any longer need pre-clearance. You can operate under the HOX code." That's the eye chart code. "You can operate under the HOX code as any other eye chart without pre-clearance." They issued this enforcement discretion policy.
Q. Okay.
A. And so then we started operating again.
Q. Okay. Did -- and was -- was that connected to any kind of emergency powers or emergency authorization issued by the FDA?
A. Yeah. There's a -- they issued a whole policy for COVID. They said during COVID -- during the COVID emergency, we're going to effectively suspend certain requirements for certain device.
Q. Okay.
A. One of those was the requirement that was presenting us from operating.
Q. All right. So that policy was in effect until May of 2023, correct?
A. To some degree, it's still in effect.

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There's a phase-out, and so I believe the bulk of it goes out of effect in November of this year.

Q. The reason I've asked the question is was -- did Visibly -- was there ever a point where Visibly had to take the service back off the market for any period of time until it got the 510(k) clearance in August of 2023 -- 2022?

A. No.

Q. Okay.

A. So we -- the entire time Visibly was off the market was from mid 2019 to early 2020.

Q. Okay. And then it's been in the -- it's been operating in the marketplace ever since without interruption.

A. Correct.

Q. Okay. All right. So -- well, so when did -- I guess when did the process start of getting the 510(k) clearance?

A. I mean, it's a little difficult to define when the process starts. But as soon as we were given the opportunity to start operating again, I believe we started planning for getting the clearance that we needed so that when the emergency was over -- at that time, no one knew the emergency was going to last three years.

Q. Right.

A. As soon as the emergency was over, we'd be able to continue operating, so we started to some degree immediately. As far as the actual filings, of course, they took a while to put together.

Q. Okay. All right. And so as we sit here today, Visibly has the clearance it needs from the FDA to -- to operate.

A. Yes. In fact, it's -- it's a -- it's even -- it's even stranger. The FDA, upon clearing Visibly, determined the same day or the day after that online vision tests no longer need clearance. So it seems that through the process of going through 510(k) clearance with Visibly, they determined that the risk was low enough that no -- no clearance was further needed.

So, yes, Visibly got the clearance. We are probably the only online acuity test that will ever get the clearance because the day we got the clearance or the day after, something like, you know, within a day or two, they changed the -- they created a new code called QTO, and this new code, that's what they classified our device under instead of the earlier HOX which is a regular eye chart.

And then they -- they made this QTO category

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exempt from -- from pre-clearance requirement categorically. So even, like, the HOX was mostly exempt from pre-clearance, but because ours operated differently than a standard eye chart, we had to go through pre-clearance. QTO does not require pre-clearance even for, you know, an online vision test because it's only online vision test.

Q. Okay. Okay. Thank you for that.

Let me go back to -- there are two more bullet points in the Illinois Attorney General's recitation of the settlement that -- that I wanted to ask you about. The third one is -- it says that Visibly would clearly label that its product had not been endorsed by any provider appearing on its "Find a Doctor" feature.

Does that sound like about accurate recitation of one of the elements of the settlement agreement?

A. Yes.

Q. Okay. And has Visibly complied with that part of the settlement agreement?

A. I don't believe we've used the "Find a Doctor" feature in a very long time, so -- so by default, yes.

Q. Okay. So you've just changed the -- made a

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change to the website to just take that feature off -- off of the website?

A. Well, I don't think it was in response to allegations by the states. I think it -- or maybe it was. It was before my time. I can't say why that was -- that happened. But it's -- for whatever reason we no longer use that feature.

Q. Okay. And then the -- the last bullet point that the Illinois Attorney General has on -- in the announcing the settlement indicates that Visibly was to disclose that its online vision test is not a substitute for an in-person comprehensive eye examination and urges consumers to seek such exam to determine overall eye health.

Has Visibly complied with that aspect -- well, first, is that an accurate recitation of one of the elements of the settlement agreement?

A. As I recall, there's something like that in there. But I -- I don't know if the exact wording is right, but --

Q. Okay. To -- with that caveat in mind, has Visibly complied with that aspect of the settlement agreement?

A. Yes.

Q. Okay. And was -- how -- how has it done

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that?

A. When you take the vision test, it -- it states that the -- you shouldn't take the vision test if you haven't had an appointment in two years, I believe, or some amount of time. It says we recommend that you get a comprehensive eye exam. I don't recall if it's every one or two years, and that -- that you should go see a eye doctor at least that often.

Q. Okay. Now, the -- the 10(k) clearance that Visibly has received, does it provide a certain -- or does it provide certain parameters in terms of an audience for whom the test is deemed appropriate?

A. Yes. They're listed -- the details are listed there in the 510(k) summary.

Q. In the summary?

A. Yes.

Q. Okay. And do you -- do you know off the top of your head what the -- what those details are?

A. There's something along the line -- I don't remember how it's worded. There's something along the lines of people who don't have serious eye health issues. I believe that's in there. And then 18 to 40 age range, and there might be others.

Q. Okay. So let's -- let's look at it again

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together. Okay. So if this is the 510(k) summary -- oh, I see. Okay. Here, the intended use, indications for use, this section where it says --

A. I said 18 to 40. I meant to say 22 to 40.

Q. 22 to 40. Okay.

A. Sorry.

Q. Does -- does Visibly market its device to or its service to individuals that are outside of this age range?

A. It allows individuals to take the test outside of that age range, and I'll explain why.

Q. Okay.

A. The -- when -- when the -- so the initial approach was to do the simplest age range first and below -- so we only got approved or we only got cleared, I should say, for 22 to 40 because we were trying to get through the 510(k) process with creating the fewest complications, and there's complications because the FDA considers adolescence to end at 21.

So if you go below 22, there are additional procedures, and then if you would go above 40, there's additional procedures, and particularly there's concerns about, you know, older populations and -- and presbyopia which tends to happen around

40. That's -- presbyopia is nearsightedness -- sorry -- farsightedness.

So in order to be able to operate on some population, not knowing that this whole category was going to become exempt and wanting to make sure that we got the clearance before the -- the enforcement discretion policy expired with the COVID emergency, we -- we got that relatively narrow age range, and then our plan was to after that provide additional data on over 40s and 18 to 21.

Q. Okay. So let me make sure I understand --

A. Yeah.

Q. -- your testimony. The -- the clearance that you've received allows you to market the product as it's called here to folks who are within the age range of 22 to 40, but you're currently marketing the service to those -- to folks as young as 18 and as old as 55, correct?

A. I don't know if I would say we're marketing it to them. What I would say is if -- if you -- if someone who is 19 comes to Visibly's website and tries to take the test, it will let them. If someone who is 56 tries to come and take the test, the test won't let them take it.

Q. Okay. But it will take -- it will let

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someone that is 55 take it, correct?

A. Yes, sir. At least 54. I'm not sure -- is 55 inclusive. I'm not certain of that. 54 for sure.

Q. Okay. Is -- is that -- is that appropriate in your mind given -- given the -- the age range that has been cleared by the FDA?

A. Yeah. So that was the next part of it that -- I wanted to give you the history to understand why we made the decision to go with the 22 to 40 because it's that the explanation related. So then when we got clearance under this new code that -- where the FDA determined that these sorts of devices don't need clearance at all because they're safe, that also made the -- the process of getting the additional age range clearances unnecessary and redundant.

Q. Okay.

A. So our initial plan was to separately clear 40 to 55, but our -- the -- the doctors we've consulted with think that 55 -- you can go up to 55 without any sort of serious risk and -- and down to 18. So we -- we don't have to then get the clearance for the additional age ranges and submit the additional data for -- you know, specifically on people 40 to 55.

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Q. Okay. And who -- does -- who does Visibly consult with for medical decisions like the one you just described?

A. The doctors at OEC and -- and our chief medical officer.

Q. And I don't know. What does OEC stand for?

A. Oh, I'm sorry. Optimized Eye Care. I described them earlier to you.

Q. Okay. Okay. So you rely on the doctors at that company to provide you with advice to the extent that there are medical considerations to be made in how your device is marketed.

A. Not just them. So we -- we do discuss with them, of course, they're using the software so we're always seeking their feedback. If they -- if they were not comfortable using the device on a population, then we couldn't be sending them the information because they wouldn't write the prescriptions, first of all, but, you know, it's good practice to get a lot of opinions. So we discussed -- we discussed with them, and then we also discussed with our chief medical officer, Taylor Tedder.

Q. Okay. And how long has Taylor Tedder been the chief medical officer?

A. Since I want to say September of 2022.
Q. And was there a chief medical officer before that?
A. Not in 2022. I imagine because Steve Lee is an optometrist -- and I'm admittedly speculating now, but because he's an optometrist, I imagine he would have filled a similar role before that --
Q. Okay.
A. -- you know, until 2019 when he left.
Q. Okay. So do you know whether there was a chief medical officer from 2019 to 2022?
A. I don't think there was.
Q. Taylor Tedder --
A. I can -- I can tell you there was not -- from 2021 to the fall of 2022, there was not a chief medical officer.
Q. Okay. Taylor Tedder is what kind of doctor?
A. Optometrist.
Q. And licensed in what state or states?
A. I believe California. Might have more than one license, but I know he went to college in Illinois, so he might be licensed in Illinois too. I'm not certain.
Q. Okay. This just occurred to me. You're the general counsel. But do you have any other lawyers

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that report to you that -- that work for Visibly?

A. Yes.

Q. How many lawyers do you have working under your supervision?

A. One.

Q. And who is that person?

A. His name is Cleve Doty, D-o-t-y.

Q. And where is Cleve Doty licensed to practice?

A. Texas.

Q. Does Visibly undertake any kind of vetting process in determining what eye care professionals or retailers it is going to partner with in -- in providing its vision test?

A. We leave the medical discretion up to the medical professionals that use the software. We don't -- Visibly doesn't second-guess that. We license the software. Now, one thing Visibly does do is make sure that the prescriptions go to a doctor that has an active license in the state and isn't on the exclusion list. So, you know, we don't want to be in a situation where we send the information to someone whose license has expired, say, and -- and then they issue an invalid prescription. So we check that the license is valid, not on the exclusion list,

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but that's the extent of it.

Q. What -- and tell -- describe for me what the exclusion list is.

A. Oh, yeah. There's Medicaid and Medicare, and there's some state ones as well. They have these lists of medical providers that they won't operate with for one reason or another. Could be disciplinary actions or some sort of -- something that has called into question that person's integrity, and so they just -- they maintain a list of people that the government won't do business with, and we use that list to double-check to make sure the providers aren't on there.

Q. Okay. So, now, with respect to the relationship with Optimized Eye Care, how does -- how does Visibly go about that process of confirming that the medical professionals working for that company or working with that company are both licensed and not on the exclusion list?

A. I don't know exactly how, but we -- we get their license information and its expiration date, and that's put into our system, and the software before it determines to send information to a given -- for a given provider, checks to make sure that their license is still valid.

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Q. Okay. All right. So let -- all right. So -- so with respect to medical professionals that work with Optimized Eye Care, the interface that we just walked through earlier where a layperson goes on to Visibly's website, takes the test and that information is sent to Optimized Eye Care, it -- it doesn't just go to that company to then be distributed to the right eye care professional. In fact, your software sends the eye -- the test result directly to a physician affiliated with Optimized Eye Care that is licensed in the state where the -- where the patient is. Is that correct?

A. I can't speak with confidence as to what software does what. I know that -- I know that somehow some software in the system checks the provider's license information to make sure it's still valid, and then somehow that person gets the information. As far as the interworkings of it and who controls what, I couldn't tell.

Q. Okay. But -- but you -- I think you've answered my question about vetting the eye care professionals. You verify that they are licensed, and you verify that they are not on the exclusion list. That's the -- that's the vetting process, correct?

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A. That's what -- that's what Visibly does.

Q. Okay. Now, with respect to retailers that you mentioned for -- for contact lenses, are there retailers that also sell spectacles, sell eyeglasses that Visibly has a relationship with?

A. Yes.

Q. Okay. With respect to those companies, is there some vetting process that Visibly goes through to make sure that those companies adhere to some sort of minimal standards?

A. No. Those companies basically just have a link or an API integration. API is application programming interface. With Visibly -- to use Visibly's vision test but those -- they're not providing any sort of medical service. It's -- someone goes to a website to buy glasses or contacts and takes a vision test to renew their prescription if it's expired, and -- and then gets their prescription.

But the -- you know, from Visibly's perspective, we deliver the prescription to the customer. We provide no suggestion so, therefore, there's no need to vet where they -- where they use that prescription. And when I say Visibly provides it, I should say OEC provides the prescription.

Visibly kind of stands in the middle and facilitates the transfer of information.

Q. Okay. But, I mean -- but you do have, you said, maybe even 50 different retailers. But couldn't you have a relationship that -- that allows for one of their customers to have a link to Visibly's website to sort of start the process that ends up in someone purchasing either contact lenses or eyeglasses, correct?

A. Yeah. But from our perspective, the process ends at the -- you know, when they get the prescription.

Q. Okay.

A. And then if they want to buy glasses from anyone they want, that's up to the customer.

Q. Okay. Has any -- has any retailer that Visibly has had a -- had a relationship with ever been the subject of any kind of governmental enforcement action, any kind of litigation that you're aware of?

A. I would imagine that some of the retailers that we -- we service has been subject to some sort of litigation. But I -- I don't monitor what litigation they're involved in.

Q. Okay. That's not a -- that's not a thing

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that Visibly actively monitors.

A. That's right. Or at least I don't.

Q. Would there be somebody else other than you that would take that on on Visibly's behalf?

A. I -- I would imagine -- I don't think there's a formal policy that I'm aware of. But I would imagine that if someone was doing something that we considered abusive or wrong that we would be disinclined to renew our contracts with them, you know, if they were defrauded customers or something. I'm not exactly sure what you're getting at, but I -- you know, I don't think we -- we don't, as a matter of course, investigate online glasses retailers, although the industry is small enough that we probably -- our sales people and our -- other people on the team likely know something about each of the -- at least the larger players, but...

Q. Since you've been with the company, can you recall an occasion where Visibly made a determination -- Visibly or Opternative made a determination to sever a relationship with either an eye care provider or a retailer because of some -- some either professional disciplinary action being taken against the -- a provider or some law enforcement or regulatory investigation or action

taken against a retailer?

A. No.

Q. Are you aware of any circumstances in which a Visibly customer reported -- either reported or alleged some sort of adverse health consequence or health event related to or arising from use -- the use of Visibly's software?

A. No.

Q. Does Visibly have any sort of process for tracking or storing customer complaints related to the online vision test?

A. Yes. Are you familiar with a quality management service or QMS for short?

Q. Not particularly, no.

A. There's a fairly developed ISO standard for medical devices that need to use this QMS service, and part of that QMS service is maintaining observation and analysis of complaints about a medical device in the market, so we have a developed policy for that at a high level. It consists of getting feedback from wherever we find it. We get the feedback, and we analyze it for complaints that might require some sort of fix or some sort of improvement to ameliorate the problem, and the main sources where that feedback comes from are from our

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retail partners, we hear things, from -- we have a survey at the end of the test where we ask for feedback, so people might put a complaint in there, and online reviews of the test. Those are typical ways we get information.

Q. Okay. And is there some requirement that that information or the analytics associated with that information has to be reported externally periodically?

A. To -- yeah. So there's -- in certain circumstances, certain circumstances that have never arisen, if there is a serious issue, then we would have to report it. That's never happened. Issues we have found -- excuse me -- are more along the lines of, you know, using the voice test. There's some background voice, and it didn't register. It didn't register the person's voice correctly or there was a difficulty in syncing the phone with the test. Some of them -- more unusual browsers, there have been issues. So there's never been the sort of thing that would been reported. It's been technical fixes like that that we improve iteratively over time.

Q. Okay. So -- all right. At present how many states is Visibly operating in?

A. 30-something.

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Q. Okay.
A. Approximately 35.
Q. And are -- the states where Visibly is not operating, other than South Carolina, are they states -- are they not -- is the company not operating in those states because of some regulatory issue or what -- what are the reasons why Visibly is not operating in those states?
A. For the most part it's some regulatory issue. Other states, with laws analogous to South Carolina. Not in every instance, though. I think for a while we weren't operating in a state because we just didn't have any customers there or didn't have any licensed professionals there briefly. But, yeah, for the most part it's regulatory issues.
Q. Okay. All right. So just going back to the FDA process, just -- I mean, just looking at information that seems to be publicly available, I just want to make sure I'm clear on a couple of details. The -- I guess originally Opternative registered the -- what we'll call the device, the software interface as a class one device. Is that correct?
A. Yes. Back in 2016 or thereabouts.
Q. Okay.

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A. That sound correct. I don't remember if it was class one or class two, but I would think -- I would think it was class one because when it was ultimately classified as with the 510(k) clearance.

Q. Okay. But the -- but in October of 2017 is when the company received the warning letter indicating that the FDA thought at that time that it was a class two device; is that correct?

A. What I can say from memory is that's when we learned -- well, that's when we -- so that's when we got the letter saying we needed to go through a clearance or approval process, and I imagine that's partially because they determined it was class two, so that --

Q. Okay. And is it your understanding a class one device is a low risk device that does not require any kind of pre-market clearance; then a class two device is considered something that has enough inherent risk associated with it that it needs the -- that pre-market clearance from the FDA?

A. I think it's more complicated than that. I -- partially because we needed clearance and we're determined to be class one. So it's -- it's not that simple.

Q. Okay. Okay. It's -- I have -- I have made

it more simple than it really actually is in my -- in the way I formulated my question, correct?

A. I think so.

Q. Yeah. Okay.

A. I'm -- I -- it's been a while since I have had to look at the class one, two, three, distinctions, and I can't precisely remember the borders between them, but I do recall that the borders that determine which class those are in are a little indeterminate.

Q. Okay.

A. Reasonable minds could disagree sort of thing.

Q. Okay. Does -- does Visibly have a -- a contractual relationship with a contact lens company known as Hubble?

A. Yes. Yes.

Q. Okay. Are you aware of any issues with the way Hubble operates and any -- any allegations that it fails to verify prescriptions, anything like that?

A. Yes. I recall seeing a news article that Hubble -- I can't remember the details of the prescription or of the issue, but I think there was some issue with them and that verification process of prescriptions and compliance with the FTC rule. Is

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that what you're referring to?

Q. I -- you know more about it than I do probably.

A. Yeah. I recall seeing something -- some sort of allegation and -- yeah, I don't know if I'm remembering that it had to do with prescription verification or if I'm getting that from the question, but there was some allegation against Hubble that I recall seeing.

Q. Okay. And -- but has -- has Visibly changed its relationship with Hubble in response to any -- any allegation by anyone, or is it -- does it still maintain the same relationship with Hubble today as it -- as it always has?

A. I remember looking into that and thinking that there was nothing there that prevented our -- the use of our software.

Q. Okay.

A. But I don't remember precisely what the allegations were. I just remember thinking that it -- there was no reason they couldn't continue using our software.

Q. All right. So earlier we talked about all of the litigation that you're aware of that Visibly has been involved in, and then we talked about the

civil investigation initiated by the attorney general of the state of Illinois. Are there any other regulatory or -- or other law enforcement actions currently pending that -- that involve Visibly?

A. No.

Q. And other than what we've already talked about, have there been any other regulatory or law enforcement proceedings lodged against Visibly?

A. Yes. There was a issue in -- I think it was 2016 in Michigan. Michigan has a rule that requires the -- the prescriber of contact lens to -- I can't remember the exact wording. But it's something along the lines of assess the physiological fit, and some doctors had used Visibly's software to issue contact lens prescriptions in Michigan, and Visibly got a letter from the board of licensing or some sort of state entity in Michigan saying not to make the software available there. And there was a back-and-forth, and ultimately we agreed that the software would not be made available for contacts but could be for glasses because the requirement to assess physiological fit or something along lines did not require -- did not apply to glasses.

Q. Okay. And other than that in Michigan and the other action taken by the attorney general for

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Illinois, are there any other investigative or regulatory or law enforcement proceedings that you're aware of that have been initiated against this?

A. I don't know what you mean by initiated. Those are the only formal ones. Now, there were -- they have -- we have received questions over the years before I started about how the software works and what it does and some -- from a number of states, and I recall -- and some of this -- they didn't go after Visibly, but they went after -- or they were asking questions about -- you know, asking questions to doctors that used Visibly, and medical boards and things like that were asking questions, and then -- and there were -- you know, for the most part, it was just asking questions, providing answers, and then, you know, nothing really happened. Michigan was the only one where there was a formal agreement.

Q. Okay. And was there any kind of a fine or monetary aspect of the agreement reached with Michigan?

A. I don't believe so. There was in 2016. I remember reviewing -- so I've reviewed the agreement, and I don't recall there being any fine.

Q. Okay. Has Visibly incurred any other fines from any -- any other regulatory body that we have

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not already discussed?

A. I don't believe Visibly has ever incurred a fine from a regulatory body.

Q. Okay. Or a law enforcement body.

A. Or a law -- yes, I don't -- as far as I know, Visibly has never paid a fine.

Q. Okay. Now, we talked about it paying $500,000 as a part of the settlement reached with the state of Illinois, but do you not consider that a fine?

A. No. I consider that the cost of avoiding litigation.

Q. Okay. Has Visibly incurred the cost of avoiding litigation in any other circumstance that we haven't already talked about?

A. No. I'm only aware of two settlements that Visibly has ever been the payor in. The one that you just mentioned with the CID in eleven states and the -- the issue with Steve Lee, the defamation case we mentioned before.

MR. SHEALY: Okay. All right.

Mr. Stonedale, I think I am fresh out of questions. I will pass the baton to see if Mr. Matthews has some questions for you.

MR. MCNAMARA: Not to interrupt, but you

said you wanted to fix the one exhibit that was truncated.

MR. SHEALY: Yeah. I got -- I have to take a break and go find my secretary, so -- but, yeah, before we close, I will definitely do that.

MR. MCNAMARA: Okay.

- - -

EXAMINATION

- - -

BY MR. MATTHEWS:

Q. Okay. Do you go by Mr. Stonedale?

A. I usually go by Joel, but --

Q. Okay.

A. -- happy to go by Bob if you like.

Q. Well, Joel, I wanted to ask that question because I noticed on your -- your -- your -- your biography on your website, you're referred to as "they." Is that something that you prefer as well? I want to make sure I'm respecting your...

A. I don't know why that is. I -- I use the he/him pronouns.

Q. Well, I got to tell you. It was a little confusing because your bio seemed to indicate that you were not necessarily attuned to that, that you had been with the Texas Attorney General, and you

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had -- I think you had written things for The Daily Caller. Is that right?

A. Yes. I --

Q. I don't think The Daily Caller uses pronouns, not like that. So just wanted to make sure I was zeroing in on your preferences.

A. Thank you for the consideration.

Q. Not a problem.

Listen, you indicated that -- I believe that the -- that the vision test states that you should not take the test if you have not had a comprehensive eye exam every two years.

A. I believe that's right.

Q. Okay. I'm looking at that test right now on the internet, and I don't see it. Where could I find it?

A. I believe it's one of the disclaimers that pops up during the -- I can't tell you exactly what screen it's on.

Q. Well, there's a -- there's a little -- there's a whole set of articles on the Visibly website that says about the vision test. And it's got all sorts of discussion about how does the online vision test work, and do I need a previous prescription to take Visibly's online vision test?

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That sort of thing.

And you essentially say, yes, Visibly's online vision test is a prescription renewal service, so the doctor will want to know our previous prescription so they will know what they need to renew for you.

And there's a -- you know, Kirby had already talked to you about, you know, the ages you're allowed to do that. I see that your website says we enforce an age of 18 to 55 our participants on our online vision test, and you explain why if you're over 55 you -- you do that. You say we recommend that those over 55 see a doctor in person to ensure that any of these health conditions that we acquire as we get older are not missed.

Does that -- I know you're not looking at it because I'm looking at it right now. Did you author that?

A. No.

Q. Okay. Who would have authored that warning that you give to your customers?

A. I don't know. It -- I don't know how long -- I don't know when that was written.

Q. Well, I'm -- I'm least likely to be voted to be technically competent. However, during the course

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of this deposition, I went on the Visibly website, clicked on, you know -- it's under the heading about the vision test. And it's Visibly frequently asked questions, then just your -- about online vision test and about the vision test. And I'll read this into the record.

And the question -- it's under the I guess frequent asked question would be why do I have to be between 18 to 55 years old to take the vision test? And it says it was -- it's from the third paragraph. "Once we reach the age of 55, there's an increasing likelihood of eye and health conditions, and our eye needs go beyond just how well you're seeing, period. Because we want to ensure that our patients' health is at its best, we recommend that those over 55 see a doctor in person to ensure that any of these health conditions that we acquire as we get older are not missed, period."

And I know you're not looking at it right now. You're just going to have to trust me that I read that appropriately. We can always print out a copy of it if we need to.

And my question to you is: Do you -- are you aware who in Visibly would have been reasonable for approving the content of that directive that you give

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to your patients?

MR. MCNAMARA: Objection.

THE WITNESS: At one point it would have been me. It may have also been the chief medical officer.

BY MR. MATTHEWS:

Q. Well, you know, it's funny you mention that. I was going to just say out loud that sounds to me like medical advice, not legal advice. You know, we're not doctors here. So is that something you would have trusted one of your physicians to author?

A. I don't know who authored it.

Q. Well, I know -- yeah, you've told me you don't know who especially doctored it, but, you know, Joel, I know unless I'm missing my mark, you're not a doctor, correct?

A. Correct. I'm not.

Q. Right. And neither am I. And if you're working at visibility and you're a physician and I think you've indicated that at some point you may have approved some of the content that's on your responses to frequently asked questions; is that right?

A. I have approved some of those changes as they've happened over the years.

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Q. Okay.
A. I don't recall the specific.
Q. Even though you don't have a current -- well, I'm putting words in your mouth. Do you have a current recollection of who would have approved that part of what you tell your patients or what I -- the part that I just read?
A. I do not know who authored that or who approved it. I do not specifically recall.
Q. Well, let me ask you the question like this then: Can we agree that that sounds to a layperson like medical advice?
A. No, I don't think so.
Q. Oh.
A. I think it sounds like --
Q. Go ahead, please --
A. Oh, I think it sounds like an explanation of Visibly's reasons.
Q. Okay.
A. It's -- yeah.
Q. Well, let me ask the question like this. I wouldn't know from anything that someone over 55 it would be proper to recommend to someone over 55 to see an in person -- a doctor in person to ensure that health conditions related to your eye as we acquire

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are not missed. I wouldn't know anything about that. Is it fair to say that you don't know anything about that, why it's 55 or 50 versus anything else?

A. We have -- I have been told by the medical professionals we work with and -- that it is -- the risk of various eye diseases goes up at approximately 55, and --

Q. Okay.

A. And I -- I understand that's why we don't -- you know, we avoid offering the test to those at that age for that reason.

Q. Okay. Do you recall that being Dr. Hillman?

A. I'm sorry?

Q. Was that Dr. Hillman telling you that?

A. I have --

Q. Isn't he the guy that owns the Optimized Eye Care?

A. I have heard -- I've heard Taylor Tedder say that.

Q. Okay.

A. And I believe that opinion has also been attributed to Dr. O'Brien who we often ask about these sorts of things.

Q. Okay. What's Dr. O'Brien's first name?

A. Chris.

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Q. Okay. Are they at all connected with Optimized Eye Care?

A. Yes.

Q. Are they owners of the some type?

A. Dr. O'Brien owns Optimized Eye Care of California, which is a separate entity.

Q. Okay.

A. And he also is a contractor with Optimized Eye Care of Illinois.

Q. Okay. How about Taylor Tedder, is he an owner of Optimized Eye Care in any fashion?

A. No. He's a Visibly employee or contractor now.

Q. Okay. And does he have a job title?

A. Chief medical officer.

Q. Okay. Good. Thank you. I missed that. I'm sorry.

So tell me this: Do you think it's likely that Dr. Tedder as your chief medical officer would have received and approved the statement that I read to you into the record?

A. I can't say for sure.

Q. Okay. Well, tell me this. If you think he disapproved of it, you better bet that that wouldn't be on your website, right?

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A. I would think he would have -- if he saw it and disapproved of it, I think he would have asked someone to change it.

Q. Right. So we have no information right now that either Dr. O'Brien or Dr. Tedder have any problem with the statement that because we want to ensure our patient's health is at its best, we recommend that those over 55 see a doctor in person to ensure that any of these health conditions that we acquire as we get older are not missed.

Sounds reasonable, right?

A. I cannot recall who looked at that before it went on the website.

Q. But you certainly have no objection to it, right?

A. I don't have it in front of me. But it doesn't sound to me like medical advice. My understanding from when you read it was that it was explaining Visibly's positive and reasoning. For context --

Q. Well, it -- I think you're right. And I don't mean to cut you off, but I want -- I also don't want you to guess. Is -- the little paragraph that I just read is responding to a frequently asked question that is stated as follows: Why do I have to

be between 18 and 55 years old to take the vision test?

So this is -- again, I'm not trying to ambush you. This is Visibly's explanation of, hey, this is why we, you know, restrict our -- the ages in which you can take the test online. Okay? And it has an explanation about, "For those under 18, we want to ensure that parental consent is given. When taking the vision test to protect our customers, we require that the minimum age of our participants is 18 years old."

Now, that is something that you probably did say, right? That's just a legal issue. That's not a medical issue at all.

A. Say that again.

Q. It doesn't strike me at all that that's medical advice. You're not talking about anybody's eyeballs. You're talking about, hey, if you're not 18 or older, we have a concern about parental consent, and that's a legal issue, not a medical issue, right?

MR. MCNAMARA: Objection.

THE WITNESS: It could be in certain circumstances.

BY MR. MATTHEWS:

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Q. Right. And you're better safe than sorry. You don't want people who are under 18 taking your test because there's a parental consent issue there, right?

A. I'm not familiar with -- enough with that to say.

Q. Well -- well, then why do you have it here?

A. Why do I have what there?

Q. Why do you have your -- why do you have the prohibition of people under 18 taking your test if you're not concerned about legal issues and parental consent?

A. You're asking why Visibly does not let -- take -- let minors take the test?

Q. Right.

A. That has -- that has been a practice since before I started. It was not my --

Q. Okay.

A. -- recommendation, so I've never looked into whether I thought it was a good idea. It strikes me as safer to avoid those issues with minors.

Q. No. I agree with you. I think you're right.

A. But I -- I've never -- I've never been asked to look into that.

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Q. Okay. Cool beans.

A. For context on the FAQ, we have this complaint process I mentioned earlier where we gather --

Q. Right.

A. -- all the complaints, and --

Q. Okay.

A. -- one of the complaints we frequently see, it's not really a complaint about the device, but one of the things we see is people are dissatisfied when they take the test and -- or they try to take the test and they can't because they're over 55. So some of the negative reviews we've seen have been that this test isn't allowed for people over 55, so I suspect that's the motivation just connecting the dots, knowing that this has been a source of complaint. I suspect it's there to address -- to explain to people why that is.

Q. Well, tell me this. As a business model, it was okay for people in your view for people -- it was okay for people over 55 to -- it was okay in your view for them to take the test. And when I say your view, I don't mean Joel. I mean Visibly. If it was okay in your view that it posed no health concerns for someone over 55 to take the test, you would be

quite pleased for them to do so, right, because that's just money in your pocket, right?

A. I don't know. That's -- that issue hasn't come up.

Q. Huh. Well, let's use an example. I am over 55, not by a lot, thank you, but I am over 55. I -- I -- as you can see, I wear glasses. And I hate eye exams. I hate people putting stuff in my eyes. I know it's important. I know you got to do it. I just hate it. I would love to be able to get a new prescription without people sticking stuff in my eyes all the time. But if I tried to use this, I wouldn't be allowed to because even though you would otherwise welcome me as a customer, I'd be a paying customer, because you guys have a concern that it's better if I see a doctor in person because you don't want me to miss out on getting a health concern identified. Is that fair?

A. That has -- qualifies as one of the many reasons or not --

Q. Okay.

A. I won't say many. I don't know if there's other reasons. What I would say is one concern with over 55 is there is a higher probability of eye diseases, eye -- other eye health issues other than

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visual acuity --

Q. Okay.

A. -- and one of -- lost my train of thought.

Q. I'll give you a minute.

A. Yeah.

I forgot what I was saying. I'm sorry.

Keep going.

Q. It happens to everyone. Please don't -- please don't feel ill at ease about that.

A. Yeah.

MR. MATTHEWS: Actually, Joel, thanks for being with us. I'm actually done with my questions. Thank you for being with us.

And, Kirby, I didn't know if you or anyone else has any follow-ups?

MR. SHEALY: Only follow-up I have concerns those exhibits. I think I've got them queued up now as separate documents. So let me show my screen.

THE WITNESS: I'm sorry. Could I correct something I just said? I remember what my train of thought was that I had lost. Would that be okay?

MR. SHEALY: Sure.

BY MR. MATTHEWS:

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Q. Absolutely. And at your pleasure.

A. Thank you. Yeah. The -- what I wanted to say was there -- we haven't addressed the issue of what other reasons there might be to not use over 55s. I believe some other online vision tests do, but -- so because we haven't addressed it, I don't want to speak to that, but, you know, one -- one thing I am aware of is that the standard of care as published by the American Ophthalmology Association or whatever trade body that is that represents ophthalmologists --

Q. Right.

A. -- does recommend frequent appointments starting at age 55, and I imagine that would be a source of that advice, and because we haven't gone past that, we haven't evaluated other issues that may arise.

Q. Well, as it happened, Joel, I don't know if this is a question, but just to give you some comfort --

A. Uh-huh.

Q. -- in your -- in your own motion for summary judgment, you state that the American Academy of Ophthalmology recommends that patients from age 55 to 64 have an eye health exam once every one to three

years, that from age 41 to 40 -- or 54, they have the examination once every two to four years. So that -- is that -- that's from an affidavit by Dr. O'Brien. So is that -- is that what you were thinking of?

A. Might be.

MR. MATTHEWS: Okay. Okay. Once again, I'm done.

Kirby, anything else?

MR. SHEALY: Yes.

- - -

REEXAMINATION

- - -

BY MR. SHEALY:

Q. So -- all right. I'm going to show you -- do you see the document on my screen that's dated August 12, 2022?

A. Yes, sir.

Q. Okay. And do you see it's two pages in length?

A. I believe so.

Q. Okay. And is it your understanding that this -- this letter was the mechanism by which you Visibly learned that it had received section 510(k) pre-market clearance for the Visibly digital acuity product?

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A. Against, my understanding is this letter is what formally recognizes that decision. I don't know -- I think we -- we may have been told on the phone or something with our contacts with FDA that it was likely to happen. We may have known a day or two early --

Q. Okay.

A. -- something like that, but this is the formal notification.

MR. SHEALY: Okay. All right.

So, Madam Court Reporter, I, I think, earlier indicated that this letter combined with another letter would be Exhibit 3. What I'd like to do is just have this letter by itself be Exhibit 3 to the deposition. Okay?

THE STENOGRAPHER: Yes, sir.

MR. SHEALY: Okay. And I'll send it to you.

- - -

(Letter Dated 8/12/2022 marked Defendants' Exhibit Number 3 for identification.)

- - -

BY MR. SHEALY:

Q. And then Mr. Stonedale, let me pull up the other one. The -- the September 30, 2023, letter I'm

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now sharing on my screen, do you see it?

A. Yes.

Q. Okay. And this is, again, just the one-page letter correcting the August 12 letter just to correct a typo, correct?

A. Seems to be.

Q. Okay. But these two letters together, am I correct, constitute the formal notification of the section 510(k) clearance for Visibly's digital acuity product, correct?

A. Yeah. I think there may be some additional documents too. They're definitely part of it. There's the 510(k) summary, which is --

Q. Which we've already looked at.

A. Yeah. That lays out the scope. I was going to say, I think there's more than just this, but, yeah, this is the notification, the formal notification.

Q. Okay.

A. Yeah.

Q. All right. This -- I'll have this letter, the September 30, 2022, letter, marked as Exhibit 4 to your deposition.

- - -

(Letter Dated 9/30/2022 marked Defendants'

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Exhibit Number 4 for identification.)

- - -

MR. SHEALY: And I'll have that -- both of those sent to you, Ms. Osborne, when we conclude.

And, Mr. Stonedale, I have no further questions for you. Thank you for your time today. Please answer any questions that your counsel may have.

- - -

EXAMINATION

- -

BY MR. MCNAMARA:

Q. Just a couple of quick points of clarification before we wrap up. You were talking to Mr. Shealy about the FDA approval process and all of the feedback the FDA gives and the back-and-forth. Do you remember that?

A. Yes.

Q. And I just want be clear about the nature of the feedback. Is the FDA giving feedback on the design of the device, or is this feedback about something like the design of the clinical studies you're going to provide to prove whether the device works?

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A. I -- I think they might in some cases offer feedback about the design of device. In our case, the feedback that was offered that I'm aware of was design of the trails. I know in the 510(k) clearance they provided feedback about design of the trials, number of the participants, things along -- you know, what statistical tests to use. They also provided feedback about the wording of disclaimers. But I -- I don't think it would be outside FDA practice to in some cases offer suggestions about the -- the design of the device itself.

Q. Okay. They talk about the design in some cases, but that wasn't Visibly's process?

A. Yeah. Our -- most of your interaction anyway, if not all of it, had to do with the design of the trials and labeling. They like to -- they like to provide feedback on labeling requirements which in some cases might be a feature of the device, depending on...

Q. Okay. You also talked at some length with Mr. Shealy about the settlement initiated by the Illinois Attorney General. Do you remember that?

A. That's right.

Q. One of the provisions you talked about was a requirement that Visibly disclose that it's not a

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comprehensive eye exam and urges customers to get a comprehensive eye exam. Am I summarizing that right?

A. Yes. That's what we talked about.

Q. Did Visibly make those disclosures to its customers before the settlement?

A. Yes.

MR. MCNAMARA: Okay. Nothing further.

MR. MATTHEWS: Okie dokie. Thank you so much.

Yep. Thanks.

MR. MATTHEWS: Thank y'all.

- - -

(Witness excused.)

(Videoconferenced deposition concluded at 12:45 p.m.)

- - -

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STATE OF SOUTH CAROLINA COUNTY OF RICHLAND Opternative, Inc., Plaintiff, v. South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation, Defendants, South Carolina Optometric Physicians Association, Defendant-Intervenor.	IN THE COURT OF COMMON PLEAS FIFTH JUDICIAL CIRCUIT Civil Action No. 2016-CP-40-06276

PLAINTIFF'S MOTION TO SUPPLEMENT THE SUMMARY JUDGMENT RECORD

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Plaintiff files this motion as an update to its August 7, 2023 motion to strike Defendant-Intervenor's motion for summary judgment and inadmissible evidence. The relevant procedural history is covered in that motion. *See* Mot. Strike 2–3. This motion relates to the portion of Plaintiff's motion requesting that the Court strike an affidavit from Dr. Mark Robinson, which Defendant-Intervenor SCOPA submitted in opposition to Plaintiff's motion for summary judgment despite repeatedly failing to produce Dr. Robinson for deposition.

Plaintiff still requests that the Court strike Dr. Robinson's affidavit from the summary judgment record for the reasons stated in Plaintiff's motion to strike. *See* Mot. Strike 3–4. However, Plaintiff was recently able to track down Dr. Robinson—at Plaintiff's own expense—and depose him. In his deposition, Dr. Robinson makes similar concessions to those SCOPA's other expert, Dr. Shipp made in his, including:

- That there are circumstances under which it's safe and beneficial to prescribe corrective lenses for patients in between more comprehensive eye exams. *See* Robinson Dep. 17:8–13.

- That a patient does not need a comprehensive eye exam every single time they interact with an ophthalmologist because whether a comprehensive eye exam is warranted depends on the patient's condition and the last time that patient had such an exam. *See* Robinson Dep. 55:14–56:21.

- That an ophthalmologist who followed the American Academy of Ophthalmology's recommendations on the frequency of comprehensive eye exams would not be "doing anything wrong medically." *See* Robinson Dep. 38:11–39:2.

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- That he has personally prescribed corrective lenses for patients in between comprehensive eye exams without first performing a comprehensive eye exam in that same appointment, even though those patients could have had hidden eye diseases. *See* Robinson Dep. 24:23–30:12, 59:13–19.

- That he has personally used unlicensed physician assistants or extenders to test patients' vision and even to perform parts of a comprehensive eye exam in his absence. *See* Robinson Dep. 36:9–37:17.

- That an ophthalmologist who prescribed corrective lenses in between more comprehensive eye exams based on visual acuity information collected by a physician extender would not be violating any medical standard of care. *See* Robinson Dep. 40:17–42:9.

- That most people's vision does not change over the course of their lives. *See* Robinson Dep. 43:24–44:24.

- That he has no concerns about patients using online tools like Visibly to renew their lens prescriptions in between more comprehensive eye exams as long as they actually obtain those exams. *See* Robinson Dep. 74:23–75:18.

- That his concern about Visibly is that patients might not follow up and get those comprehensive eye exams—a concern he agrees would apply to any kind of limited care an ophthalmologist might provide (including in-person care), and that would even apply to all other types of medical practices (not just eye care). *See* Robinson Dep. 79:3–81:17.

- That comprehensive exams to detect hidden eye diseases are no more important than comprehensive exams to detect hidden diseases in all other areas of medicine (e.g., skin exams to detect skin diseases). *See* Robinson Dep. 82:5–83:9.

- That his concern about patients using telemedicine to obtain prescription lenses would apply equally to patients using telemedicine tools to obtain any other eye care (e.g., eye drops). *See* Robinson Dep. 83:14–84:3.

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- That he is not concerned about patients obtaining improperly fit contact lenses through Visibly because Visibly's doctors only renew prescriptions for contact lenses that were fit during an in-person visit, and contact lens fits don't typically change. *See* Robinson Dep. 89:1–91:11.

- That he is not aware of any evidence of population level harms to patients who have used Visibly's software over the past 6 years. *See* Robinson Dep. 76:7–25.

This recent testimony meaningfully informs the Court's evaluation of the testimony in Dr. Robinson's years-old affidavit that SCOPA submitted in opposition to Plaintiff's motion for summary judgment. Accordingly, should the Court deny Plaintiff's motion to strike Dr. Robinson's affidavit, Plaintiff moves to supplement the summary judgment record with a copy of Dr. Robinson's deposition transcript (attached as Exhibit 1) so that this Court—and any appellate court—have the benefit of a complete factual record.

October 2, 2023

Respectfully submitted,

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EXHIBIT 1

STATE OF SOUTH CAROLINA
COURT OF COMMON PLEAS
COUNTY OF RICHLAND
OPTERNATIVE, INC.,
Plaintiff,
vs. CASE NO. 2016-CP-40-06276
SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS, SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION,

Defendants,

SOUTH CAROLINA OPTOMETRIC PHYSICIANS ASSOCIATION,
Defendant-Intervenor.

DEPOSITION OF: MARK E. ROBINSON, M.D., M.P.H.
DATE: September 6, 2023
TIME: 9:32 a.m.
LOCATION: Prisma Health Ophthalmology
4 Medical Park Road
Columbia, SC 29203
TAKEN BY: Counsel for the Plaintiff
REPORTED BY: TRISHA M. THOMAS, RPR
(Appearing by videoconference)

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MARK E. ROBINSON, M.D., M.P.H.
being first duly sworn, testified as follows:

EXAMINATION

BY MR. WINDHAM:

Q. All right. Well, good morning, Dr. Robinson. My name is Josh Windham, and I represent Visibly, Incorporated, which was formerly called Opternative, Incorporated, the Plaintiff in this case.

How are you doing today?

A. I'm doing well. Thank you. How are you?

Q. Good, good.

A. Good.

Q. I'm thankful that you're here today and that we finally get to meet you.

Do you understand that you're here today to testify in a lawsuit challenging what's called the Eye Care Consumer Protection Law in South Carolina?

A. I do.

Q. Okay. And do you understand that you're here to testify regarding, at least in part, an affidavit that you authored in this case?

A. I do.

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Q. Okay. And is there anything, you know, that would prevent you from testifying truthfully today?

A. No.

Q. You're not on any drugs or medications that would impact your ability to testify?

A. No, no. Thankfully not.

Q. All right. And have you ever been deposed before?

A. I have.

Q. Okay. I may ask you about that in a moment, but is it fair to assume you kind of understand how depositions work?

A. I think so. It's been a little while, so if there's any pertinent points you want to refresh me on, that would be fine too.

Q. I'd be happy to. So the basics here are that I'll ask a question, you'll provide an answer, and the court reporter, Ms. Thomas, will try to get everything down. What that means for us today is that our goal is going to be to speak clearly for the court reporter so that she can understand what we're saying. Does that make sense?

A. Uh-huh. It does.

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Q. So no nonverbal answers, right? Sometimes we make sounds, as opposed to using words, and I think, you know, it's most helpful for her if we can articulate what we're thinking in words. Does that make sense?

A. That makes sense.

Q. Okay. And then, you know, I'm going to try to let you finish your answer when I ask a question. Sometimes I get excited and I'm bad at that, so I'm going to do my best today. And then on the other -- on the other end of that, please let me finish my question before you provide an answer. Does that make sense?

A. Sure.

Q. Okay. And, you know, an attorney may object today to a question that I -- that I pose. You know, please still provide an answer unless you're instructed not to -- not to do that.

A. Okay.

Q. And let me know -- ultimately, you're going to be the master of when we take breaks here. You know, if you get tired, feel free to say you need a break, and just -- you know, finish your answer and let me finish my question and then we can kind of go off the record and take a little

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break if we need to use the restroom or get lunch or whatever. Hopefully it doesn't go that long.

A. That's right.

Q. All right. Does that make sense?

A. That makes sense.

Q. Okay. Very good. All right. Well, with all that said, did you do anything to prepare for today's deposition?

A. I did. So I looked over the Visibly website. I looked over the statement that I made back in, I think, 2017, was it, that I -- I'm not seeing the date now. I looked -- I tried to find if the American Academy of Ophthalmology had a statement about this, and it looks like the last thing they put out was 2014 and then a news release in 2015. I looked over a systematic review of "Improving Access to Eye Care" as well, which that may not be as relevant but...

And I spoke with Kirby Shealy, the lawyer on the other side. I spoke with him last night, just going over deposition and -- and those sorts of things, sort of our case.

Q. Okay. In terms of that list of documents that you reviewed, we may ask you to produce -- I don't know if you saw -- and I'll

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introduce it as an exhibit in a moment. In fact, it might just be easiest to do that right now. Let me pull it up. By the way, do you have access to the Veritext exhibit sharing portal?

A. I do, yeah. I logged on to that -- when I logged on a few days ago, there weren't exhibits in there, at least not that I found, anyway, but...

Q. Okay. And there aren't going to be until I introduce them.

A. Oh, okay. Fair.

Q. Let me try that now, and let's see if it's working for everybody. Just give me one moment.

A. So should I try to log into that too, I guess?

Q. Oh, yes. Let me give you a moment to do that. Just log into that, and the way this will work, I think, is that if I introduce an exhibit in the portal it should show up on your screen as a marked exhibit.

A. Let's see. I see. Access Veritext.

Q. And while you do that, I'm going to introduce what's been marked as -- or, you know, what's going to be marked as Plaintiff's Exhibit 1.

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(PLF. EXHIBIT 1, Subpoena in a Civil Case, was marked for identification.)

BY MR. WINDHAM:

Q. Okay. It should be introduced. Let me know if you see it when you're in the portal.

A. Good. Yeah. I've just forgotten my user name. Let's see.

Q. Okay.

A. I remembered the password but not the -- sorry about that. I should have made --

Q. Yeah. Take a moment.

A. Let's see. I think they told me my user name on one of my e-mails, so...

Q. And if you end up having trouble, I can always just share my screen.

A. Okay. Thanks. Let me get one more. All right. Let's see. Where were -- okay. Let me just try one more. Maybe it was just my name was the user names.

Yeah. Maybe, if you don't mind just sharing your screen, that would be great.

Q. Sure. Yeah.

A. Sorry.

Q. I'd be happy to do that. No. No worries.

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A. I was so proud I logged into this this morning I didn't double-check that I could still get into the Veritext.

Q. Not a problem.

Okay. Do you see what I've got there on the screen?

A. I do. State of South Carolina. Yes, I see it.

Q. Okay. And I'm going to scroll through this. It's just a few pages. And I just want to ask if you've seen this document before.

A. I have, yes. That was just requesting that we come to this meeting, I believe.

Q. Okay. So you've seen it. This is the deposition notice in this case -- or the subpoena asking you to attend this deposition. And if we scroll down to the last page there, Exhibit A, have you seen that before?

A. You know, I didn't pay attention to that last thing. It says please provide documents I relied on when writing my deposition -- or my statement.

Q. That's right. And then the second line there has to do with evidence that, you know, you contend supports the assertions in your affidavit,

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which we can get to in a moment, the affidavit itself.

A. I see. Okay. Yes. I can -- yeah. I did not notice that at the bottom, so I apologize for that.

Q. Okay. And I may circle back to this in a moment, but what I just want to ask about right now is you mentioned reviewing a few documents before attending this deposition.

A. Uh-huh.

Q. If we asked you to produce those documents to us, would you be able to do that?

A. I would, yes.

Q. Okay.

A. Yeah.

Q. All right. And you mentioned speaking with -- I'm going to take this exhibit off the screen for now. You mentioned speaking with Mr. Shealy before today. Can you describe the nature of your conversation?

A. Yeah. Just about this case and talking about a deposition, what -- the things that I would -- well -- sure if they asked me what I would probably be asked. We talked about, I guess, what the -- that it was an issue of constitutionality

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and, I guess, in challenging that, that Visibly would be looking for, I guess, is this arbitrary or not or is there some medical grounds why this law is -- is protecting people, that that would maybe be the main focus; that I am not to receive coaching during the deposition. Those were the main things.

I think I asked if I was supposed to have reviewed any documents ahead of time, and he said no. I think that was mostly -- there was probably a few other details but...

Q. Okay. So -- and this was last night?

A. Uh-huh, yes.

Q. Okay. So last night Mr. Shealy told you not to review any documents before the deposition?

A. No. Let me clarify. I asked him -- I had told him I had gone onto the Veritext and that that deposition file was empty, and I was wondering if that was appropriate. He said that you would probably introduce documents here and there wasn't anything I had to review on -- on Veritext. He did say I should prepare and look at documents I thought were relevant, but --

Q. Okay.

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A. -- that there were not -- that there weren't documents already displayed in the Veritext that I was supposed to review. I was concerned because I received that e-mail earlier and logged on and the folders were empty.

Q. Got it. And those will be introduced throughout this deposition, just to clarify that for you.

How long did you talk with Mr. Shealy for last night?

A. Maybe 30 minutes.

Q. And besides the points that you just mentioned, did he tell you what to say in any particular way?

A. He did not. He sort of asked me what -- we kind of went over the main points, and I told -- he asked me what I thought. I told him -- again, so just -- which maybe is getting into things we would say later -- that the issue is it's a partial eye exam.

He asked me if I had any trouble with the technology itself. I said no, not that -- not that I knew of and -- and he -- and he said yeah, that that wasn't their case, that there was a problem with the technology itself.

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Yeah. So I think -- I think he did a good job of asking me what -- what my points were but didn't -- didn't tell me what -- what to say.

Q. Okay. That's what I'm getting at. So Mr. Shealy didn't tell you what to say during this deposition one way or the other?

A. No.

Q. Okay. And we'll circle back to some of the stuff you just mentioned. As you noted, it's going to come up throughout the deposition today. I do want to ask about one thing you just mentioned, though, which is --

A. Sure.

Q. -- you used the word trouble, did you have any trouble with the eye exam. What do you mean by that? I'm sorry. Trouble with the technology. What did you mean by that?

A. Oh, about whether their -- their refractive services were accurate or not.

Q. Okay. And so by saying you didn't have trouble with the technology -- just help me understand you. You're saying you didn't have a concern that it was inaccurate?

A. Right. Yeah, yeah. That the -- the issue with -- with the -- with the case, with my

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position, is not that I'm questioning whether they can give accurate refractions or not.

Q. Okay. That's helpful to know. Thanks.

A. Sure.

Q. All right. And you mentioned that you have been deposed before. Can you just, you know, tell me how many times, if you recall?

A. Twice.

Q. Okay. And I don't think we need to get too far into those, but what were those two depositions about?

A. So one was about a patient had been injured in a store, and she was -- I don't remember the exact details. She was, I think, suing the owner of the store, versus the person who -- who injured her, was claiming that she had significant eye injuries afterward, and so I was deposed to report on -- on whether I thought her eye was injured or not after that injury.

The other case was a patient who came to me, and she had cataracts and refractive error, and she felt the other doctor had given her a glasses prescription when she should have been referred for cataract surgery, and so I was giving my opinion on the level of cataract and whether

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glasses were a reasonable treatment at that point for her eye.

Q. Okay. And do you recall what your recommendation was one way or the other on that?

A. So on that -- on that last case or on -- on both cases?

Q. On the latter, the second case.

A. Yeah. So on the last case, she had very mild cataracts. It was reasonable to have treated her with glasses beforehand. I think she was concerned that the other eye doctor had been trying to sell her glasses unnecessarily. And she had mild cataracts. It was -- it was reasonable to treat with glasses at that point.

Q. And we'll probably get into some of these concepts today, but if you could just maybe explain for me now why you thought it was reasonable for her to get the glasses at that point in the treatment process.

A. Just 'cause her cataracts were very mild. So a cataract is a cloudy lens, that starts to get a little cloudy, which the process -- well, it probably starts from the time we're very young, but you start having a bit of a cloudy lens in your 40s, usually. And cataracts don't do any damage to

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the eyes, so when the vision can still be corrected well, to 20/20, 20/25, we don't recommend cataract surgery at that point. You just get a pair of glasses and -- and fix the refractive error. You don't -- you don't need to have a cataract surgery until it's stopping your best corrected vision to being 20/40 or worse.

Q. Okay. So there are at least some situations, then, when in your medical opinion it's okay to prescribe lenses for patients, you know, even though they may have other kind of systemic or hidden eye diseases, for lack of a better term?

A. Yeah. Absolutely.

Q. Okay. How do you figure out when it's appropriate to do that?

A. Well -- so there's maybe a couple issues there. One is if it's something that's actually making their vision blurry, the underlying disease, one would be, well, if it's something that just makes the vision blurry, or is it something that is damaging the eye. So in the case of a cataract, it does not damage the eye except in rare cases where the cataract has gotten so advanced it could narrow the angle and -- or sometimes it leaks lens material and causes inflammation, but those --

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those are unusual.

So if it's just making the vision blurry and you can correct their vision with glasses to better than 20/40 and as long as it's not causing glare issues at night or something where even if they're not -- even if they can get to better than 20/40 you might still recommend cataract surgery. But if you can get their vision corrected well enough, then they don't need cataract surgery. So that would be one example.

Now, it's different if they have diabetic macular edema causing blurred vision. In that case glasses -- so that's a problem on the retina, and that can -- it both blurs the vision and damages the retina. So in that case you wouldn't want to just prescribe glasses. You would want to fix the underlying problem. So it depends on what the -- what the underlying problem is, if that makes sense.

Q. Okay. Yeah. That makes sense to me.

All right. And we -- we talked a little bit a second ago about the fact that you wrote an affidavit in that -- in this case. I'm just going to put that on the screen so that we all have it and make sure that you know what we're

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talking about when I mention it. One second here.

(PLF. EXHIBIT 2, Affidavit of Mark E. Robinson, M.D., M.P.H., was marked for identification.)

BY MR. WINDHAM:

Q. Okay. I'm introducing what's been marked as Plaintiff's Exhibit 2. And I'll share my screen because I think that's what we're going to have to do here.

All right. Do you see this?

A. I do. And I have a copy of it myself but...

Q. I'm sorry?

A. Yeah. And I have a copy myself, which I have ready as well. But, yeah, I can see it.

Q. Okay. All right. And do you recognize this document?

A. I do.

Q. All right. And I'll just scroll through from front to back just so that we've got full thing on the screen. And what is this document that I'm showing you?

A. Yeah. This is the affidavit. This is the -- my summary of -- of my testimony on the issue.

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Q. Okay. Great. And you wrote this document, looks like in -- let me back up. Who wrote this document?

A. Yeah. I wrote it.

Q. Did you write the first draft?

A. I did. And I think I edited it, and I may -- you know, so it's -- yeah. It's been a while. I don't remember if anyone else gave me any editing tips, but, yes, I wrote it, edited it, and approved it.

Q. Okay. Did you receive any documentation from Mr. Shealy before drafting this document?

A. Not that I remember.

Q. Okay. Did Mr. Shealy offer any sort of compensation for putting this document together?

A. He did. He asked me what my hourly rate was.

Q. Okay. And what did you say?

A. I think I -- I gave him a rate. I don't -- I don't remember what it was, but in the end I felt like I was just giving my opinion for what was best for the state, so I -- I did not charge anything.

Q. Okay. So at the end of the day, you

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didn't charge anything?

A. I did not.

Q. Got it. So Mr. Shealy did not provide you documentation before you put this together. That's right?

A. Not that I'm remembering. I don't know if he gave me -- you know, it's possible I was given some sort of pertinent -- you know, what the case was or what the issues were, but not that I remember.

Q. Okay. And did --

A. Oh, go ahead.

Q. I'm sorry. Go ahead.

A. Well, yeah. Just that, from what I remember, this is -- you know, I thought about -- I mean, I say that. You know, some of the -- the stuff at the beginning, like -- like Opternative is a health care technology company that has produced certain technology which allows -- those sort of description may have been something I was given, just some of the -- of the facts of the case, but the -- the opinions about what I wrote as far as the medical issues were my own.

Q. Okay. So let me see if I can clarify this a little bit. It looks like the first couple

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pages of this document -- well, let's put it this way. Paragraph 3, it looks like isn't about you. The first two are about you. Is that fair to say? Paragraphs 1 and 2?

A. Let's see. Yes. The first two are about me. Number 3 becomes -- right. So number 3 is more of a general statement about ophthalmologists. Yeah. So it's -- it's possible some of those things that were more just sort of facts -- that maybe that came from somewhere else.

Q. Okay. By somewhere else, do you mean Mr. Shealy or an attorney?

A. Yes. Or -- yeah. Or some other fact sheet, maybe. Again, it's -- I don't remember.

Q. Okay. But that category of allegations -- or sorry. That category of paragraphs in this affidavit looks like it would be 3 through -- I'm just scrolling through the shared screen here -- 3 through -- well, you tell me where it ends because you're distinguishing between facts of the case and then your opinions. So where would you kind of cut it off, where the facts of the case end and your opinions begin?

A. Right. Okay.

Q. And let me know if you need me to

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scroll on my screen. I think you have a physical copy, right?

A. Yeah. I'll look at my physical copy just 'cause it's easier to read. Let's see.

Q. Sure.

A. Okay. So -- so it looks as though -- again, as I'm skimming, again, I think these other facts are correct on the earlier ones, at least as they relate to the -- to the medical issues, but number 13 is where I give a more specific opinion about corneal irritation and contact lens overwear.

Q. Okay. Any others that you would describe as a specific opinion of yours, as opposed to a fact of the case?

A. Let's see. So number 14 talks about systemic or body-wide disease processes. Number 15, they may go undiagnosed. Number 16. So number 17 is a fact about who the American Academy of Ophthalmology is.

Q. Okay.

A. Number 18 says how frequent the visits should be. Again, it's been so long since I -- I wrote this it's hard for me to remember, again, if, some of this, I could have had help with the editing of it, even on these later statements,

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possibly, or maybe just -- just by the way, like, some of it was -- was phrased, but, again, I would still agree with -- like number 14, for example: Ophthalmologists are under an affirmative obligation to look after the health and safety of their patients.

I agree with that. I don't think I would have just written that off the top of my head to have phrased it that way, if that makes that sense.

Q. Okay. Let me see if I can -- I can summarize this. And tell me if this is a fair statement. I'm not trying to put words in your mouth, but I think we can probably pass this topic if we can agree on this.

A. Okay. Good.

Q. It sounds to me like you drafted this document with perhaps some help from Mr. Shealy on some of the items, at least in the process of editing the language, but that you ultimately agree with all of the statements in this affidavit today?

A. Right. I think that sounds reasonable.

Q. Okay. And, you know, having reviewed this document before today, is there anything in here that was true in 2017 when you wrote it but

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that you no longer feel is true today?

A. I essentially agree with everything. The only -- again, this is probably a small point, but I said I had never given anyone a refraction without an eye exam in number 20, and that's certainly true professionally. There was a relative I gave a refraction to probably a couple years ago, but I emphasized the importance of them -- of getting a complete eye exam, which they did within a year after I -- I did that.

Q. Okay.

A. So with that one exception, I think, yes, I stand by everything that's in the affidavit.

Q. Okay. My understanding of Paragraph 20 -- and you can correct me if I'm reading this wrong. Let me just read it, and let's see if we can understand it together: It is my opinion to a reasonable degree of medical certainty that almost all practicing eye care providers are very rarely providing a refraction without an eye exam, unless they had previously given the patient an eye examination within the prior year. I cannot ever remember doing so myself, end quote.

So when you say that you are now saying you can recall at least one example of doing that,

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what work is within the prior year doing there?

A. I'm sorry. What is --

Q. Well, let me ask that a different way. When you say within the prior year, what do you mean there?

A. Oh, well, so normally our -- our refractions, they expire after one year. So if I had examined a patient in May and given them a refraction and they lost the refraction for some reason and they call within that year and request another one, then we would print that off and send it to them because it had not expired yet.

Q. Okay. So in that situation you can think of examples of you having done that. Is that fair to say?

A. Oh, yeah. Yeah. Absolutely. If it's within a year and the prescription hasn't expired, we would give them -- we would give them a copy of that prescription, yes.

Q. Okay. And so when you're --

A. And so, again -- and I should say I'm not giving them another refraction. We're just printing off the prescription that was already, you know, given three months prior or six months prior.

Q. You're just essentially renewing the

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prescription. Is that a fair way to say?

A. Well, just giving them a copy of the -- of the -- right. Yeah.

Q. Would the new -- would the prescription that you're giving them there be for -- for a year, or would it be for the duration of the year that you had given it to them for?

A. Right. Yeah. It should still expire whenever the original one expired, yeah.

Q. Okay. So in Paragraph 20 here, when you say that you can't remember having doing so -- having done so yourself, you're referring to providing a refraction to a patient without an eye exam outside that one-year period?

A. Right.

Q. Okay. Got it. And then can you tell me what the situation was with the relative, kind of how that played out?

A. Oh. Just that for some reason she wanted to get a pair of glasses quickly, and, again, it was just for glasses, not contact lenses, and so I said, okay, you know, we can give you the prescription and -- but just make sure that you -- you know, you still get a complete eye exam when you're due, so...

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Q. Okay. How old was this relative?
A. I don't remember. Now she's -- she was probably around 43.
Q. Okay. Did she come into your practice?
A. No.
Q. How did that -- well, tell me how -- you tell me how it worked 'cause I don't want to keep guessing.
A. Well, right. So -- so this person just asked for me to renew the -- she had an expired prescription and said that she saw fine with it and that she understood -- and so one issue with that is, well, if you renew it and it's not right, you know, it -- there may be something a little bit off, and she understood that, and so 'cause she was my relative, I was willing -- I was willing to do that for her, although normally, again, for my patients I don't do that because if they just come in with an old prescription, it could be off and now they're trying to get a new glasses prescription after they just bought one, so, again, it's not something that you would normally do with somebody, you know, in that sort of person that you don't know or in that professional relationship but that I was willing to do for a relative.

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Q. Presumably, though, for your relative you have the same medical standard of care and duty to that person as you would for a patient, right?

A. Oh, absolutely. But -- but, again, I think what this is -- the issue, medically, is that a refraction -- whether you do a refraction or not or whether you want to do it or not, the key is that they still get a dilated, complete eye exam when they're supposed to get one.

Q. Understood. So for that patient who is -- you said 43, approximately?

A. Uh-huh.

Q. It looks to me like on Paragraph 19, this American Academy of Ophthalmology standard, she would be between 40 and 54.

A. Uh-huh.

Q. The academy would recommend her getting that comprehensive eye exam every two to four years; is that right?

A. That's right.

Q. And is that standard, as articulated in Paragraph 19 of your affidavit, consistent with your professional standards?

A. Yes.

Q. Okay. And is it fair to say that's an

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accurate reflection of the ophthalmological standard of care, generally speaking?

A. Yes.

Q. Okay. So for that patient who was your relative who was 43 years old who did receive the prescription for glasses without having a comprehensive eye exam, what was your recommendation in terms of how soon she needed to get her comprehensive eye exam?

A. Yeah. I said -- again, it's been a couple years. I think I said within the next year or so.

Q. Okay.

A. And she got back to us and said that she did do that, so...

Q. Good. Okay. Were you aware one way or the other if she had had a comprehensive eye health exam before coming to you?

A. She said she had, yeah. It's been a while now, so, again, I don't remember exactly -- exactly when that was.

Q. Okay. Did you feel that with this particular patient who happened to be your relative that you were doing anything unsafe?

A. No. Because I trusted her to -- to get

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the eye exam.

Q. Okay.

A. And we -- and we have enough follow-up, too, that I would see her -- I would see her again to be able to -- to ask her if she did it.

Q. Okay. That's helpful. Let me take this off the screen for now. We're probably going to come back to your affidavit, but I want to zoom out just a little bit.

I know we kind of jumped the gun on some of these topics, but if you could just step back with me for a second and -- I don't know a ton about your professional background. Would you mind just running me through your career? And I realize this may be a tall order for, perhaps, any of us on this call, but if you could give me kind of a -- the highlight reel of how you got from Mark Robinson, not the doctor, to Mark Robinson the doctor.

A. Sure. Yeah. So for undergraduate I went to the University of North Carolina at Chapel Hill and then did my medical school there, got a one-year degree, my master's of public health. I did my residency. I did an intern year in -- in Virginia, which for ophthalmology your intern year

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can be -- can be separate from the ophthalmology residency. I did my ophthalmology residency at Georgetown in Washington Hospital Center in Washington, D.C.

I then went into private practice in Roanoke, Virginia, for three years and then in Danville, Virginia, for three years. And then I did a one-year fellowship in neuro-ophthalmology at Dean McGee Eye Institute in Oklahoma. Then I came here, the University of South Carolina and Prisma Health, in 2015 and have been practicing neuro-ophthalmology and general ophthalmology and being part of a program to train ophthalmology residents since that time.

Q. Okay. About how much clinical experience in terms of years do you have?

A. Well, so I started my residency when I was about 27, and I'm 46, so about 19 years. Well, I guess almost 20 years now.

Q. Okay. And are you -- today, are you practicing in a clinical setting, or are you mostly in a teaching capacity?

A. So it's mostly clinical setting. The way we teach in -- in medicine, for the most part, is we're in a clinical setting, and the residents

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come and -- and work with us. So I'll give maybe, you know, a few hours of lecture a month, but most of our teaching is in the setting of seeing patients.

Q. Got it. Okay. What about during the COVID-19 pandemic? How did your practice work during that time?

A. Yeah. So things slowed down a little bit. There may have been a week or two at -- where sort of, with the -- the peak concern of infection, that we stopped seeing patients except for an emergency, but otherwise -- so it was a little -- I don't know if quiet is quite the right word. It was less busy for some number of months in clinic 'cause fewer patients came.

Q. Okay. But y'all were ultimately still practicing for the vast majority of the pandemic?

A. Yes.

Q. Okay. And let me just pull the affidavit that you wrote back up. Wanted to ask a question about just a few definitional things, if you don't mind, so we're kind of all using the same terms today. So let's just start with one that you've already used. It shows up in Paragraph 20, and you talked a little bit about it. What is a

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refraction?

A. Yeah. So a refraction is the process by which you give someone a pair of glasses to correct their refractive error, so that's -- refractive error is just how the light comes into the eye. If it's not focused on the retina, then the vision is blurry, and so a refraction is to help focus that light right onto the retina, so if it's normally focused in front of the retina, you're going to push -- you're going to use lenses to push that focus back. If it's behind the retina, you use lenses to bring that focus forward.

Q. Okay. And is a refraction something that you give to a patient who is receiving a new prescription or a changed prescription, or does a refraction only apply to -- well, let me -- scratch that.

Let me ask it this way. Would you perform a refraction for every single eyeglass prescription you would write?

A. Yes. Yes.

Q. Okay. And that includes renewals of a prescription that hasn't changed?

A. Well, yes. 'Cause if they're -- if they're seeing 20/20, we will double-check that the

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prescription is -- is what it -- what it should be.

Q. Okay. And can you walk me through -- as if I know knowing about it, can you walk me through the process of a patient walking into your office and then them walking out of the office with a pair of glasses and a prescription? How does that work?

A. Yeah. So when they come in, if they would -- if they're not seeing well, if they aren't seeing 20/20, then a refraction -- you put a -- it's called a phoropter -- it's spelled P-H-O-R-O-P-T-E-R -- up in front of their face. They can look through. You check one eye at a time. You give them different lenses until you find what the right correction is. You may use a machine called and autorefractor to begin with, which is a machine that can see how the light is focused in the eye, so that would give you a starting place. So you would do that.

And then if they were a new patient or if they were due for their complete eye exam, which most of them are when they come in, then we do the complete eye exam as well. And when they leave, if nothing else was found, you know, that -- that we have to do, we -- then we tell them that their eyes

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are healthy and we -- and if they would like the glasses prescription, then we give them the glasses prescription.

Q. Okay.

A. There is -- there is a fee they have to pay for the refraction because that's not paid for by insurance, so that would be, I guess, part of the process as well.

Q. Okay. Do you have any assistants or physician extenders who work in your office?

A. I do, yeah. Yeah. So my -- so my refractions are usually done by my technicians.

Q. Okay. And sorry. Just to get our terms straight, what's a -- what's a technician, in your understanding?

A. Yeah. So an ophthalmic technician is someone who we train to do parts of the eye exam. So they'll check the vision. They can do a refraction. They check the pressure. They can check some of the initial parts of the eye exam before the doctor comes and sees the patient.

Q. Okay. And just so that I understand that, how much of a -- how much of the eye exam can a technician perform before you get involved?

A. They -- they do the initial part, so

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they'll help document, I guess, eye exam plus -- in terms of the whole visit, they'll help document the history. So they'll fill out the history. They'll check the vision. They can do a refraction. They can check the eye pressure. They'll check how the eyes move, the motility. They'll check visual fields to finger counting where you close one eye and you will have them count fingers in the different parts of their visual field.

Q. Okay. And are these technicians licensed to practice medicine or optometry or anything like that?

A. No. There's no license. They can get certifications at different levels, but there's no -- there's no requirement of a certification or license for an ophthalmic technician to be an ophthalmic technician.

Q. Okay. You mentioned that most are due for a complete eye exam when they come in to see you, but presumably some are not due for that; is that fair?

A. Yes, that's fair.

Q. Okay. And whether they're due for a comprehensive eye health exam, is it -- that depends on whether they're meeting the frequency

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recommendations set forth in Paragraph 19 of your affidavit?

A. Yes. I would say -- and in practice, though, if I have a patient come in after one year and they have not had a dilated exam, I dilate them if it's been a year, in general, not that I would always do that because that's more frequent than what's recommended, but, in general, if it's been a year and they haven't been dilated, then we dilate them so that we've looked at their whole eye.

Q. Okay. I mean, the standard of care set forth in Paragraph 19, there's nothing unsafe about a physician following that, right, when deciding whether a patient gets that comprehensive eye health exam?

A. Right. Nothing -- you know, so some of those recommendations, right, they're -- they're sort of just things that they think the -- that the statistical risk of something bad happening in a year or two years or four years is low enough and, given the resources that we have, those are their recommendations, at least that's my understanding. Somehow, when I've seen a patient, if they're in my office and it's been a year, I like to dilate because something could have happened in that time

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even though it's less than the guidelines set up.

Q. Okay. But I mean, if you decided to follow these recommendations to the letter, do you think you would be violating any kind of patient safety rule or putting patients at risk or anything like that?

A. Well, not violating a rule, but, again, I just recognize that those rules aren't absolutes, right. It's -- again, it's statistics. There -- there could be something I could miss if I did not do that. It would be rare, thankfully.

Q. Let's put it this way. You wouldn't be at risk for discipline, would you, from the medical board or anything like that?

A. No. No.

Q. Okay. And if you heard of a different physician than yourself, a different ophthalmologist, you know, following these guidelines to the letter, would you think that they were putting patients at risk?

A. Well, again, the way you're -- that you're phrasing it, I would say they aren't doing anything wrong medically.

Q. Okay. What about an eye chart? What is that?

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A. So an eye chart has different-sized letters that are put usually -- you know, the standard would be at some distance from the eye and then you use that to see how small of the letters someone could read, and that usually correlates with if they have either refractive error or some other eye disease making things blurry but -- but, yes, that's what we use as we refract the patient or just to measure their vision in general.

Q. I see. So an eye chart is part of the refraction process?

A. Well, yes. And also just checking the eye health in general, right, that someone -- if someone can see 20/20, that's -- that's a good sign that -- that certain parts of their eye are -- are working well.

Q. Okay. Have you ever been in a situation where one of these technicians that you work with performs the refraction and then -- suppose there's somebody who doesn't need that comprehensive eye health exam that day and then you prescribe the lenses for them but you don't actually see the patient that day. Has that ever happened?

A. Not that I'm remembering. Usually I

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like to at least pop in and -- and see them, look at their eye, double-check the refraction. Because if the refraction hasn't expired yet, then we just print it off. And if a patient comes in for refraction, I like to see them myself.

But if what you're getting at -- is that the standard of care -- I think there probably are -- well, but, again, if somebody's -- yeah. I'm trying to think when somebody would need a refraction checked outside of that one year where it had already expired where I wouldn't see the patient. Yeah. I don't think I would. I'm trying to think, though, if you're getting at, well, what's the standard of care with respect -- would someone just get a glasses prescription. Again, it might be some doctor would think, hey, if it's -- if they had their -- their complete exam, say, 18 months ago, so like you're saying, if they're within that two-year window, then someone -- I imagine there -- that there might be practices where a technician might give that -- might give that refraction and -- and the doctor would sign off on it.

Q. Okay. And at least in that case without performing the comprehensive eye health

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exam because they're within that recommended range or frequency, right?

A. Yes. Yes. I could see that -- I could see that happening, yeah.

Q. Okay. And even if -- even if you haven't done that yourself -- you used the phrase earlier -- there's nothing medically wrong with that. Is that fair to say about this example too?

A. Yes. I think so.

Q. Okay. I want to ask about expirations of prescriptions. So you mentioned that in South Carolina eyeglass prescriptions, contact lens prescriptions expire after one year; is that right?

A. Well, I think -- I believe it's up to the prescriber's discretion when to put, you know, expiration date. I put a year on mine, but I don't know that there's a particular rule about -- about that.

Q. Well, I guess setting aside the law, then, 'cause we're not -- we're not sure about that, you said your practice is to put a year. Is that how all ophthalmologists do it, or is that just, you know, your preference? Or explain how that works.

A. Yeah. It's been my preference and just

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what I've, yeah, been used to doing, yeah.

Q. Okay. I just want to understand why.

A. Well, so I would say that one reason is if their refractive error changes and it's more than a year out, they will get an inaccurate glasses prescription. That -- that's probably the main reason why I'm -- I'm putting expiration date on there.

Q. I'm not sure I understand your answer, but that's probably just because I'm not --

A. Well, just -- yeah. No. That's okay. So just that over time our glasses prescriptions can shift a little bit, and so if you've got a prescription and it's been 18 months and then someone takes that into an optical shop and those glasses are made and then they're not quite right, it could be because, well, the patient waited 18 months. You know, so now you've gone through that hassle of getting a wrong pair of glasses rather than just having an up-to-date glasses prescription would -- which would reduce the chance of having a pair of glasses that -- that didn't work for the patient.

Q. Are there patients for whom their vision remains relatively stable for a period of

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years?

A. Yes.

Q. How common is that?

A. Yeah. I'd say that's the most common, probably.

Q. Okay. Is that particular to a certain age group or demographic?

A. I would say retractive error in general stays relatively stable for everybody. Well -- everybody. I guess kids, when they're becoming more nearsighted, you know, that's where every -- I mean, sometimes their prescription can change six months or a year, but if we're talking the kind of adult -- you know, adult age range, most of the time it stays stable. Maybe younger adults in their late teens, early 20s may still have progressive refractive error if they're becoming more nearsighted, but I would say for a lot of folks, even 50-year-olds, 60-year-olds, their prescription usually stays about the same unless they're developing a cataract that's worsening that makes them more nearsighted. So most people, it stays relatively stable, I would say.

Q. Well, that's actually sort of why I'm -- that's my understanding too, as somebody who

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wears glasses, so I'm just sort of trying to understand why your practice is that you would put a one-year expiration on prescriptions as a matter course if, largely speaking, refractive error is not changing.

A. Yeah. Because let's say 5 percent -- and, again, I don't know what it is. Let's say 5 percent of people, that prescription is going to be wrong. That's a -- you know, that's still enough of a -- of a problem, right? People go and they get glasses made. They don't work. They come in to see us and then we have to -- you know, we give them a new prescription. They have to go get the glasses remade. That's significant time and expense to getting -- you know, getting that problem fixed.

Q. So for that 95 percent, approximately, of patients whose refractive error is not changing -- let me give a -- let me give an example and just see what -- what you would say about this. So suppose I'm -- I'll just use myself. I'm 31. You know, suppose my prescription is working great for me, or at least that's how I perceive it. I'm asymptomatic and that I don't have any noticeable signs of eye disease to my knowledge. I feel good.

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And I come to you and say, hi, Dr. Robinson. My prescription has expired. I'd like to get it renewed because I'd like to go get a different pair of glasses somewhere. How would you treat me in that situation?

A. Yeah. So -- and when was your last complete eye exam when you're coming to see me?

Q. So I'm 31 years old. Let's say it was two years ago.

A. Yeah. So I would recommend that you have a complete eye exam and -- and give you a refraction and give you a prescription.

Q. Okay. And would I -- what if I wanted to opt out of that complete eye exam? What would you say?

A. Yeah. I mean, that's a good question. I think, yeah, if somebody came to me and said, hey, I just want the refraction, I don't want the complete eye exam, and they hadn't had one -- and it's been, what, two years?

Q. Let's even just say 18 months for purposes of the example.

A. I mean, if -- probably what I would do is explain, hey, there are rare risks that there could be something worse, you know, going on in

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your eye. But if they were there in my chair and had made the appointment, then I -- then I probably would give them that refraction but with that warning that, hey, you know, there are things that could be potentially vision or even life-threatening that we did not check on today.

Q. Okay. So you would -- you basically would provide them a disclaimer that, hey, you're not getting a comprehensive eye health exam today, but those are important and you should get one in the future?

A. Yes. But I wouldn't necessarily be happy with that situation. That's just the -- that's sort of the practical reality of what I would do. I would -- I would prefer that -- and, like, if someone just called my office saying, hey, that's what I want to do, I don't think we would make them an appointment, but once they were in my chair, the reality of the situation is -- is, yes, that's -- that's what I would do, I think.

Q. Okay. I'm a little confused on that, but maybe you can help me understand. So I'm looking at Paragraph 19, and I'm just -- I'll read the first sentence: The American Academy of Ophthalmology recommends that adults with no signs

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or risk factors for eye disease should receive a comprehensive medical eye evaluation at age 40 if they have not previously received one, end quote.

So in this example, I'm 31. I have previously received one. Just kind of help me understand the relationship between what you're saying and this recommendation.

A. Well, right. I would say those recommendations are a minimum standard. It's hard -- like if I'm taking care of a patient, I like to have examined them and looked at their -- at their eye health, so that's why that makes me uncomfortable, that they want to come in and say, hey, actually I just want the glasses prescription; don't examine my eyes.

That -- even though, yes, I say, hey -- you know, if they ask me about what the minimum standards are, I'd say you are within the minimum standards, but you're here in my exam lane, like you're this -- you know, you're just this far away from a complete eye exam and there are rare risks. Why not just go ahead and get it. And that way, if it's my patient and now I've established that doctor-patient relationship, I like to have obviously examined the patient and looked at their

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eyes, so...

Q. I understand. Okay. So it's -- this is a preference of yours, but ultimately, if a patient comes in and they're in your room and they say, look, I don't have time for this today, I just need a new pair of glasses, that's -- you would do that?

A. I think I would, but I wouldn't be entirely happy with it, but, yes --

Q. Okay.

A. -- I would give the warnings and do it.

Q. Let me ask -- let me ask this with a wrinkle. If you're the one who did the initial comprehensive eye health exam -- suppose you did the exam yourself 18 months ago. Would that change your answer at all?

A. Yes. I would -- I would feel much more comfortable in that situation. I'd still say, hey, you know, you're here. I'd recommend a complete eye exam 'cause rare things can be missed, but they're rare and if -- if you want that refraction and that's all you want today, then -- then I would do that, yes.

Q. Okay. And I think I still want a little clarity on the term refraction and how that

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relates to somebody who has a prescription they like. So when -- if I come in and I've got what I perceive to be perfect vision with my glasses but they've expired, how would that vision testing or vision examination process work for you?

A. Right. So we would check their vision with their glasses on with each eye, see what they saw. So let's say, like in your -- in your case, let's say their prescription hasn't changed and they see 20/20 in each eye, then they would take their glasses off, and we would put that little machine called the phoropter in front of their face, again, check one eye at a time. We would put in different lenses and see if we could improve their prescription from what they had before, and if it ends up measuring the same, then we would end up giving them the same prescription as their old glasses.

Q. Okay. Just out of curiosity, could I -- well, let me back up. With the phoropter, you're using the eye chart, right?

A. You are, yes.

Q. Okay. Is there a way to -- suppose I walk into your office and I've got the glasses that I love and I think I'm seeing great and, instead of

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looking through a phoropter, I just look at the eye chart. Is there a way you can figure out if I'm still seeing okay with my glasses without the phoropter?

A. Yeah. Sure. If you see 20/20 with your current glasses, that's a good sign that they are either right or they're awfully close to being right.

Q. Okay. And so the phoropter would be a way of trying to figure out if we can improve the prescription from where it's at if I'm not seeing perfectly?

A. Yes.

Q. Okay. Scrolling up to Paragraph 10, mentions comprehensive eye examinations. I know we've talked about that a few times already, and I know you've written about it here, but let me just ask if you could say it, you know, today in your own words and then we might go through some of this language. Just could you tell me a comprehensive eye health examination is?

A. A comprehensive eye exam?

Q. Yes.

A. Okay. Yeah. So -- so we check the vision. We, again, check ocular motility. We

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check how the eyes can -- can move in all the different directions. We'll check the visual fields, at least a finger counting with each eye. We'll look at the front of the eye. We like to dilate the eye and then look at the back and look at the optic nerves and the retina. And then also we also take their history as part of that exam.

Q. Okay. Is the technician able to do all of those things, or can they only do some of those things?

A. So they do some. They will record all of the histories for us, past medical history, allergies, medications. We are supposed to -- and I do. I like to double-check that -- what we call the history of present illness, so we'll say, hey, I saw you reported this, is that right, and ask any clarifying questions, so we'll clarify that. But otherwise -- or if there's some pertinent thing where if they're coming in for a problem, I might ask about, oh, are you still on this medication or something like that. But if -- let's say that -- that they're healthy. Then I don't double-check with the -- with the patient the other parts of the histories.

And then I don't -- so, again, the

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technician can check vision. They check the refraction. I'll double-check the refraction sometimes if something has changed in way that I think I -- I want to double-check but not always.

The technician checks the pressure. Most of the time, that's fine, but in my glaucoma patients or if there are other things, I'll double-check the pressure myself. The technician will check the peripheral vision to finger counting and the ocular motility unless I see something.

And then from there, I look. I use -- it's called a slit lamp, which that's our microscope that's mounted horizontally so we can look at the eye. So I'll do the slit lamp to look at -- at the front of the eye, which, again, the eyelids, the conjunctiva, which is the lining on the front of the eye, the cornea, the anterior chamber, the iris, the lens, and then, once the eye is dilated, I can use other lenses to look back at the optic nerve and retina. So the actual looking at the eye with the microscope, sometimes checking the pressure, are parts that the -- that the doctor does.

Q. Okay. I mean, that's a lot of different tests. What I'm wondering is does a

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comprehensive eye health exam always involve every single one of those tests?

A. Well, I guess it depends on the definition of comprehensive, but if it's comprehensive, then, yes, I think everything I listed would be part of a comprehensive eye exam. Now, if you mean do we always examine all those things for every patient, like, again, if it's their yearly exam, then yes, we -- now, we don't always do a refraction at their yearly eye exam, but we should always do those other parts that I listed.

Q. Okay. What about it's not a yearly exam? What about -- we're going to keep using me an example. I'm making myself the center of attention today. So suppose I saw you six months ago. I got a comprehensive eye health exam. Again, I'm 31, feel healthy, and I come in and I have something like -- suppose I think I have pink eye, and I come in and you've done the full comprehensive eye health exam six months ago. How would you -- how would you treat me that a situation?

A. Yeah. So normally, if you came in with pink eye, we would still give you a comprehensive

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eye exam 'cause we just want to make sure that we're not missing something else, but to -- you know, so the eyes are red 'cause what if there's something inside causing inflammation or that.

But let's say -- what if you came in 'cause you had, like, you know, gotten some particles in your eye. Maybe that's maybe more to your point. If you have some irritation on the surface, then, yeah, we'd look at the surface. We would not perform a comprehensive eye exam. We would make sure your cornea wasn't scratched, and we wouldn't need to dilate your eyes -- eyes for that.

Q. Okay. So it's not the case that every time you see a patient for any reason you're performing this -- the full battery of these tests you described in Paragraph 10, right?

A. That's true.

Q. And whether you perform that full battery of tests depends on the last time the patient got the full battery of tests, right?

A. Yes.

Q. Yes?

A. Sorry. I was nodding my head. Yeah.

Q. That's okay. That's okay. I do it all

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the time.

A. Yes.

Q. It depends on -- does it depend on anything else?

A. Well, and their presenting symptoms of what they're coming back with, right? So, yeah, like is there -- do they have something that would make me think, hey, let's just dilate your eyes and make sure nothing's going on in the back of the eye. So it just depends on what their other symptoms were, but if there wasn't something that made me think that, then, no, I wouldn't dilate their eyes.

Q. Okay. Basically you're treating patients on an individualized basis based on their symptoms, history, age, and those kinds of considerations, right?

A. Yes.

Q. Okay. There's not a cut-and-paste approach to this?

A. Right. Although, like you said, as you've been pointing out, the general guidelines, yeah, give you some guidance, but yeah.

Q. Okay. So what you're saying is the -- basically the outer bounds of when they would need

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that full battery of tests are set forth in Paragraph 19 in those guidelines, but otherwise you exercise your discretion on a case-by-case basis to figure out what a patient needs?

A. Yes. I think that sounds accurate.

Q. Okay. Oh, and you mentioned certain diseases. Let's see here. Oh, Paragraph 16. And so you have a list of diseases there that a comprehensive eye health examination can detect. And it looks like you mention, glaucoma, cataracts, macular degeneration, binocular vision disorders and corneal dystrophy, diabetes, hypertension. I can't even say the next one, if you could say it for me.

A. Yeah. Hypercholesterolemia.

Q. Autoimmune disorders --

A. It just means high -- yeah. It's just high cholesterol.

Q. Right. Autoimmune disorders and other systemic diseases. So setting aside other systemic diseases, which is maybe -- well, actually, let me just ask it this way. What diseases other than the ones that are listed here in 16 are you looking for during a comprehensive eye health exam?

A. Yeah. So things can be seen on the

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retina, on the optic nerve that are from -- so if someone had something like central nervous system pathology, so a condition -- I'm trying -- so as a neuro-ophthalmologist, one that I see is something called -- it's a bit of a mouthful -- idiopathic intracranial hypertension, where people can have raised intracranial pressure, and that will present as swollen optic discs, which can be detected on an eye exam.

Q. And you wrote a -- you wrote a paper on that, didn't you?

A. I did, yes.

Q. Yeah. Any other diseases that come to mind as ones you would look for during that comprehensive eye health exam?

A. Yeah. So you can look for inflammation in the eye, so that kind of goes along with underlying autoimmune disorders, so do they have inflammation in the front of their eye, inflammation in the back of their eye. So one particular autoimmune disease is called sarcoid, S-A-R-C-O-I-D.

What other things can we see sometimes? I mean -- so -- and I guess to be pertinent to this conversation would be systemic things that are

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otherwise asymptomatic, I would think, but sarcoid could fit that bill. Idiopathic intracranial hypertension could -- could be asymptomatic to the patient.

Q. Let me ask it this way. Is there any other major category of problem that you would be looking for that isn't covered by Paragraph 16 here?

A. No. I don't think so.

Q. Okay. I'm just trying to make sure I'm not missing something major. That's all.

A. Uh-huh.

Q. With that relative of yours that we talked about a little while ago, is it possible that she would have -- she could have had any of these diseases as a sort of hidden disease at the time you wrote her that prescription?

A. Well, yeah. I mean, it's possible anybody, yeah, could have these things, yes.

Q. Okay. And so that would have been a reason to recommend that she go get a comprehensive eye health exam, you know, in the future, right?

A. Right. Yeah. In a timely -- in a timely manner, yes.

Q. Okay. Let me take -- oh, actually,

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while we're here, Paragraph 18 -- 17 and 18 mention the American Academy of Ophthalmology. We've talked about them a couple times, but could you just tell me what they are?

A. Yeah. So what -- what I have here from -- that I wrote down earlier, so under the age of 40, every five to ten years; age 40 to --

Q. I'm sorry. I'm sorry. I'm just asking what the AAO -- what your understanding of that organization is.

A. Oh, I'm sorry. What the under -- oh, just their organization, the American Academy of Ophthalmology?

Q. Yeah.

A. Oh. Okay. Well, sort of -- like it's our professional organization. They help set guidelines for the practice of ophthalmology. They help provide educational material for both ophthalmologists and patients. We have an annual meeting that is run by the American Academy of Ophthalmology that's educational.

Is that sort of getting at what you were asking?

Q. Yes. Continue if you have more. That's what I'm looking for.

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A. Yeah. Just to -- yeah. So, again, they give guidelines. They give education. They give education to the public too, if I didn't mention that before. They now help facilitate a website called EyeWiki, which is really helpful, where ophthalmologists can write articles on different eye health issues, and so that's a pretty comprehensive online resource that's run by the American Academy of Ophthalmology.

Q. Okay. Do you have any involvement personally with the American Academy of Ophthalmology?

A. So I'm a member. I have been on a committee that writes questions, review questions, for their question bank, which I did, I think, for about three years. I haven't done it in the last year and a half. I've attended their meetings. I don't think I've gone in the last couple years, but I've been, probably, to four or five of their annual meetings.

Q. Is it fair to assume, based on the fact that you're citing them in this affidavit, that you consider them to be generally trustworthy?

A. Yes. Absolutely.

Q. Okay. Have you relied on their

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guidelines outside of what you cite in this affidavit?

A. Yes. I think so.

Q. Just generally, in your practice you tend to follow what they recommend?

A. Yes. I try to.

Q. Okay. Let me pull this down. And we'll pull up -- just because you mentioned it in your affidavit, let me pull up another exhibit here.

(PLF. EXHIBIT 3, American Academy of Ophthalmology Policy Statement on Frequency of Ocular Examinations, was marked for identification.)

BY MR. WINDHAM:

Q. Okay. I'm introducing what's been marked as Exhibit 3. And I'm going to share my screen.

All right. Let me know when you see this document.

A. I can see it.

Q. Okay. What is this document?

A. So it says it's a policy statement from the American Academy of Ophthalmology and then the next subheading is Frequency of Ocular

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Examinations.

Q. Okay. I'm asking, really, do you recognize this document. Have you seen it before?

A. I probably looked at it before. I'm not -- again, I did not look at that particular document in preparation for -- for this deposition, so I'm -- I'm not remembering, but, yes, I've probably looked at it in the past.

Q. Okay. Let me just scroll down a little bit to the second page of this. I guess the bottom of the first page and the beginning of the second page. It talks about evaluation and mentions -- well, actually, let me give you a second, if you haven't looked at this before, just to read through the paragraph that starts with Evaluation in bold, and let me know when you've finished.

A. Yeah. Let me see if I can just...

The light's going off. Sorry. That's why I'm waving.

Q. That's okay.

A. Okay. So I just read the evaluation section.

Q. Okay. Is that the information that's cited in your affidavit, to the best of your knowledge?

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A. Yes. So I probably did review their -- again, it's been a while, right, so -- and, again -- 'cause I didn't comment on anything prior to the age of age 40 in my affidavit. Let's see. So, yes, I was probably referencing -- yeah. I would have. I would have referenced the -- these guidelines.

Q. Got it. Okay. Is this paragraph an accurate reflection of what you believe today?

A. Well, the only thing -- I think it's interesting. So they say, if you look in -- which is probably why you've pulled this up, but it says: Before the onset of presbyopia (at approximately age 40), the majority of American adults experience no changing refractive error or significant ocular disease and routine eye examinations are not indicated.

So that's interesting 'cause I have this news release from the AAO, and, again, I don't -- you know, which may not be as official as -- as this document, but it says under the age of 40 they're recommending an eye exam every five to ten years.

But I think it's interesting that even in -- even in this sentence here it says, you know,

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the majority of American adults experience no significant refractive or ocular disease. I don't know that I would -- personally, I wouldn't go from that statement to then the -- you know, sort of the conclusion of that is and routine eye examinations are not indicated. So I might not agree with that, with that sentence.

Q. And this sentence about before age 40?

A. Right. In the sentence about before age 40, yeah.

Q. Okay. I guess your preference would be something like the other statement that the AAO put out about five to ten years?

A. Yes. I think -- and, again, I have to -- you know, I mean, that's a pretty broad range too, every five to ten years. I think some of what's going into these underlying statements is taking into account resources that a society has to -- you know, to perform these -- these eye exams.

Q. Sure. Okay. So maybe let's put it this way. And tell me if this makes sense. Would it be fair to say it's ideal that if we have infinite resources every single day of your life you would get a comprehensive eye health exam?

A. Well, no. Because there's still the

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resource of time, right, that that -- you know, for the patients, that isn't a good use of their time even if you had -- you know, you're right. It's -- it's a judgment call. At some point you have to come up with some interval that seems reasonable, so...

Q. Okay. Got it. And I guess what I'm trying to understand is whether you believe that this is an interval that seems reasonable or whether you have a different opinion.

A. Yeah. I might say, under age 40, maybe every five years. I don't know that I like the -- as much the five to ten, but, yeah, I might say every -- every five years sounds reasonable.

Q. Okay. So this paragraph sounds reasonable except the under age 40, at which point you would recommend every five years?

A. Yes.

Q. Okay. With regard to -- I think you mentioned a second ago that your -- you were talking about your affidavit, and you said that you weren't commenting on anything under age 40. Did I have that right, or did I mishear you?

A. Oh, I was saying it looks like in my affidavit, because I was quoting those -- let's

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see. Yeah. In Section 19 we did not talk about under the age of 40, probably because I was referencing their policy statement which didn't mention anything under the age of 40.

Q. Okay. Does your affidavit -- generally speaking, do the things you say in it apply to folks under age 40 as well?

A. Well, again, for under the age of 40, I think I would say an eye exam -- again, I would -- I would rather go on the -- the shorter end of that five-to-ten-year interval of, say, every five years under the age of 40.

Q. Okay. I'm just asking about the affidavit, broadly speaking. So, for example, you have some commentary in Paragraph 20 of the affidavit. That commentary, does it apply to all age groups or only some age groups, or what are you getting at there?

A. Yeah. I would say all age groups, that I would want a -- yeah. In terms of Paragraph 20, that I would want a complete eye exam on my patients, yes.

Q. Okay. Give me just a second. Let me try to -- all right. Just a few questions about Paragraph 20 here. So let's just start with -- I

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want to go sentence by sentence, if you don't mind. The first sentence, I'll just read it: It's my opinion to a reasonable degree of medical certainty that almost all practicing eye care providers are very rarely performing -- or providing a refraction without an eye exam, unless they had previously given the patient an eye examination within the prior year, end quote.

When you say it's your opinion to a reasonable degree of medical certainty, what are you basing that opinion on?

A. Yeah. So that's a good question. Just that this is what I was taught, I guess, in my training, that as doctors, if it's been -- if it's been a year or longer, we -- we do a complete eye exam when they come back.

Q. Okay. When you say your training, do you just mean the school you went to?

A. Yeah. And my residency, from what -- yeah.

Q. Okay. So you're not relying, in this paragraph at least, on data or a study or something like that, are you?

A. No. No.

Q. Okay. No empirical evidence underlying

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this statement, right?

A. No. Just, I guess, my experience and being around other eye doctors, but, no, I can't -- I can't quote anything beyond that.

Q. Okay. And then you say -- I'll skip forward a couple sentences. You say, and I'm quoting again: Although giving a refraction online in and of itself would be low risk -- and I'll just stop there for a second. Why do you say giving a refraction online in and of itself would be low risk?

A. Well, 'cause in and of itself, I don't think it's doing -- it's doing harm.

Q. Okay. Why don't you think that?

A. Well -- well, I'm trying to think how to -- maybe I can phrase it in the other way. I think the risk of -- the risk of a -- of a refraction is that the patient now has gotten their glasses. They think that they've gotten the key points of their eye exam and then they don't go somewhere for a complete eye exam when it's due. I guess that's -- that's my concern, is that it's -- it's a partial -- it's part of an eye exam. I don't think that that itself has much risk other than, you know, maybe the glasses aren't quite

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right or something like that but...

Q. Right. In this paragraph, in Paragraph 20, when you use the word refraction, are you talking -- is it fair to say that's a word you're using to describe just providing a prescription for corrective lenses, any prescription for corrective lenses?

A. Yes. Yes.

Q. Okay. So it would include something like -- do you recall the example we went through earlier where, if I'm the patient, I go into your office. I have 20/20 vision with my existing prescription, and I look at the eye chart and you're renewing that prescription without using a phoropter. Would it include that as well?

A. Well, again, we don't -- if they came into my office, we wouldn't renew the prescription just based on them reading 20/20. We would still put them in the phoropter and check their prescription, even if they read 20/20, but -- but that's not -- but that's not my -- my issue here. I think if -- again, that you can -- if somebody was 20/20 and happy, I think you could probably give them that pair of glasses and that would be accurate for -- you know, for most people.

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Q. If they had looked at the eye chart and they were seeing well with it, is what you're saying?

A. Yes. Uh-huh.

Q. Okay.

A. Yeah.

Q. What if that patient had -- let me put it this way. If there were an FDA-cleared software, so the FDA has cleared the software for use by physicians, and a patient takes an online vision test in the way we're describing, they're looking at an eye chart online, and the FD -- again, the FDA has cleared this, and the results are sent to a physician and they're still seeing well with their prescription and they have received the disclaimer that says this is not a comprehensive eye health exam, do you have a problem with renewing the prescription in that context?

A. Yeah. Just I think there's something different about it being online and a paper disclaimer versus the patient being in your office and you're actually able to talk with them and sort of have that face-to-face relationship.

Q. And what is different about it?

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A. Yeah. That -- we might be getting into philosophy here but --

Q. Well, just to be clear, I'm not -- I'm actually not asking about anything abstract or philosophical. I'm trying to understand, empirically, what the difference is.

A. Well, again, I think there's a difference between a patient in your office that you are speaking to face to face, giving -- giving that disclaimer in person that, like, hey, you know, in -- like you said, in that case of that person comes into my office and they -- and they really want a refraction and that's all they want, I think there is a difference between me saying, in person, hey, this is not what -- you know, what I think is best and -- but since you made the appointment and you're here in my chair, you know, okay, I'll do this, but I would say I wouldn't -- if that -- if that kept happening, I think we would come up with a policy to be, like, whoa, who are all these patients that think they're just coming in for a -- for a refraction and we would -- you know, we would stop doing that. So I think -- I think we have to be careful of the fact I might do something one time as an exception, maybe -- again,

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the fact that it's in person I think makes it different, but if that kept happening, I -- then I don't think I would keep making that exception, if that makes sense.

Q. Well, you know, earlier you were talking about the fact that if other ophthalmologists were following these AAO guidelines with regard to frequency of exams, they wouldn't be doing anything medically wrong, and so I'm just trying to understand -- let's just suppose one of your colleagues, somebody else who is not you, was using an FDA-cleared software that operated as a digital eye chart, it provided a disclaimer to a patient that they were not receiving a comprehensive eye health exam, it required them to have had one within these guidelines, within the range required in the guidelines. Is there anything wrong with that physician using this tool for that patient?

A. Yeah. I -- what I think is hard is that -- my light's going off again. What I would be concerned about -- and it's hard, like -- so, you know, again, this word wrong or what have you, what I'd be concerned about is I think what will -- what will happen on a population level, if people

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are getting a partial eye exam, I think some number of people who would have had a -- you know, a disease caught on this otherwise routine eye exam will end up not following through on the comprehensive eye exam and will have, you know, some type of health -- you know, either vision loss or if it was -- you know, rarely, like ocular melanoma, life-threatening something -- that those things will happen.

So I don't want to -- you know, if one of my colleagues was going it, you're right. In some degree it's sort of -- each physician, when it comes to technology and practicing, they have to sort of make their -- make their own decisions, but I think there -- the issue I have with it, I think there's going to be a certain number of people that aren't going to follow through on their -- on their comprehensive eye exam, and I guess that's -- that's what's wrong with it, I think. Again, whether I would judge another doctor, is it -- are they doing something wrong? Maybe that's -- maybe that's sort of a subtly different question.

Q. Okay. You know, you talk about what might happen at a population level, and let me just ask this a little bit of a different way. If the

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patients who are using these kind of online tools to take a vision test, if the tools don't write new prescriptions, right, if they only do renewals of existing prescriptions if the patient is still seeing well and the patient actually has had a comprehensive eye health exam within the recommended guidelines, would your answer change at all?

A. Well, right. So if -- if somebody actually followed the advice, like if they got their comprehensive eye exams as indicated, then -- then, right, then I don't -- then I wouldn't have a problem with it, yeah.

Q. And, ultimately, the responsibility is the physician, right, who is reviewing that information to say whether the patient has had that exam recently enough, right?

A. Yes. On an individual level, yes.

Q. Okay. And are you aware of -- well, let me back up a little bit. The affidavit mentions Opternative, Incorporated. I know you mentioned earlier today Visibly, right?

A. Right. That's what the company, I think, has changed its name to.

Q. Right. Yeah. Exactly. I just wanted

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to make sure you understood the -- the change. In the -- you know, since you wrote this affidavit, which was around 2017 -- what's that difference between now and today? It's six years, right? Do I have that math right?

A. Yes, that's right.

Q. Are you aware of any examples at all of any kind of population effect of patients using Visibly or any similar technologies according to what you're saying in Paragraph 20?

A. I am not, no.

Q. Were you aware of any when you wrote the affidavit?

A. No.

Q. Okay. So you're -- you're not basing this on any statistical evidence or study or anything like that, are you?

A. No. I would say I'm basing it on the -- that there are incidences of asymptomatic eye diseases that can cause vision loss or, rarely, be -- be life-threatening that are picked up on routine eye exams. So I get referred, you know, some of those. So they do exist, but I don't -- and I've seen some of them, but I don't have any statistical data or study.

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Q. Okay. Have you ever personally used the -- well, actually, let me ask it this way. I'll scroll up a little bit. So you mention -- let's see here. Well, you say in the first -- the first paragraph, actually, before 1 but in the paragraph, starts with personally. Do you see that? You say that it's -- this affidavit is based on your personal knowledge. Is that right?

A. Okay. Let me see here. Okay. Yes. Personal knowledge of matters set forth herein, yes.

Q. Okay. Do you have any personal knowledge of Visibly's technology?

A. You mean have I done it myself, so to speak? Would that be --

Q. Yeah.

A. So, no, I have not gone online and done their -- yeah, their refractive test.

Q. Okay. So you don't know how the technology works, do you?

A. Not exactly, no. I realize -- I think I have a general idea, but, no, I don't know exactly what they do.

Q. Okay. Are you aware of -- of whether Visibly is cleared by the FDA or not?

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A. I did read on their website that it was FDA-approved, but I haven't read, again, the details of exactly what the FDA said.

Q. Okay. Would you have any -- if the FDA has cleared this software for marketing to the public and use by the public, do you have any reason to question that determination by the FDA?

A. Well, again, I think it gets at what -- you know, what factors was the FDA, you know, considering. I'm not questioning whether it can give an accurate glasses prescription. Again, my concern is that that's just a partial eye exam and, like we said before, that we're not getting a comprehensive eye exam at that time which could result -- which I think would result, if you did it across populations, some number of people not getting their comprehensive eye exam. So it isn't -- I don't have a problem with the technology itself. It's more just that people aren't going to get the comprehensive eye exam that they -- that they need.

Q. Okay. So just to be clear, I think you said this at the very start of the deposition, but I want to make sure we have it -- have it clear. You don't have any concerns about the actual

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efficacy of the technology itself?

A. I don't, yeah.

Q. Okay. And this concern you have about patients not getting comprehensive eye health exams if they use a technology like Visibly, isn't it a concern that would apply to any kind of limited care that a patient gets from an ophthalmologist?

A. Generally speaking, yes. It would be -- we could look at the details of that, but, yes, any limited care, you could always miss -- miss something.

Q. Yeah. Well, I'll just give an example you gave earlier. You mentioned the patient who comes in and they've got -- you know, they've had a comprehensive eye health exam in the past from you but they have, like, a corneal scratch or something like that. So in that examination you're focusing on the cornea and the scratch there. Do I have that right?

A. That's right.

Q. Okay. And so it's possible, right, that that patient leaves your office that day with the corneal scratch problem addressed but then they never come back for a comprehensive eye health exam, right?

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A. Yes. If it's a corneal scratch, though, if it's our first time seeing them, we -- we will dilate them and look, but if they're a follow-up, then we wouldn't, yeah.

Q. That's what I'm getting at. I'm getting at a patient who is just coming in for a limited set of care on a discrete issue like the corneal scratch.

A. Yes. If we've done a comprehensive eye exam before and they come in six months later and have a scratch, we -- we will just address that -- that problem for that day, yes.

Q. Yeah. And what I'm getting at is just that the problem of a patient not coming back for a comprehensive eye health exam seems like it's a problem that's just sort of true of all ophthalmological practice, right?

A. Yes. I mean, it's -- it's always -- yeah. I mean, we have lots of patients, even when we have an in-person relationship, they know they have glaucoma, we've told them you can go blind, and they don't follow up for their appointments. So, yes, it is -- it is a universal problem.

Q. And that sounds like it might even apply -- tell me if you're getting out of your

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depth with this question, and it's okay if you are, but it sounds like that might even apply to other kinds of medical specialists. So, for example, you know, patients who are supposed to get cancer screenings with a certain degree of frequency from a dermatologist, it's possible that you go see a dermatologist, right, for a skin rash and that you just never go back and get that screening, right?

A. Yes. Yeah. I think that -- I think that makes sense. It makes sense it would occur in all areas of medicine, yeah.

Q. Okay. Basically what I'm getting at is the problem of patients not following up and getting comprehensive exams of any form seems like a problem that's just endemic to the practice of medicine.

A. Yes. I agree.

Q. Okay. I think I want to take about a five-minute break, if that's fine with you?

A. Sure.

Q. Okay.

A. Five-minute break sounds good.

MR. WINDHAM: Great.

(A recess transpired.)

BY MR. WINDHAM:

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Q. We are back on the record then. Dr. Robinson, do you understand that you're still under oath?

A. Yes.

Q. Great. Okay. Well, we left off -- before the break we were talking about screenings for health problems that might come up in other medical specialties like dermatology, for example. Do you recall that?

A. I do, yes.

Q. Is your concern that patients need to get comprehensive eye health exams any different than a dermatologist's concern that a patient come in for a comprehensive screening of their skin?

A. I wouldn't think so.

Q. Okay. Certainly not any more dire or important than any other medical specialist's concern that a patient come in for a comprehensive screening, right?

A. I mean, you could add up, like, what are the potentially life-threatening things they're finding versus ophthalmology, but in general, right. I think -- I think the idea or the -- the idea or the principle is the same, yes.

Q. Okay. And I think what I'm just

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getting is that, you know, hidden diseases or long-term chronic diseases could be a problem in really any medical specialty, right?

A. Yes. I think they could.

Q. Okay. And so it's important that patients really in any area of medicine get that comprehensive exam within the recommended frequency by that specialty, right?

A. Yes.

Q. And I know that you have a concern about online vision testing software based on Paragraph 20 of your affidavit. Is that fair?

A. Yes. Yeah.

Q. Okay. Is the concern about patients getting prescriptions for corrective lenses through online tools any different than a concern -- well, let me ask it this way. Would you have the same concern if a patient was getting eye drops through telemedicine?

A. Yes. I would -- I would think I would. Anything where you're not getting a comprehensive eye exam, I would be concerned about, yes.

Q. Okay. So really any ophthalmological service that you could provide via telemedicine where you're not in the room with the patient, you

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would have this same concern about patients getting comprehensive eye health exams, right?

A. Yes. I mean, there might be -- like let's say it was glaucoma drops, for example, and you were renewing them. Well, now you're weighing, you know, if they don't -- if they don't get their glaucoma drops renewed, they're going to lose vision, so you have something -- a compelling reason to continue to prescribe those glaucoma drops, but in general, yes, I would be concerned about going too long without a comprehensive eye exam, yes.

Q. Okay. Is there anything about prescription lenses that suggests it's a greater concern, or is the concern just sort of ever present when a patient is getting a service through telemedicine?

A. Yeah. I think it's ever present. I think the concern would just be that needing glasses is an incentive for a patient to go get a comprehensive eye exam, so I'd say, you know, that's the kind of concern, is if they don't have that incentive anymore, life's busy, life's expensive, and then they get their glasses and they just don't go. So that would be my concern for

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glasses. And there may be some similarities to that in other areas, but that's why -- it isn't just that they're getting a treatment. It's that that treatment is actually an incentive that helps people to go see the eye doctor.

Q. You said there may be some similarities in other areas. Can you think of any examples?

A. Not off the top of my head, but I certainly believe that there -- you know, that there are. Maybe -- have you thought of some?

Q. No. I just -- you know, you mentioned it, so I thought I'd ask you what you meant.

A. Yeah. No. I -- yeah. There could be, but...

Q. I guess what I'm getting at with my question is it sounds to me like glasses is one example of a -- of a type of care a patient can get through telemedicine where, if they get it, they might not have a comprehensive eye health exam, but the same could be true of eye drops or any other kind of ophthalmological care, right?

A. Yes. Again, it's just that eyeglasses are a big incentive, I think, for people to go to -- you know, to -- to get an eye exam but...

Q. Okay. Let's see here. I wanted to ask

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about -- let's just start general with this. So telemedicine, just the concept of telemedicine, can you explain to me as a layperson what that is?

A. Well, it's -- so you have a doctor visit over some sort of virtual platform, I'm assuming like -- like what we're doing here. I have not participated in that myself as a provider, but -- so that's the idea, is you could -- you can get history, you can -- you can see the patient, but to some degree physical exam -- either to some or to a large degree the physical exam is -- is limited.

Q. Okay. You've never used or participated in telemedicine before?

A. Not as a provider, no.

Q. Oh, okay. What about as a patient?

A. Not as a patient myself, no.

Q. Oh, okay. I don't know. I sense that there that's something you're not --

A. Well, I just --

Q. -- that you mean.

A. I have a family member. I have a family member that has -- a child that has done some telemedicine visits.

Q. Okay. What was that for? You don't

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have to tell me their identity, of course. I'm just curious at a general level what that was about.

A. Yeah. So I have a child who has some sort of chronic illness, chronic fatigue. We think it's tickborne, but anyway, long story short, that there's not -- we haven't found a local provider who has been as helpful as a provider that was out of town, so...

Q. Okay.

A. So the telemedicine helped us overcome that -- that distance.

Q. Okay. The child with the -- you know, your child, right?

A. Yes.

Q. What specialty is the -- is your kid seeing in this context?

A. So it was a doctor who was -- they specialize in tickborne illnesses, so...

Q. Okay. Presumably that -- your child is not getting, you know, a full, in-person examination by that physician, right?

A. Well, yes. Well, because we've been to see the physician in person too, but -- but yes, but not every visit but...

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Q. Not every visit. Okay. And that's okay with you?

A. Yeah. I mean, they've -- she's also had a pediatrician full visit and -- yeah. So she has had a complete exam otherwise but...

Q. Okay. Basically the more limited consultations you have with this physician in between, you know, the comprehensive visits is what gives you confidence that the care is adequate?

A. Yes.

Q. Okay. Is there any reason to think that that principle would be different in the ophthalmological context?

A. No. No. Again, I think if people are really getting their dilated fundus exams, their complete eye exams, then I don't have a problem.

Q. Okay.

A. I think the issue is just, again, some number of people won't actually, you know, do the complete eye exam.

Q. Got it. I was going to ask you some things about telemedicine, but since you haven't used it, I'll probably skip those things.

A. Sure.

Q. May be fruitless.

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Let me ask about contact lenses for a second. You know, we were talking earlier about a patient getting a prescription for glasses and the process for that. Is the process of prescribing contact lenses any different?

A. Yeah. So it's a little bit different because the contact lens actually sits on the surface of their eye, so -- and, again, I -- actually I don't prescribe contact lenses anymore. It's been a long time. But most of the time you're going to look at the -- well, not most of the time. All the time you're going to look at the fit of the contact lens after you've prescribed it. So that's for a new prescription. Now, I think for your technology it's for a renewal, so presumably the fit is already correct but -- but yeah.

So you would look at the -- look at the fit on the eye. Sometimes you have to adjust the prescription a little bit from what their glasses prescription is, but -- but yes. So it's a similar process. You still need a refraction but then there's some other parts just to check the fit on the eye, I guess.

I think you're -- you might have muted yourself, maybe.

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Q. Thank you.
A. You're welcome.
Q. I was going to ask why you say, for a technology like Visibly, presumably the fit is already correct?
A. Well, I think you said you were just doing renewals, right? So if it's renewal --
Q. Sorry. Not me but just for clarity on the record, Visibly.
A. Oh. Yeah. So for Visibly I believe the Visibly's website was saying they do renewal prescriptions, so -- so I was just kind of thinking out loud. So the fit there wouldn't -- wouldn't -- it shouldn't be an issue 'cause the fit was already, you know, determined by an in-person visit.
Q. I see. And is that because the fit of a person's contact lenses typically doesn't change? Is that what you're getting at?
A. Right. I think it typically doesn't. Now, I'm a little outside my area of expertise here just because I haven't prescribed contact lenses now in about ten years, so I don't -- sorry. Light going off again -- so I don't -- I don't have personal experience on how often the fit would

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change or -- or not change, but my impression is it -- I don't think that would be a big issue.

Q. Your impression based on your training?

A. Well, yeah. My training and then I did prescribe contact lenses for six years in private practice before becoming --

Q. Okay. So also based on your personal experience, then?

A. Yeah. So for at least six or seven years, I didn't see contact lens fits change very much.

Q. Okay. Let me just look over my notes for a second. We may be at the end here.

I think that's all I have for you today, Dr. Robinson, unless anything is raised on -- on any other questions that my friends on the other side want to ask, so I'll pass the witness.

A. Sounds good. Thanks.

MR. MATTHEWS: Mr. Allen, do you have any questions?

MR. ALLEN: Go ahead. If you have some, I'll defer to you if you want to go first but...

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EXAMINATION

BY MR. MATTHEWS:

Q. Let's see. I've just got a couple of questions. Dr. Robinson, how you doing?

A. I'm doing well. How are you?

Q. Hey, my name is Gene Matthews. I'm the -- kind of the third wheel here. I'm representing the Department of Labor, Licensing and Regulation and the Board of Medical Examiners, and the reason we're here is because we're required to defend the constitutionality of a statute that our administrative agency enforces.

One basic question I have is this. As I understand it, the rational basis for the ECCPL, the statute that's being challenged, is that the state has an interest in supporting good eye health and that undiagnosed diseases of the eye are a legitimate public health concern and the legislation at issue isn't designed to encourage in-person comprehensive eye examinations to increase the chances of detecting diseases of the eye. Just presume for a moment that's what the legislature had in mind. Do these themes seem to be reasonable to you?

MR. WINDHAM: Objection.

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BY MR. MATTHEWS:

Q. Please answer.

A. Yes.

Q. Okay. Tell me why.

A. Well, just -- I mean, I think there is -- there is a concern that there are these undiagnosed diseases that can be either vision-threatening or life-threatening that are sometimes picked up on a routine eye exam.

Q. Okay. And with that in mind, one of the issues that has come up here is that the law does not appear to require an eye care professional to conduct the -- the eye examination if it -- if you come to the -- say I come to my ophthalmologist. As you can see, I wear glasses. I go to my ophthalmologist and I say I just want prescriptions. I don't want an eye exam. The law does not appear to require that physician to say, well, tough, you're going to get one or I'm not going to serve you. Doesn't appear that that's required. To your mind, does that impair in any way the idea behind the law which is that in-person -- requiring in-person eye exams versus remote eye exams will encourage that patient to get the examination that you prefer?

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A. Right. I don't -- I don't think so, no.

Q. Okay. The issue has come up also that, you know, there's a -- well, how best to put this -- that the sole purpose for the law is to essentially corner the market for optometrists and ophthalmologists at the expense of those who offer eye care remotely. Do you have any information about that one way or another?

A. I don't. I've heard that that was what maybe was the -- that that was the -- a reason against the law -- I could say it that way but -- but, no, I don't have any other information about that.

Q. Okay. Do any set of physicians other than ophthalmologists or specialists such as optometrists conduct eye exams? Like would a general practitioner conduct an eye exam?

A. Well, there are times where a general practitioner might look -- you know, try to peek inside at the retina. They use a different device called a direct ophthalmoscope. So they might try to screen and look in at the optic disc, look at the blood vessels, look for hypertension, look for diabetes, but those exams are pretty limited, and I

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tend to think most of them don't do it because it's just too hard, so...

Q. Well, I guess my question is: Ordinarily I would not go to a GP for a comprehensive eye exam?

A. No, no, no.

Q. All right. Because ordinarily they couldn't provide one?

A. Right.

Q. All right. So maybe just -- we can end this pretty quickly then. As I understand your testimony, you do believe that there is a rational basis -- that's a bit of a legal term, so let me change it. You believe that there's a good reason for a law that encourages in-person eye exams and -- and that's -- the reason for that is to assist in detection of eye diseases?

A. Yes.

Q. Do you have any information that these diseases could be detected by a remote exam?

A. Well, yeah. I mean, if we had cameras that can -- you know, that could take a photograph of the fundus, you know, that would be one technology that could be done remotely. And checking pressure, I think would be harder in the

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eye, to screen for glaucoma, but I'm sure, you know, a device could be made that the patient could use somehow, so it may be in the future there are ways to do -- you know, to sort of get the information you need, but at the moment there's no sort of -- that I know of -- no sort of up-and-running system that's --

Q. Right.

A. -- doing the things of a comprehensive eye exam.

Q. And, again, this may -- question to you may seem hardly -- or horridly elementary, but when you talk about eye pressure, is that, when I'm in an eye exam and that thing, like, comes at your eye and kind of sticks in it and it's so comfortable that I want to run screaming from the room? That's what that is?

A. Right. Yeah. They can do it either noncontact, with an air puff -- so if you ever have the air puff checking your pressure, that would be the air puff -- or there are other devices that gently tap on the eye or touch the eye to get the pressure.

Q. Okay. Got it. Got it. Those are all the questions I have. Thank you so much.

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A. You're welcome. Thank you.

EXAMINATION

BY MR. ALLEN:

Q. Hi, Dr. Robinson.

A. Hi.

Q. My name is Luke Allen. I represent the South Carolina Optometric Physicians Association, otherwise known as SCOPA. I just have a couple quick questions.

You testified earlier with the situation with your relative when you gave them the refractive eye reading without the eye exam. Do you know what date that occurred?

A. I don't. It was two or three years ago, maybe. I don't remember exactly.

Q. Was it after you prepared that affidavit in this case?

A. Oh, yes. Yeah.

Q. So apart from that one caveat, is there anything that you would change in your affidavit as far as its accuracy or anything else?

A. No. I don't -- I don't think so.

Q. Have there been any instances in your practice personally where a patient came in for an eye exam and you were able to discover a potential

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problem with diabetes or high blood pressure or other systemic problem that the patient wasn't already aware of?

A. Yeah. So I've certainly diagnosed a good number of patients with glaucoma who didn't know it. That would be one of the more common things. Diabetes, where they have some -- yeah. So diabetic retinopathy, that would be one. And I've seen other patients that have been -- it's been -- because now I'm a neuro-ophthalmologist, so things are referred to me. I've seen people with idiopathic intracranial hypertension where their -- sorry. My light's going off again -- where their optic discs are swollen, and that's been diagnosed on -- on a routine examine and then referred to me. And I've seen some folks with that who didn't present until they had lost a lot of vision, but whether they would have -- you know, those folks didn't go for a routine eye exam, but I don't remember, if they had glasses, whether they, you know, would have or not, but there certainly are some things I've seen that -- that were caught on a routine eye exam.

Q. What types of medicines are you able to prescribe as an ophthalmologist?

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A. Yeah. Well, so as an ophthalmologist, we're medical doctors, so we're not limited. We can prescribe anything, I believe. I mean, we're supposed to -- but prescribe within our scope, so most of what we prescribe are eye drops, but we can prescribe prednisone if there's an autoimmune condition. I prescribe something called acetazolamide, which reduces the intracranial pressure in patients with idiopathic intracranial hypertension. So that's a pill by mouth. We also use that for glaucoma. If the pressure is really high, general ophthalmologists will prescribe that as well. So yeah. So mostly, as eye doctors, we prescribe eye drops, but we're allowed prescribe more if needed.

Q. Are you able to prescribe any of that to a patient that you have never personally examined just based on a set of questions?

A. So I haven't done any telemedicine, so I don't know the rules about that.

Q. Well, would you personally do that?

A. You know, as an eye doctor, I don't think that I would. I mean -- so no. As far as a neuro-ophthalmologist who -- you know, my practice is very much -- I need to see the eye to -- and

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inside the eye, so I guess no. No, I wouldn't.

Q. Okay. Now, I don't believe I have any further questions. Thank you.

A. Thank you.

EXAMINATION

BY MR. WINDHAM:

Q. I think I just have one and then maybe you'll be out of here.

A. All right.

Q. All right. So Mr. Allen asked a question about whether you ever had caught -- I think the -- the way you put it was -- or he put it was caught or diagnosed certain hidden diseases or undiagnosed diseases in your office. Do you remember that?

A. Yes.

Q. Okay. Do you recall if any of those patients who you've uncovered hidden diseases for were seeing 20/20?

A. Well, so I -- I don't remember their particular visual acuity. What I will say about glaucoma though, because it takes out peripheral vision first, they see 20/20 until the very end, so -- which is -- I mean, it's still good to catch it then, before it goes all the -- you know, before

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they lose all their vision but -- so I imagine many of those folks were -- you know, were 20/20, but I can't tell you for sure.

Q. Okay. I think that's all the questions I have for you today. Thanks so much for being here.

A. Yeah. Thank you. Thanks for all the good questions.

MR. WINDHAM: Thank you, Doctor. Enjoyed it.

(The witness, after having been advised of his right to read and sign this transcript, does not waive that right.)

(The deposition was concluded at 11:39 a.m.)

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CERTIFICATE OF REPORTER

I, Trisha M. Thomas, Court Reporter and Notary Public for the State of South Carolina at Large, do hereby certify that the foregoing transcript is a true, accurate, and complete record.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.

Witness my hand, I have hereunto affixed my official seal this 18th day of September, 2023, at Hardeeville, Jasper County, South Carolina.

TThomas

Trisha M. Thomas, RPR
My Commission expires
December 2027

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Mark E. Robinson, M.D., MPH

September 19, 2023

RE: Opternative v. South Carolina Board Of MedicalExaminers
9/6/2023, Mark E. Robinson , M.D., MPH (#6074916)

The above-referenced transcript is available for review.

Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at cs-midatlantic@veritext.com.

Return completed errata within 30 days from receipt of testimony.

If the witness fails to do so within the time allotted, the transcript may be used as if signed.

Yours,

Veritext Legal Solutions

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Opternative Inc. v. South Carolina Board Of Medical

Mark E. Robinson , M.D., MPH (#6074916)

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No corrections.

Mark E. Robinson 9/26/23

Mark E. Robinson , M.D., MPH Date

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Opternative Inc. v. South Carolina Board Of Medical Examiners

Mark E. Robinson , M.D., MPH (#6074916)

ACKNOWLEDGEMENT OF DEPONENT

I, Mark E. Robinson , M.D., MPH, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

Mark E. Robinson 9/26/23

Mark E. Robinson , M.D., MPH Date

*If notary is required

SUBSCRIBED AND SWORN TO BEFORE ME THIS

_____ DAY OF _____, 20___.

_____

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STATE OF SOUTH CAROLINA COUNTY OF RICHLAND Opternative, Inc., Plaintiff, v. South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation, Defendants, South Carolina Optometric Physicians Association, Defendant-Intervenor.	IN THE COURT OF COMMON PLEAS FIFTH JUDICIAL CIRCUIT Civil Action No. 2016-CP-40-06276

PLAINTIFF'S RESPONSE TO
SCOPA'S MOTION FOR SUMMARY JUDGMENT

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ISSUES PRESENTED

In 2016, South Carolina made it legal for doctors to practice telemedicine, including writing prescriptions, as long as they follow the medical standard that would apply during an in-person visit. At the same time, however, the state adopted the Eye Care Consumer Protection Law (ECCPL), which banned eye doctors from prescribing corrective lenses based on information collected using telemedicine. The ban—which treats doctors who prescribe corrective lenses differently than all other doctors who use telemedicine to prescribe anything else—was drafted by a group of South Carolina optometrists to ban competition from Plaintiff Visibly's online vision testing business.[1] The issues presented are:

1. Does the ECCPL violate South Carolina's equal protection clause, S.C. Const. art. I, § 3, either on its face or as applied to eye doctors who want to use Visibly's online vision testing software?

2. Does the ECCPL violate South Carolina's due process clause, S.C. Const. art. I, § 3, either on its face or as applied to eye doctors who want to use Visibly's online vision testing software?

[1] Visibly was originally called Opternative (as the caption indicates) but changed its name to Visibly in 2018 while this case was on appeal from a dismissal for supposed lack of standing. *See Opternative, Inc. v. S.C. Bd. of Med. Exam'rs*, 437 S.C. 258, 878 S.E.2d 861 (2022) (affirming Court of Appeals decision that Opternative had standing to sue).

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INTRODUCTION

South Carolina has two different approaches to telemedicine: one for doctors who prescribe corrective lenses and another for doctors who prescribe anything else. The Telemedicine Act, enacted in 2016 to expand access to healthcare, allows doctors to prescribe treatments based on information collected online as long as they follow the standard of care. The ECCPL, drafted by brick-and-mortar optometrists to shield themselves from online competition, is an exception to that rule. It bans eye doctors from prescribing corrective lenses based on information collected online—even if it would benefit countless patients. That disparate treatment violates Article I, Section 3 of the South Carolina Constitution.

First, the ECCPL violates the equal protection clause. That clause forbids the legislature from drawing irrational distinctions between similar groups. The ECCPL does just that. It distinguishes between similar groups: doctors who prescribe lenses and doctors who prescribe anything else. And the distinction is irrational: SCOPA's only proffered justification for the ECCPL is that patients who receive prescriptions for lenses online might have hidden diseases that could be detected in-person. But that's just an objection to telemedicine generally. After all, *any* patient receiving *any* treatment (including *eye* treatment) online could have a hidden disease. The fact that the Telemedicine Act broadly embraces telemedicine, even despite this hypothetical concern, shows that SCOPA's focus on hidden diseases is specious.

Second, the ECCPL violates the due process clause, which requires economic laws to rationally further a legitimate state purpose. The ECCPL violates this clause for the same reason discussed above: It's patently irrational to ban eye doctors from prescribing *lenses* using telemedicine out of a concern for "hidden diseases" when all other patients receiving *any other treatment* through telemedicine could have hidden diseases. And the undisputed evidence confirms

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as much: Visibly is FDA-cleared. Doctors have been using Visibly across the country for a decade, and there is zero evidence that any patient has ever been harmed. (If such evidence existed, surely SCOPA would have produced it by now.) And the ECCPL's real-world operation has nothing to do with public health. It does not require doctors to test for hidden diseases or change the medical information on which a prescription must be based. It simply bans doctors from collecting that information using Visibly. That doesn't protect public health—it merely protects brick-and-mortar optometrists, including SCOPA's members (who drafted the law to ban Visibly) from online competition.

That is all this Court needs to know to decide the cross-motions for summary judgment. There are no disputed material facts here.[2] Nothing in SCOPA's motion raises a genuine dispute about any facts on which Visibly's pending cross-motion (filed June 15, 2023) relies. Instead, this case comes down to a straightforward legal question: Does the ECCPL rationally protect public health? And the answer is no. Because "there is no indication in this record that [this] provision[] exist[s] for any other purpose than economic protectionism," *Retail Servs. & Sys. v. S.C. Dep't of Revenue*, 419 S.C. 469, 474–75, 799 S.E.2d 665, 667–68 (2017) (plurality), the Court should deny SCOPA's motion for summary judgment and grant Visibly's pending cross-motion.

UNDISPUTED MATERIAL FACTS

I. Visibly allows patients to renew their lens prescriptions online.

A. Visibly's online vision test.

Visibly is a technology company that invented an FDA-cleared online vision test. App 3, 6 (Foley Aff. ¶¶ 2, 4, 20).[3] Visibly's test "allows customers with prior corrective lens prescriptions

[2] Visibly's summary judgment evidence is compiled in the appendix to this response. Record cites will follow the form App __.

[3] Mr. Foley is Visibly's CFO and COO. App 3 (Foley Aff. ¶ 2).

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to take an online vision test and have their results sent to a licensed eye doctor (an ophthalmologist or an optometrist), who can then use that information to help determine whether it is appropriate to renew the customer's prescription." App 3 (*id.* ¶ 4). Visibly's test offers an innovation on the traditional lens-prescription model.

Under the traditional model, a patient visits an eye doctor to have her vision tested. App 74–75 (O'Brien Aff. ¶¶ 5–7).[4] The patient looks at a chart from a distance while the doctor or an assistant asks the patient to identify symbols on the chart. App 74–75 (*id.* ¶¶ 6–8); App 236 (Shipp Dep. 44:4–9).[5] The doctor uses the patient's responses to determine if the patient is seeing well or needs corrective lenses. App 74 (O'Brien Aff. ¶ 5); App 236 (Shipp Dep. 44:4–7). If the patient already has glasses or contact lenses and wears them while looking at the chart, the doctor can also use the patient's responses to determine "how well that person is able to see with their current prescription." App 236 (Shipp Dep. 44:4–22).

Visibly's online vision test works the same way. Indeed, the FDA has cleared Visibly as an online "Visual Acuity Chart." App 20 (Foley Aff., Ex. 2 (P00420)). To take the test, patients go to Visibly's website and answer screening questions about their age, prior lens prescription, most recent eye-health exam, and medical history (e.g., symptoms, medications, or conditions that may affect the eyes). App 3 (*id.* ¶ 5). Visibly's software then guides patients through an online vision test that they take by looking at images on a computer screen, standing a certain distance away, and using their smartphone to report their responses. App 4 (*id.* ¶¶ 9–10).

Once the test is complete, qualifying patients' results and responses to the screening questions are sent to a licensed eye doctor for review, in the same way that an assistant would hand

[4] Dr. O'Brien is a licensed ophthalmologist. App 74 (O'Brien Aff. ¶ 2).
[5] Dr. Shipp is a licensed optometrist. App 249 (Shipp Aff. ¶ 1).

the patient's responses to a doctor for in-office review. App 76, 78 (O'Brien Aff. ¶¶ 12, 19–20).[6] A patient whose information is sent to a doctor is not guaranteed a prescription. "Rather, Visibly requires its partnering eye doctors to abide by their professional duty to determine, based on the information they have about each individual customer, whether it is medically appropriate to renew the customer's lens prescription based on the applicable standard of care." App 5–6 (Foley Aff. ¶ 16). If a doctor decides that it would be improper to renew the patient's lens prescription for any reason, the doctor cannot and will not issue a prescription. App 6 (*id.* ¶ 19). But if a doctor decides that it would be proper to renew the patient's prescription based on the information available, the doctor will do so. App 6 (*id.* ¶ 18).

B. Visibly safely expands access to care.

Visibly does not offer—and does not claim to offer—a full eye-health exam. App 4, 14, 19 (Foley Aff. ¶ 8 & Ex. 1 (P00414) (website disclaimer that Visibly "does not perform or replace a comprehensive eye examination"), Ex. 2 (P00419) (FDA document recognizing same)). Comprehensive exams use a battery of procedures—a tonometer to gauge eye pressure, a pupil dilation to look inside the eye, a slit lamp to look at the retina, an ophthalmoscope to examine the optic nerve—to assess total eye health and detect diseases. App 253 (Shipp Aff. ¶ 21). While these eye exams are generally important, they "are not always medically necessary for otherwise-healthy patients." App 78 (O'Brien Aff. ¶ 21).

The American Academy of Ophthalmology (AAO) sets the standard of care for ophthalmologists. App 79 (*id.* ¶ 23); *see also* App 242 (Shipp Dep. 68:13–69:24 (SCOPA's

[6] Patients do not qualify to have their information sent to an eye doctor for review if they do not have a prior lens prescription, have never had an eye-health exam, their test results show that their vision has changed, or their screening question responses show that they have conditions or are taking drugs that may affect their eyes/vision. App 3–4 (Foley Aff. ¶¶ 6–7); App 80 (O'Brien Aff. ¶ 26).

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optometry expert agreeing that the AAO's standards are "consistent with what I understand to be reasonable")). The AAO recommends that patients with no symptoms or risk factors for eye disease should get an eye-health exam at least once by age 40; once every 2–4 years after that until age 54; once every 1–3 years after that until age 64; and once every 1–2 years moving forward. App 79, 101–02 (O'Brien Aff. ¶ 23 & Ex. 3 (P00500–501)).

Consistent with the AAO's recommendations, every eye doctor who has testified in this case agrees that it can be beneficial to prescribe lenses in between more detailed eye-health exams *and has personally done so*. App 77–78 (O'Brien Aff. ¶¶ 17–18 (ophthalmologist who has used Visibly to renew prescriptions for years testifying that patients "benefitted from increased access to vision care")); App 372–73 (Chaum Aff. ¶¶ 2, 4 (South Carolina ophthalmologist testifying that, when it was legal, he used Opternative to prescribe "lenses for multiple individual patients" who enjoyed "improve[d] . . . access" to care)); App 237–38 (Shipp Dep. 47:24–48:24, 50:8–18 (SCOPA's expert optometrist testifying that if a healthy patient just wanted a lens prescription, the appointment "would not [involve] a comprehensive eye exam" but would involve "a very problem-focused exam")); App 342–45, 347, 350 (Robinson Dep. 17:8–13, 24:23–30:12, 38:11–39:2, 59:13–19 (SCOPA's expert ophthalmologist testifying that a doctor who prescribed lenses for a patient in between eye-health exams would not be "doing anything wrong medically" and that he has done so)); App 116 (Zolman Dep. 32:8–33:1 (SCOPA optometrist testifying that where a patient was not able to visit his office, he renewed the patient's lens prescription without an eye-health exam and the prescription "improve[d] her quality of life")).[7]

In other words, Visibly is safe. As Dr. O'Brien, an ophthalmologist who has personally used Visibly for years, testified: "The key to safely using telemedicine in any medical practice,

[7] Dr. Robinson is a licensed ophthalmologist. SCOPA Br., Ex. 1 (Robinson Aff. ¶ 3).

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including an ophthalmological practice, is to evaluate each patient on a case-by-case basis and to ensure that using telemedicine meets the relevant standard of care." App 76 (O'Brien Aff. ¶ 14). Visibly is designed around that principle and requires eye doctors to follow it. App 5–6 (Foley Aff. ¶ 16). The results speak for themselves: Tens of thousands of patients across dozens of states are using Visibly. App 7 (Foley Aff. ¶¶ 22–24); App 77–78 (O'Brien Aff. ¶ 18). And there is no evidence that any patient has ever been harmed by Visibly or from a prescription issued by one of its partnering doctors. App 7–8 (Foley Aff. ¶¶ 25–28); App 77–78 (O'Brien Aff. ¶ 18); *see also* App 351 (Robinson Dep. 76:7–25 (SCOPA's expert ophthalmologist conceding he is not aware of any evidence of population level harms to patients who have renewed their lens prescriptions using Visibly)).

Since hitting the market in 2014, Visibly has seen "a genuine demand for [its] services." App 368 (Bodde Aff. ¶ 10). Especially among patients who lack access to care: "patients in rural areas, patients with lower incomes who work long hours or have multiple jobs, handicapped patients, and patients with children, who are often unable or unwilling to travel to a doctor's office just to take a vision test." App 75 (O'Brien Aff. ¶ 9); App 7 (Foley Aff. ¶ 24). For a time—when Visibly was still called Opternative—it operated in South Carolina too. App 8–9 (Foley Aff. ¶ 30); App 368–69 (Bodde Aff. ¶ 11); App 372 (Chaum Aff. ¶ 2). But that changed in 2016.

II. SCOPA drafted the ECCPL to shut out online competition.

A. SCOPA mobilized to destroy Visibly's business.

Vision care is big business. In 2014, the total vision-care market generated over $35 billion in revenue, $23 billion of which came from the sale of glasses and contact lenses alone. App 270, 294 (SCOPA000153, 177). And optometrists—who prescribe and sell lenses and frames—have a major stake in this market. Michael Zolman, an optometrist affiliated with the South Carolina

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Optometric Physicians Association (SCOPA),[8] testified that about half of optometrists' appointments come from patients seeking lens prescriptions, and that optometrists try to sell lenses after these appointments "most of the time." App 111–12, 123–24 (Zolman Dep. 9:2–11:5, 65:5–66:15). SCOPA agrees "most South Carolina optometrists sell eyeglass frames," App 186 (Rivers Dep. 28:20–22), and that these sales often comprise a majority of optometrists' profits, SCOPA Ans. ¶ 20.

Visibly—which offers a way to renew lens prescriptions online—threatens optometrists' profits. SCOPA Ans. ¶ 20; App 124 (Zolman Dep. 66:16–67:9). So, not long after Visibly entered the market as Opternative, the American Optometric Association (AOA)[9] announced a national campaign to address "the Opternative issue." App 323 (SCOPA000501). In 2015, the AOA hosted a webinar for its local affiliates on how online technologies would impact the optometry business. App 298–310 (SCOPA000181–193). The webinar announced that the AOA had drafted a model bill and recommended that local affiliates push the bill to "Fight" online vision care. App 295–96 (SCOPA000178–179).

SCOPA answered the call. After the webinar, Zolman—who ran SCOPA's lobbying efforts at the time—warned SCOPA's leadership that online vision care would pose "a huge threat to our profession" and impact the "business side" of optometry. App 270–71 (SCOPA000153–154); App 120–21 (Zolman Dep. 51:3–5, 54:2–12). He urged SCOPA to "address [the issue] quickly and attack aggressively," explaining that the "AOA is on the ball and recently drafted a bill that can be

[8] SCOPA is a local advocacy group for optometrists and the Defendant-Intervenor in this case. App 181–83 (Rivers Dep. 9:25–11:11, 15:18–16:8).

[9] The AOA is a national advocacy group for optometrists. App 112 (Zolman Dep. 11:15–13:7). SCOPA is a subsidiary of the AOA. App 183 (Rivers Dep. 15:18–16:8).

modified on a state-by-state basis to prevent this . . . [which] is something we definitely want to do." App 270 (SCOPA000153).

SCOPA took Zolman's advice. Over the next few months, SCOPA adapted the AOA's bill and lobbied for its passage as the ECCPL. App 130 (SCOPA000152); App 185, 188 (Rivers Dep. 23:13–15, 34:17–35:2 ("the ECCPL is a bill that SCOPA passed")). While SCOPA tried to hide its economic motives—taking care to avoid mentioning Opternative because "[l]egislators frown upon legislation that singles out and restricts a specific business" (App 329 (SCOPA0001258))—internal emails show that the ECCPL was always designed to shut Opternative down. App 193 (Rivers Dep. 55:16–22, 56:6–11 (Rivers agreeing that SCOPA pushed the ECCPL to ban "online eye exams" and there were "internal discussions at SCOPA about the importance of discussing the ECCPL as if it were not an effort to ban Opternative")).

The ECCPL hit a snag when then-Gov. Haley vetoed the bill for "us[ing] health practice mandates to stifle competition for the benefit of a single industry . . . . put[ting] us on the leading edge of protectionism, not innovation." S.C. State Library (Digital Collections), *Veto of R.178, S.1016*, https://tinyurl.com/a7w4kfdy (emphasis omitted).

But SCOPA rallied to override the veto, and when the ECCPL finally passed, SCOPA celebrated the law's crushing impact on Opternative's business. App 263 (SCOPA000116) ("[T]ake that Opternative!!!!!!); App 268 (SCOPA000129) ("It's with the utmost pleasure to announce that Opternative and 'eye exam' kiosks are now **PROHIBITED BY LAW** in the great state of SC!"). Months later, when the AOA asked SCOPA to present for other state affiliates on what it had achieved, SCOPA put it this way (App 320 (SCOPA000203)):

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B. The ECCPL bans doctors from using Visibly.

The ECCPL bans eye doctors from prescribing lenses based on information collected by Visibly and similar online technologies. Under the law, a valid lens prescription "must take into consideration medical findings made and refractive error discovered during [an] eye examination." S.C. Code Ann. § 40-24-20(B). Eye examinations are defined to require a "visual status," *id.* § 40-24-10(3), which can't be "based solely on . . . information generated by an automated testing device," *id*. § 40-24-10(9). It's an oddly phrased law—but it bans Visibly just as SCOPA hoped it would.

Notably, the ECCPL does not say what the "examination" must involve or what "findings" must support a lens prescription. Nor, in practice, are there any substantive requirements that doctors must follow: The law imposes "no explicit [testing] requirement," "doesn't say how the eye examination is to be conducted," "doesn't identify diagnostic methodologies that have to be

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employed in order to develop the medical findings," and does not "specify what those medical findings must be." App 225–26 (Coleman Dep. 64:16–66:17).[10] All the ECCPL requires is "some type of human involvement" in the exam—even if the human is just an "unlicensed professional[]." App 226 (*id.* at 67:3–68:2).

Put another way, the ECCPL does not regulate the information on which a lens prescription must be based. It remains perfectly legal (as it always has been) to renew a prescription based entirely on a patient's self-reported medical history and responses to images on an eye chart. ECCPL merely requires that at least some of this information be collected by a human being—who need not be licensed, trained, or qualified in any way. This achieves nothing except what SCOPA always wanted: to protect brick-and-mortar optometrists from online competition.

The ECCPL destroyed Visibly's South Carolina business. After the law passed, eye doctors could no longer prescribe corrective lenses "based solely on . . . information generated by an automated testing device." S.C. Code Ann. § 40-24-10(9). That made it impossible for Visibly to operate in South Carolina. App 369 (Bodde Aff. ¶ 12); App 372 (Chaum Aff. ¶ 3); App 8–9 (Foley Aff. ¶¶ 29, 31).

There are no other legal barriers at play here. Visibly is FDA-cleared. App 6, 16 (Foley Aff. ¶ 20 & Ex. 2). And the Telemedicine Act embraces telemedicine for doctors who "adhere to the same standard of care as a licensee employing more traditional in-person medical care," S.C. Code Ann. § 40-47-37(A)—a rule Visibly's partnering eye doctors can follow by renewing lens prescriptions in between more detailed eye-health exams. App 78–80 (O'Brien Aff. ¶¶ 19–25). If

[10] Ms. Coleman testified as the 30(b)(6) designee for Defendants. App 215 (Coleman Dep. 6:1–7:12).

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the ECCPL were struck down, Visibly would promptly resume operating in South Carolina. App 9 (Foley Aff. ¶ 32).

III. SCOPA misrepresents the summary judgment record.

SCOPA makes several assertions about the safety of Visibly's online vision test that find no support in the summary judgment record and require correction:

First, SCOPA asserts that Visibly "is demonstrably less accurate, less effective and less safe than . . . in-person eye examinations." SCOPA Br. 2. But SCOPA cites no evidence for this claim. Further, the claim is misleading because it conflates two ideas: vision tests (which Visibly offers) and full eye-health exams (which Visibly does not offer and does not claim to offer). App 4, 14, 19 (Foley Aff. ¶ 8 & Ex. 1 (P00414) (website disclaimer explaining that Visibly "does not perform or replace a comprehensive eye examination"). The FDA, which cleared Visibly's online vision test after extensive study, recognizes this distinction: Visibly helps doctors assess "visual acuity" online but "does not provide screening evaluation or diagnosis of eye health or other disease, nor is it intended to replace an in-person eye exam." App 19 (Foley Aff., Ex. 2 (P00419)).

Regarding the service Visibly *actually offers*, the FDA could not have been clearer: "performance data demonstrate that" Visibly's online vision test is a "safe and effective" alternative to an in-office chart. App 27 (Foley Aff., Ex. 2 (P00427)). And eye doctors who have *actually used* Visibly agree that it's safe and beneficial. App 77–78 (O'Brien Aff. ¶ 18) ("not aware of any patient ever having been harmed or suffering adverse health effects" but instead "patients benefitted from increased access to vision care"); App 373 (Chaum Aff. ¶ 4 (similar)). SCOPA's ophthalmology expert *agreed* that it's safe to use an online tool to renew a patient's lens prescription in between full eye-health exams, App 351 (Robinson Dep. 74:23–75:13 ("I wouldn't

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have a problem with it")), and he's not aware of any empirical evidence that would suggest otherwise, App 351 (*id.* at 76:7–18).

In short, the FDA, eye doctors who have actually used Visibly, and SCOPA's own expert agree that it's safe to use Visibly to renew a patient's lens prescription in between full eye-health exams. SCOPA—despite asserting otherwise—cites zero evidence to the contrary. This is not a factual dispute; SCOPA's assertion simply has no basis in the record.

Second, and relatedly, SCOPA asserts that allowing patients to renew their lens prescriptions using Visibly poses "an identifiable risk to the public's eye care" because eye doctors have "an affirmative obligation" to conduct comprehensive eye-health exams. SCOPA Br. 2, 13, 15. But every single eye doctor who has testified in this case agrees that the standard of care allows doctors to provide more limited care *in between* full eye exams as long as patients are getting full eye exams at the AAO's recommended frequency. *See supra* p 8 (collecting testimony). As SCOPA's expert ophthalmologist put it, an eye doctor who prescribed lenses for a patient in between more comprehensive eye exams would not be "doing anything wrong medically"—and indeed, he has personally done so. App 342–45, 347, 350 (Robinson Dep. 17:8–13, 24:23–30:12, 38:11–39:2, 59:13–19). So, while eye doctors have a general duty to perform full eye-health exams every few years depending on the patient's age, they do not have a duty to perform one every time they interact with a patient. Again from SCOPA's ophthalmology expert:

> Q: [S]o it's not the case that every time you see a patient for any reason you're performing this—the full battery of tests you described in Paragraph 10 [of your affidavit], right?
>
> A: That's true.
>
> Q: And whether you perform that full battery of tests depends on the last time the patient got the full battery of tests, right?
>
> A: Yes.

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App 349 (Robinson Dep. 55:14–56:21). SCOPA's assertion about eye doctors' general duty to perform comprehensive eye-health exams ignores the undisputed evidence that eye doctors can and do safely provide more limited care *in between* those exams.

Third, SCOPA asserts that patients who take Visibly's online vision test "may mistakenly believe that they have received a comprehensive eye examination after receiving a prescription for spectacles or contact lenses." SCOPA Br. 5–6. The basis for this assertion is unclear, but it's divorced from the record either way. The point of Visibly's FDA clearance is that Visibly can legally market to the public as long as Visibly makes clear that it's not "intended to replace an in-person eye exam." App 89–92 (Foley Aff., Ex. 2 (P00488–91)). Visibly, in turn, informs every patient that it "does not perform or replace a comprehensive eye examination." App 4 (Foley Aff. ¶ 8). And, as SCOPA's optometry expert conceded, the same is true for in-person care as well: Patients are always free to opt-out of eye-health exams as long as they give informed consent to seek more limited treatment that day:

> Q: Can a patient in practice opt out of any part of the comprehensive eye exam?
>
> A: Of course.
>
> Q: It's always up to the patient's choice then?
>
> A: Of course.

App 234–25 (Shipp Dep. 37:20–39:15). Despite all this, SCOPA points to the fact that Visibly entered into a settlement, in response to an Illinois Attorney General inquiry, that required Visibly to disclose that its online vision test was not a substitute for a full eye-health exam.[11] But Visibly

[11] SCOPA omits unrebutted testimony from Visibly's 30(b)(6) witness that the Illinois inquiry focused on whether it was misleading for Visibly to describe its online vision test as FDA "registered" (which, at the time, it was) when customers might think that meant FDA "cleared" or

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included that disclosure on its website well before the settlement. SCOPA Br., Ex. 3 (Stonedale Dep. 104:24–105:6); App 368 (Bodde Aff. ¶ 9) (quoting disclosure in 2017). In sum, nothing in the record supports SCOPA's suggestion that Visibly's online vision test is in any way misleading.

LEGAL STANDARD

Summary judgment is proper when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Rule 56(c), SCRCP. The movant has the burden of showing that there is no material factual dispute. *Ellis v. Davidson*, 358 S.C. 509, 518, 595 S.E.2d 817, 822 (Ct. App. 2004). The movant can meet that burden by showing that there is no evidence in the record supporting the nonmovant's case. *See Lanham v. Blue Cross & Blue Shield of S.C., Inc.*, 349 S.C. 356, 361, 563 S.E.2d 331, 333 (2002). The burden then shifts to the nonmovant to identify specific facts in the record that show there is a genuine issue for trial. *Ellis*, 358 S.C. at 518–19, 595 S.E.2d at 822.

ARGUMENT

As Visibly showed in its pending cross-motion for summary judgment, the ECCPL violates Article I, Section 3 of the South Carolina Constitution in two ways. ***First***, it violates equal protection because it irrationally treats doctors who prescribe lenses differently than all other doctors who prescribe anything else. ***Second***, the law violates due process because banning doctors from using online tools like Visibly to prescribe lenses does not rationally further patient health—it merely protects brick-and-mortar optometrists from competition. Because nothing in SCOPA's

"approved" (distinct categories). The issue became moot after Visibly obtained FDA clearance in 2022—so in 2023, Visibly entered into a settlement whose terms "were largely redundant . . . with the law" requiring Visibly to correctly describe its FDA status. *See* SCOPA Br., Ex. 3 (Stonedale Dep. 43:8–48:17).

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motion for summary judgment shows otherwise—and because there are no disputed material facts that would bar this Court from declaring the ECCPL unconstitutional here and now—the Court should deny SCOPA's motion and grant Visibly's cross-motion.

I. The ECCPL violates South Carolina's equal protection clause.

Article I, Section 3 forbids laws that deny "equal protection." To provide equal protection, the ECCPL must pass the "rational basis test." *Denene, Inc. v. City of Charleston*, 359 S.C. 85, 91, 596 S.E.2d 917, 920 (2004). That test has three parts: A law that (1) "treats similarly situated entities differently" must (2) "ha[ve] a rational basis for the disparate treatment" and (3) "bear a rational relationship to a legitimate government purpose." *Joseph v. S.C. Dep't of Lab., Licensing & Regul.*, 417 S.C. 436, 451, 790 S.E.2d 763, 771 (2016) (plurality) (citing *Ed Robinson Laundry & Dry Cleaning, Inc. v. S.C. Dep't of Revenue*, 356 S.C. 120, 124, 588 S.E.2d 97, 99 (2003)). The ECCPL fails this test.

A. The ECCPL treats doctors who prescribe lenses differently than all other doctors who use telemedicine.

The first question is whether the ECCPL "treats similarly situated entities differently." *Joseph*, 417 S.C. at 451, 790 S.E.2d at 771 (cite omitted). It plainly does. Doctors who want to prescribe lenses are in the same "trade," *Ed Robinson Laundry*, 356 S.C. at 124, 588 S.E.2d at 99—the practice of medicine—as all other doctors who want to use telemedicine to prescribe anything else. So they're similarly situated, at least for purposes of telemedicine regulation. *See Hanvey v. Oconee Mem'l Hosp.*, 308 S.C. 1, 5, 416 S.E.2d 623, 626 (1992) (charity hospitals were similarly situated to other healthcare providers for purposes of liability regulation). Yet the ECCPL treats them differently: Doctors who want to prescribe lenses are banned from using online tools like Visibly, while all other doctors who want to prescribe anything else may do so under the Telemedicine Act. *See* S.C. Code Ann. § 40-47-37(A).

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SCOPA rejects this comparison as "inapposite" because "none of these other doctors are allowed to prescribe . . . lenses." SCOPA Br. 16. SCOPA misses the mark. The question, under the first equal protection prong, is not whether the two groups provide identical services, but whether they are similarly situated given the subject of the challenged law. That's why the charity hospitals in *Hanvey*, cited above, were similarly situated to different healthcare providers (like the Red Cross): they could all commit the kind of medical harm the challenged liability cap was focused on. *See Hanvey*, 308 S.C. at 5, 416 S.E. at 626; *see also Broome v. Truluck*, 270 S.C. 227, 230–31, 241 S.E.2d 739, 740 (1978) (architects, engineers, and contractors were similarly situated to all "persons whose negligence in the improvement of real property may cause damage or injury to others" for purposes immunity from liability).

Or look at *Joseph*, which is on all fours with this case. There, a plurality of the South Carolina Supreme Court struck down a law that forbade physical therapists—but no other healthcare professionals—from working for physicians, supposedly to prevent "conflicts of interest." *Joseph*, 417 S.C. at 451–52, 790 S.E.2d at 771.[12] Under SCOPA's logic, the mere fact that physical therapists are different from other types of healthcare professionals would have killed the equal protection claim. But that's not what happened. Instead, the Court held that physical therapists—alone among licensed healthcare professionals—were being "singled out and provided disparate treatment for self-referral purposes." *Id.* at 452, 790 S.E.2d at 771.

The same is true here. Doctors who want to prescribe lenses are being treated differently, for purposes of telemedicine regulation, than all other doctors who want to prescribe anything else.

[12] The lead opinion in *Joseph* was a plurality, but the relevant analysis drew no dissent. One justice would have reached the same result on statutory grounds. 417 S.C. at 455, 790 S.E.2d at 773 (Kittredge, J., concurring). And two justices dissented on standing but praised the majority's opinion as otherwise "laudable." *Id.* at 466, 790 S.E.2d at 779 (Beatty, J., dissenting).

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Indeed, the ECCPL even treats *eye doctors* differently from one another based on the treatment they prescribe. Eye doctors, SCOPA agrees, can "still prescribe whatever types of drugs that South Carolina law and their standard of care allows." SCOPA Br. 16. For example, eye doctors can and do use online tools to prescribe eye *drops*. App 376 (Second O'Brien Aff. ¶ 4). But the moment they want to prescribe eye *lenses*, the ECCPL's ban kicks in. That's disparate treatment.

B. There is no rational difference between doctors who prescribe lenses and all other doctors who use telemedicine.

Because the ECCPL treats doctors who want to prescribe lenses differently, the next question is whether there is "a rational basis for the disparate treatment." *Joseph*, 417 S.C. at 451, 790 S.E.2d at 771 (cite omitted). To be rational, the disparate treatment must be based on a "real difference" between the groups. *Daniel v. Cruz*, 268 S.C. 11, 14, 231 S.E.2d 293, 294 (1977) (cite omitted). And that difference must be rationally related to the law's purpose. *In re Luckabaugh*, 351 S.C. 122, 150, 568 S.E.2d 338, 352 (2002); *see also Standard Oil Co. v. City of Spartanburg*, 66 S.C. 37, 44 S.E. 377, 379 (1903) (rational classification "primarily depend[s] on purpose, the problem presented"). Simply put, there is nothing about doctors who prescribe lenses that could justify treating them differently than all other doctors who use telemedicine.

The only basis SCOPA has offered for the disparate treatment is that patients who renew their lens prescriptions "may" have hidden diseases that only a full eye-health exam could uncover. App 337 (SCOPA Resp. Interrogatory 1). But that is not a "real difference" when it comes to telemedicine. *Daniel*, 268 S.C. at 14, 231 S.E.2d at 294. Any patient seeing any doctor for any reason could have a hidden disease. Yet dermatologists, cardiologists, endocrinologists, psychiatrists, family doctors, and all other doctors are allowed to prescribe using telemedicine. *See* S.C. Code Ann. § 40-47-37(A). Eye doctors are just as qualified as these other doctors to use telemedicine in a way that accounts for hidden diseases. App 76 (O'Brien Aff. ¶ 12).

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Indeed, *eye doctors are allowed to use telemedicine to prescribe eye treatments other than lenses*. SCOPA Br. 16 (conceding same). In other words, the same patients who SCOPA says "may" have hidden diseases that will go undetected without full eye-health exams can obtain *any other eye treatment* online without those exams. Patients can, for example, obtain prescription eye drops and serums via online tools similar to Visibly. App 376–77 (Second O'Brien Aff. ¶¶ 3–6). To borrow a phrase, SCOPA has not "articulated any plausible reason why [doctors who prescribe lenses] are so different from [doctors who prescribe anything else] that they must be singled out and provided disparate treatment for [hidden disease] purposes." *Joseph*, 417 S.C. at 452, 790 S.E.2d at 771.

Just the opposite: SCOPA's own ophthalmology expert agreed that a concern about hidden diseases would apply with equal force to *all* online care—not just lens prescriptions:

> Q: Would you have the same concern if a patient was getting eye drops through telemedicine?
>
> A: Yes. I would—I would think I would. Anything where you're not getting a comprehensive eye exam, I would be concerned about, yes.

App 353 (Robinson Dep. 83:14–22). What's more, Dr. Robinson agreed that patients' need to get full health exams, rather than more limited care, would apply equally to all other medical specialties—not just eye care. App 352–53 (*id.* at 79:3–83:9). In other words, SCOPA's expert believes that a concern about hidden diseases would justify banning *all* telemedicine. And yet, that is precisely the logic the legislature rejected when it embraced telemedicine as a valuable tool for expanding access to care writ large. *See* S.C. Code Ann. § 40-47-37(A).

South Carolina Supreme Court caselaw confirms that the ECCPL's disparate treatment is irrational. In *Joseph*, it was irrational for physical therapists to "stand alone" as the only healthcare professionals banned from working for physicians when other professionals working for

physicians could create similar conflicts of interest. 417 S.C. at 442, 452, 790 S.E.2d at 766, 771. In *Hanvey*, it was irrational to cap charity hospitals' liability when other entities could cause medical harm. *See* 308 S.C. at 5, 416 S.E. at 626. And in *Broome*, there was "[n]o rational basis" for immunizing architects, engineers, and contractors from liability when other workers "may cause damage or injury." 270 S.C. at 230–31, 241 S.E.2d at 740. The ECCPL is no different: It bans eye doctors from using online tools to prescribe lenses even though any patient seeking any treatment online could have a hidden disease.

C. The ECCPL does not rationally further SCOPA's proffered interest in detecting hidden diseases.

Because the ECCPL lacks a rational basis for treating eye doctors who prescribe lenses differently, that is enough to declare the ECCPL unconstitutional. But if the Court elects to continue the equal protection analysis, the third prong requires that the ECCPL "bear a rational relationship to a legitimate government purpose." *Joseph*, 417 S.C. at 451, 790 S.E.2d at 771 (cite omitted). The ECCPL fails this prong too.

For one, the law does not require doctors to perform full eye-health exams more frequently than the Telemedicine Act already requires. Doctors have a general duty to ensure that patients have had a full exam within the AAO's recommended frequency. App 78 (O'Brien Aff. ¶ 23). And, under the Telemedicine Act, eye doctors are required to follow that standard when providing more limited treatment online. *See* S.C. Code Ann. § 40-47-37(A). The same would be true for lens prescriptions if the ECCPL were struck down. That's because the ECCPL says nothing about how often doctors must perform full eye-health exams. It bans doctors from prescribing lenses using online tools like Visibly *even when* patients have recently had a full eye-health exam. A law that changes nothing about the frequency of eye-health exams is not a rational way to require more eye-health exams.

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Worse, the ECCPL changes nothing about the information on which a lens prescription must be based.[13] It does not require doctors to check for hidden diseases or to perform any particular tests. App 225–26 (Coleman Dep. 64:16–66:17). Under the ECCPL, doctors can prescribe lenses based on the very same information Visibly collects: (1) a patient's self-reported medical history and (2) the patient's responses to what she sees on an eye chart. The only real difference under the ECCPL is that a human being—not "an automated testing device" (like Visibly's online vision test), S.C. Code Ann. §§ 40-24-20(B), 40-24-10(9)—must collect the information on which the prescription is based. App 225–26 (Coleman Dep. 65:17–67:18). There must be "some type of human involvement," even if that human is an "unlicensed" assistant. App 226 (*id.* at 67:3–18). Forcing patients to leave their homes just to go sit in a room with an unlicensed assistant, who is not required to seek any more information than Visibly already collects, is not a rational way to detect hidden eye diseases.

In reality, the ECCPL achieves one thing only: shielding brick-and-mortar optometrists (SCOPA's members) from online competition. The reason the ECCPL works the way it does—banning doctors from prescribing lenses based on online tools while changing nothing about the medical information or tests required for prescriptions—is that SCOPA drafted the ECCPL to destroy Visibly's business. The AOA first pitched it to address "the Opternative issue." App 323 (SCOPA000501). SCOPA adapted it to "address [the issue] quickly and attack aggressively" because it thought Opternative would threaten "the business side" of optometry. App 270–71 (SCOPA000153–154); App 120–21 (Zolman Dep. 51:3–5, 54:2–12). And, when the ECCPL

[13] Recall: The ECCPL says that lens prescriptions must be based on "medical findings made . . . during [an] eye examination"—defined (bizarrely) to mean a "visual status" *that is not* "based solely on . . . information generated by an automated testing device[.]" S.C. Code Ann. §§ 40-24-20(B), 40-24-10(9).

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passed, SCOPA bragged "with the utmost pleasure" that "Opternative . . . [was] now **PROHIBITED BY LAW**." App 268 (SCOPA000129). As SCOPA later summarized its achievement (App 320 (SCOPA000203)):

But the South Carolina Supreme Court has repeatedly struck down laws that dish out "mere favor[s]" to market groups while doing little to serve the public. *City of Laurens v. Anderson*, 75 S.C. 62, 55 S.E. 136, 137 (1906). Most recently, a plurality of the Court struck down a cap on the number of liquor permits a store could obtain because "there [was] no indication in this record that these provisions exist for any other purpose than economic protectionism," which "is not a constitutionally sound basis for regulating liquor sales." *Retail Servs. & Sys. v. S.C. Dep't of Revenue*, 419 S.C. 469, 474–75, 799 S.E.2d 665, 667–68 (2017) (plurality). Before that, similarly, the Court struck down a law that forbade insurers from firing agents because the "purpose of the challenged provision was to protect the private interests of affected agents rather than any broader

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societal interest." *G-H Ins. Agency, Inc. v. Continental Ins. Co.*, 278 S.C. 241, 248–49, 294 S.E.2d 336, 340–41 (1982) (cite omitted). The most on-point case, though, is once again *Joseph*.

In *Joseph*, the government argued that a law banning physical therapists from working for physicians was meant to prevent conflicts of interest. 417 S.C. at 443–46, 452, 790 S.E.2d at 766–68, 771. But the Court held that an employment ban was an irrational way to prevent "receiving or giving illegal kickbacks and participating in referral-for-pay agreements"—especially when the law could have addressed those things directly, and when no other professionals (only PTs) were subject to the ban. *Id.* The Court then exposed the law for what it was: "anti-competitive protectionist legislation intended to protect [some PTs'] personal financial interests . . . rather than actual benefits to patients." *Id.*

The ECCPL is more of the same. Like the physical therapists in *Joseph*, eye doctors who prescribe lenses (and only lenses) "stand alone in South Carolina" as the only ones excluded from the Telemedicine Act. *Id.* at 442, 790 S.E.2d at 766. As in *Joseph*, the ECCPL takes the drastic step of "depriv[ing] physicians of their right to practice medicine in the best interests of their patients" while failing to require the one thing that would further its alleged purpose: full eye-health exams to check for hidden diseases. *Id.* at 452, 790 S.E.2d at 771. And, like the law in *Joseph*, the ECCPL's only real effect is to preserve some optometrists' business models by banning online competition. *Id.* That is unconstitutional.

II. The ECCPL violates South Carolina's due process clause.

Article I, Section 3 also forbids the state from "depriv[ing] [any person] of life, liberty, or property without due process of law." To survive, the ECCPL must bear "a reasonable relationship to any legitimate interest of government." *R.L. Jordan Co. v. Boardman Petroleum, Inc.*, 338 S.C. 475, 477–78, 527 S.E.2d 763, 765 (2000); *see also Luckabaugh*, 351 S.C. at 140, 568 S.E.2d at

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347 ("arbitrary" laws are not reasonable). The ECCPL fails this test for all the reasons Visibly provided under the second and third equal protection prongs (which require the law to have a rational basis and a rational relationship to a legitimate purpose). *Supra* pp 24–31. To avoid duplicative briefing, Visibly will add just a few points here.

For starters, a factual "record" that shows the law does not serve "any other purpose than economic protectionism" is fatal under the rational-basis test. *Retail Servs.*, 419 S.C. at 474–75, 799 S.E.2d at 667–68; *see also St. Joseph Abbey v. Castille*, 712 F.3d 215, 222–23, 227 (5th Cir. 2013) (striking down protectionist restriction on casket sales based on the record because the rational-basis test "does not demand judicial blindness to the history of a challenged rule or the context of its adoption nor does it require courts to accept nonsensical explanations for regulation"). SCOPA agrees this is an "evidentiary" standard, in the sense that the court must weigh the record to determine whether the ECCPL rationally protects the public. SCOPA Br. 13, 15.

Further, because facts matter, it should matter that all the hard evidence in the record supports Visibly's safety. Visibly is FDA-cleared because the FDA found, after extensive study, that "performance data" show its online vision test is a "safe and effective" alternative to an in-office chart. App 27 (Foley Aff., Ex. 2 (P00427)). Dr. O'Brien, an ophthalmologist who has used Visibly for years, is "not aware of any patient ever having been harmed" and has seen thousands of patients "benefit[] from increased access to vision care." App 77–78 (O'Brien Aff. ¶ 18). Meanwhile, SCOPA's ophthalmology expert agreed that he "wouldn't have a problem" with eye doctors using online tools to renew lens prescriptions in between eye-health exams (App 351 (Robinson Dep. 74:23–75:13))—as Visibly's partnering doctors do. That's consistent with the views of every single eye doctor who testified in this case, all of whom agreed that it can be

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beneficial to prescribe lenses in between full eye-health exams *and have personally done so*. App 77–78 (O'Brien Aff. ¶¶ 17–18).[14]

Surely if SCOPA possessed any evidence that Visibly had ever harmed even one patient, then SCOPA—in the nearly eight years it has been litigating this case—would have produced it. And yet there is nothing. Nothing more than hand-waving about hidden diseases and a record bursting with evidence that SCOPA drafted this law to destroy a competitor. That—against the undisputed evidence that Visibly is safe and that there's no reason to treat doctors who prescribe lenses differently than all other doctors who use telemedicine—is just not enough. Because "there is no indication . . . that [this] provision[] exist[s] for any other purpose than economic protectionism," *Retail Servs.*, 419 S.C. at 474–75, 799 S.E.2d at 667–68, the ECCPL violates due process.

* * *

This case is not complex. The ECCPL bans eye doctors from using FDA-cleared tools like Visibly to prescribe corrective lenses. It does this even though the Telemedicine Act empowers all other doctors to prescribe anything else—*including eye drugs*—using telemedicine. It does this even though every eye doctor who has testified in this case—*including SCOPA's own witnesses*—agrees that they can safely prescribe lenses in between full eye-health exams. And it does this

[14] *See* App 77–78 (O'Brien Aff. ¶¶ 17–18 (ophthalmologist who has used Visibly for years testifying that patients "benefitted from increased access to vision care")); App 372–73 (Chaum Aff. ¶¶ 2, 4 (same point from South Carolina ophthalmologist who used Opternative before the ECCPL passed)); App 237–38 (Shipp Dep. 47:24–48:24, 50:8–18 (SCOPA's expert optometrist testifying that if a healthy patient just wanted lenses, the appointment "would not [involve] a comprehensive eye exam" but would involve "a very problem-focused exam")); App 342–45, 347, 350 (Robinson Dep. 17:8–13, 24:23–30:12, 38:11–39:2, 59:13–19 (SCOPA's expert ophthalmologist testifying that a doctor who prescribed lenses for a patient in between full eye-health exams would not be "doing anything wrong medically" and that he has done so)); App 116 (Zolman Dep. 32:8–33:1 (SCOPA optometrist testifying that he renewed a patient's lens prescription without a full eye-health exam and that doing so "improve[d] her quality of life")).

without changing *any of the information* on which a prescription must be based. The ECCPL is patently irrational. On this record, there is simply no reason to believe it achieves anything other than what SCOPA hoped it would: shutting out online competition. Because that's an invalid use of state power, the ECCPL violates Article I, Section 3 of the South Carolina Constitution and Visibly is entitled to judgment as a matter of law.

CONCLUSION

The Court should deny SCOPA's motion for summary judgment and grant Visibly's pending cross-motion (filed June 15, 2023) for the reasons stated above and in Visibly's cross-motion.

Respectfully submitted,

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Attorneys for Plaintiff

May 29, 2024

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Affidavit of Paul Foley (and Exhibits)

Originally attached to Plaintiff's (Second) Motion for Summary Judgment and can be found in the Record on Appeal at pages 285-355

(First) Affidavit of Christopher O'Brien (and Exhibits)

Originally attached to Plaintiff's (Second) Motion for Summary Judgment and can be found in the Record on Appeal at pages 356-388

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Opternative, Inc. v. S.C. Board of Medical Examiners, et al.
(Civil Action No. 2016-CP-40-06276)

AFFIDAVIT OF JOSHUA WINDHAM
PART 1
(APP 105-APP 229)

ELECTRONICALLY FILED - 2024 May 29 3:14 PM - RICHLAND - COMMON PLEAS - CASE#2016CP4006276

IN THE COURT OF COMMON PLEAS FOR THE FIFTH JUDICIAL CIRCUIT

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND Opternative, Inc., Plaintiff, v. South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation, Defendants, South Carolina Optometric Physicians Association, Defendant-Intervenor.	Civil Action No. 2016-CP-40-06276

AFFIDAVIT OF JOSHUA WINDHAM

I, Joshua Windham, submit the following testimony under oath:

1. I am a citizen of the United States over eighteen years of age. I am of sound mind and fully competent to make this affidavit, which I make knowingly and based on my personal knowledge.

2. I am an attorney at the Institute for Justice, and I represent Plaintiff Visibly (formerly called Opternative) in this case.

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3. I submit this affidavit in support of Visibly's response to SCOPA's motion for summary judgment.

4. Attached as Exhibit 1 are true and correct copies of excerpts and exhibits from the August 2, 2017 deposition of Defendant-Intervenor South Carolina Optometric Physicians Association vice president and legislative chair Michael Zolman.

5. Attached as Exhibit 2 are true and correct copies of excerpts and exhibits from the August 1, 2017 deposition of Defendant-Intervenor South Carolina Optometric Physicians Association executive director Jackie Rivers.

6. Attached as Exhibit 3 are true and correct copies of excerpts and exhibits from the August 3, 2017 deposition of Defendants South Carolina Department of Labor, Licensing and Regulation and South Carolina Board of Medical Examiners through their joint Rule 30(b)(6) designee Darra Coleman.

7. Attached as Exhibit 4 are true and correct copies of excerpts and exhibits from the March 1, 2023 deposition of Melvin Shipp, O.D.

8. Attached as Exhibit 5 are true and correct copies of documents produced by Defendant-Intervenor in discovery.

9. Attached as Exhibit 6 are true and correct copies of documents produced by Defendants in discovery.

10. Attached as Exhibit 7 is a true and correct copy of Defendant-Intervenor South Carolina Optometric Physicians Association's Answer to Plaintiff's First Set of Interrogatories.

11. Attached as Exhibit 8 are true and correct copies of excerpts and exhibits from the September 6, 2023 deposition of Mark Robinson, M.D.

12. This testimony is true and correct to the best of my knowledge.

FURTHER AFFIANT SAYETH NOT.

Joshua Windham

SWORN to and subscribed before me:

This the 28 day of May, 2024

Notary public for the State of Virginia.

My commission expires 8/31/2025.

Gretchen I. Embrey
Commonwealth of Virginia
Notary Public
Commission No. 360350
My Commission Expires 8/31/2025

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EXHIBIT 1

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STATE OF SOUTH CAROLINA

COURT OF COMMON PLEAS

COUNTY OF RICHLAND

OPTERNATIVE, INC.,

Plaintiff,

vs. CASE NO. 2016-CP-40-06276

SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS,

and

SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING and REGULATION,

Defendants.

DEPOSITION OF:	DR. MICHAEL W. ZOLMAN
DATE:	August 2, 2017
TIME:	9:30 a.m.
LOCATION:	Magna Legal Services 960 Morrison Drive Suite 200 Charleston, SC
TAKEN BY:	Counsel for the Plaintiff
REPORTED BY:	Jessica R. Dixon
JOB NUMBER:	332543

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it is fair to assume you understood the question unless you say otherwise?
A. Correct.
Q. If you don't understand the question, I just ask that you let me know and I will try to clarify as well as I can.
A. Okay.
Q. When you received the notice in front of you, did you understand it was in regards to a lawsuit?
A. Yes, I did.
Q. And what, if anything, did you know about that lawsuit?
A. I knew there was a lawsuit against our state regarding the constitutionality of the law we had just passed as far as Eye Care Consumer Production.
Q. When you say "we," who are you referring to?
A. "We" as in the South Carolina Optometric Association -- Physician's Association.
Q. Okay. Can I call it SCOPA for short?
A. Yes, that's fine.
Q. How is SCOPA involved in passing the law?

A. We were the ones who initially were considering moving forward with such a law. And we consulted with ophthalmologists within our state. And so that was to the extent of us at least getting our bearings to move forward with such a law.
Q. I want to circle back to that a little bit later.
Did you do anything to prepare for this deposition today?
A. I reviewed emails that were sent back and forth to you in regards to this lawsuit.
Q. Did you talk to anybody at all?
A. Just our attorney.
Q. Anybody else?
A. Did I talk to anybody else regarding this? No one outside of our SCOPA Board of Directors.
Q. If you don't mind me asking, who did you talk to?
A. It was our current president, our president elect, and we had a brief board meeting, but not all members were there. But everyone that was on the board expect for two doctors. Dr. Campbell and Dr. Taylor.

Q. You mentioned a few positions of people on the board. Can you give me the names of the people?
A. Yes. So our current president, Jennifer Zolman. Our president elect is Dr. Johndra McNeely. And our -- the rest of our board of directors are -- they are director positions within our board.
Q. And you spoke to those people in preparation for today?
A. Not in preparation. Only in regards to that we had a deposition coming up.
Q. You mentioned a board meeting. When was that meeting?
A. That was -- I'd have to look at my calender. Two weeks ago. I'd have to look at my calendar.
Q. About two weeks ago?
A. Yes.
Q. At the board meeting did you discuss anything other than the deposition?
A. Yes, we did. Just normal affairs that we have during a meeting.
Q. I want to learn a bit more about you. What do you do for a living?

A. I'm an optometrist.
Q. Forgive the obtuseness of the question. But what, in general terms, is an optometrist?
A. So an optometrist is an eye care provider who provides care for patients seeking vision improvement and ocular health treatment and management.
Q. What kind of services do optometrists provide, generally?
A. We provide prescriptions for eye glasses, contact lenses. We provide care for any number of ocular pathology. That's in general what we do.
Q. So to break it into kind of two categories. So I understand it is corrective vision on the one hand. And pathology on the other?
A. Correct.
Q. Do you work primarily out of your office?
A. I do.
Q. Is that pretty typical in optometry in your experience?
A. Yes.
Q. As far as the corrective vision, the

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prescriptions, and the other prong you mentioned there, what -- how much of your time each day would you say is devoted to each of those -- allocated?

A. Me, personally?

Q. Sure. Let's start with that.

A. My practice is literally -- it is 50/50, roughly. We have a lot of patients coming in hoping to get improved vision. The other is more specific for, you know, some kind of pathology of the eye.

Q. When you say "50/50," are you talking about just sort of the number of minutes each day or do you mean number of appointments?

A. I would say number of appointments.

Q. And do you happen to know whether others operate in a similar way?

A. Within optometry there is different modes of practice. So some I know do a lot more pathology management and treatment. And I know there is others that deal more with the refractive care and corrective vision.

Q. Would you say your practice model, though, is fairly typical of the rest of the profession?

A. It is hard to say because there is so

many different types of practices that are within optometry nowadays. Is it typical? I would say probably. I mean, yes. But again, there is so many variations of what or how an optometrist practices these days, though.

Q. Would you say the majority of optometry have something like a 50/50 split between pathology and corrective lens care?

A. I would not and I'm surely speculating, because again, there is so many different types of practices.

Q. Fair enough. Are you familiar with the American Optometric Association?

A. Yes.

Q. So what is the AOA?

A. American Optometric Association is an association that is formed of optometrists. It is an organization that we feel sets the standard of care for how an optometrist practices. Every state is an affiliate of the American Optometry Association. Well, every state has an association. Each association is an affiliate of the American Optometry Association.

Q. What does it mean to be an affiliate?

A. I guess, on a national level, that is

our organization. Each state then has its own association which is an extension of the American Optometric Association.

Q. You mentioned that the AOA sets the standard of care for optometrists. Does the AOA do anything else?

A. They advocate for patients. The AOA, they are very involved in, I guess, properly legislating for our profession to ensure that, you know, patients receive proper care. They have a lot of, I guess, outreach as far as providing means to give access to care and to those who may have difficulty affording care.

Q. Anything else?

A. I would say that is the majority of what the AOA does.

Q. You said that the AOA engages in proper legislation. Can you unpack that a bit. What is proper legislation?

A. I guess, legislation is -- our profession is a legislative profession. We can only practice to the extent of our laws. There is always legislation that is brought up from time to time, both on a national and a state level that can sometimes potentially jeopardize patient safety,

patient health care. And so the AOA works within legislation to, I guess, maintain a certain standard of care that does not lessen.

Q. It sounded like you are describing the AOA when legislation comes up. When legislation comes up, do they also propose legislation?

A. They do.

Q. Do you have any examples in mind on what legislations they've proposed?

A. I don't recall within recent memory.

Q. When did you join the AOA?

A. I joined the AOA when I first was a student in optometry school. So that would have been 2002. I'm trying to remember how old I am now.

Q. Is that one of those things where they give you a membership through your enrollment?

A. No, you have to sign up for it. They have what they call American Optometric Student's Association. The AOSA, and they present and describe what the AOA is and offer membership in school. If I'm not mistaken, it is free to join. And then after you graduate, you have the opportunity to transition into a member of AOA.

Q. Why did you join, originally?

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A. To have a -- the message that they send is, you know, to strengthen the profession within numbers. To be as much as we can on the same page on any aspects of our care.
Q. What does it mean to strengthen the profession?
A. You know, strength in numbers. It is one thing to personally want to accomplish something. But you know, when you have a strength in numbers you can accomplish a lot more.
Q. By "accomplish," are you referring to legislation or any other efforts?
A. Any other efforts.
Q. Today, what is your role in the AOA?
A. Today, I'm simply a member of the AOA.
Q. Has that always been the case?
A. Yes.
Q. Have you ever had any other responsibilities instead of just being a paying member?
A. No.
Q. Not any leadership positions?
A. Not within the AOA.
Q. Have you ever been a speaker for any AOA conference or event or done any research for

the AOA?
A. I have not.
Q. Are you familiar with the State Government Relations Committee at the AOA?
A. I am.
Q. What is that committee?
A. That is a committee that works with individual states regarding regulations within the state.
Q. When you say "it works with states," do you mean affiliates?
A. Yes, affiliates.
Q. Can we call it the SGRC for short?
A. Yes.
Q. The SGRC works with SCOPA?
A. Yes.
Q. And that is to promote various legislative efforts and so forth?
A. Yes.
Q. Have you ever dealt with that committee in any capacity?
A. Through email, yes. We work with them specifically for any type of legislation that we may be considering.
Q. When you say "we," are you referring to

SCOPA?
A. Yes, SCOPA.
Q. That raises a good question.
What is SCOPA? If you don't mind explaining that in short.
A. So the South Carolina Optometric Association is an association of optometrists who share the same, I guess, values as the AOA.
Q. Are there any differences at all?
A. I would say there could be differences of opinion, but there are no -- I mean, you can't be a member of SCOPA without being a member of the AOA.
Q. So just to be clear, are there any SCOPA members who are not members of the AOA?
A. No.
Q. Okay. And does that mean that SCOPA members as a general matter support the same legislative initiatives and same advocacy and same standard of care and all of that?
A. Correct.
Q. Okay. So I take it you are a SCOPA member?
A. I am a member.
Q. What is the reason you joined,

initially?
A. For the same reasons I joined the AOA.
Q. When did you join?
A. Upon graduation. So that would have been 2006.
Q. At the time you joined, did you hold any leadership positions at all?
A. At the time I joined, no.
Q. Do you hold any today?
A. I do.
Q. What are those?
A. I am currently the vice president of SCOPA as well as the legislative chair for SCOPA.
Q. How long have you held those positions for?
A. One year.
Q. So let's take each individually. So have you been a vice president for one year?
A. Yes.
Q. So you were not a vice president before 2015?
A. Not of SCOPA.
Q. Okay. And did you do any work on legislation before 2015?
A. I did.

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Q. You did. Okay. Was that in your capacity as the legislative director?
A. In 2015, I was a co-legislative director.
Q. With whom were you a co-legislative director?
A. Dr. David Mckenzie.
Q. Was he also a member of the board?
A. He was at that time.
Q. Okay. Can you give me a timeline so I'm clear.
How long were you the legislative director or co-director?
A. I began from 2015 to 2016 -- I was the co-legislative chair. From 2016 to present, I'm the legislative chair.
Q. Okay. How did you end up in the legislative chair position?
A. I was asked by our current president.
Q. How did you end up in the co-legislative chair position?
A. I was asked by the then SCOPA president, Michael Campbell.
Q. Why did he ask you?
A. I don't know. He liked my smile. When

he became president he was a big advocate of putting -- as he says, the right people in the right seats on the bus. And for one reason or another, he thought I would do a good job in the legislative capacity and I accepted.
Q. So you don't have any sense of why he might have picked you?
A. I mean, I've been on the board for a while. We within our SCOPA board -- we have different directorship positions. And I had done several of those positions, and honestly, I don't know why he asked me to do it. But maybe he didn't know anyone else to do it or what the case may be. And I wanted to help my profession the best I could and so I accepted.
Q. Fair enough. How long were you on the board before he approached you?
A. I can't remember. I'm now going on my -- I don't recall exactly. Forth or fifth year on the board.
Q. So just help me do the math here. When would you have started on the board?
A. I would have started I believe in 2013. Yes, I believe that is correct.
Q. And you were tapped as legislative

co-chair in 2015? Is that January 1st or after that?
A. Our board starts a new cycle once a new president is elected. And that happens at our annual conference and that is usually in either late August or early September.
Q. So to the best of your recollection, you were probably appointed to the co-chair position sometime in late summer?
A. It would have been once Dr. Campbell became president which was in 2015. So would have been -- yes. I may be off a year here. I can't do the math in my head right now. But regardless, I was appointed or asked to do the position when Dr. Campbell became president.
Q. Which was in 2015?
A. Yes.
Q. Okay. What does your legislative responsibilities consist of?
A. I guess my capacity of legislative chair is I am responsible for being aware of any new legislation that may come up that has anything to do with vision or eye health and, let our board know of those new legislation or bills.
I'm also responsible for trying to

establish a grassroots effort. Making sure that our optometrists know their legislative people and making sure our optometrists know they are constituents of certain legislators within South Carolina.
Q. You mentioned monitoring legislation. How do you monitor?
A. We work with a law firm who monitors and tracks any new legislation that comes up, as well within the SGRC. They help monitor as well as any new legislation that comes up and that is based on key words.
Q. So the AOA's, SGRC -- do they send you updates on legislation?
A. They do, and that is something they just recently started.
Q. When is the earliest they started?
A. That was 2016. Just last year.
Q. As far as SCOPA goes, do you get legislation for just South Carolina or nationwide?
A. We get updates based on -- it is specific to South Carolina.
Q. And you also mentioned grassroots efforts. Do you work with anybody -- SCOPA's leadership board, employees, so forth on the

grassroots stuff?
A. I do.
Q. Who do you work with?
A. Within, I guess, the structure of our legislative positions that we have. I am the chair and then I have an elect committee. Each local society that we have has a director for each of those societies. Some societies are larger than others. So some societies have more than one director.
Others are smaller and have just one director of their society. But I work with them to help establish grassroots efforts within the entire state.
Q. So just to get a sense of the hierarchy here. Is it fair to say there is the AOA nationwide and the AOA has got state affiliates, right? So SCOPA is a state affiliate. And then you've got more local societies that are affiliates of you?
A. Correct.
Q. Are those local societies also affiliates of you?
A. Correct. You cannot be a member of the local society without being a member of the AOA.

Q. And on the grassroots stuff still -- do you work with Ms. Rivers at all, Jackie Rivers?
A. Yes.
Q. What does she do on the grassroots?
A. She helps with, I guess, a lot of the recordkeeping. Knowing which legislators have what we consider key people and maintaining contact information so that we can easily assess those individuals.
Q. When you say "assess," what do you mean by that?
A. So if we needed to contact a legislator because of any number of reasons she would know who our key person is as well as the constituents.
Q. Is it fair to say she would know the right optometrist in the right area to contact the right legislator?
A. Yes.
Q. And does Ms. Rivers help at all on the legislative stuff?
A. She does.
Q. What does she do?
A. So she is very -- if we have -- say any events in Columbia, whether it is a caucus or helping distribute information to legislators --

she is oftentimes there to help us do that.
Q. When you say "helping distribute information to legislators," what do you mean?
A. So if there is any particular piece of information that we feel that we want them to understand as far as our point view or concerns, it is not uncommon that we would perhaps draft something to give to her to pass out to those legislators.
Q. And that is in the capacity of not just legislation that you are monitoring, but is it also true she helps out on legislations you propose?
A. Yes.
Q. Do you know what the Tim Burrow Legislative Award is?
A. Yes. That is an award that we give out to an optometrist who is a member of SCOPA who has demonstrated a certain amount of passion for legislative efforts, I would say.
Q. Have you ever won it?
A. I have.
Q. When did you win it?
A. I won it last year.
Q. Why did you win it?
A. I would assume it was because of the

work that I did to reorganize our grassroots efforts that, I guess, needed to be done, and try to organize our legislative grassroots a bit better. And perhaps even the work that I did with the Eye Care Consumer Protection Act.
Q. What is that law?
A. The Eye Care Consumer Protection Law is the one we passed just last year that helps to protect vision correction and eye health and maintain the standard of care for the citizens of South Carolina.
Q. Which standard of care does it maintain?
A. The standard of care it maintains is with, I guess, was long established as the way to conduct an eye examination.
Q. Since SCOPA has the same standard of care as the AOA, or at least takes it from the AOA, is it fair to say that the ECCPL, Eye Care Consumer Protection Law, comes from AOA?
A. Correct. We based our law on the model language that they provided.
MR. WINDHAM: So I'm asking the court reporter to mark this as Exhibit 2. Just take a minute to look over this for me.

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status definition from the ECCPL?
A. I was.
Q. Is it fair to say that the first part of that definition for the word "however" defines visual status in the second part --
MR. SHEALY: Object to the form, but you may answer.
THE WITNESS -- it is.
MR. WINDHAM: Okay.
BY MR. WINDHAM:
Q. Is it possible to get a visual status without conducting an examination of the ocular health of the patient?
MR. MATTHEWS: Object to form.
MR. SHEALY: Object to form.
THE WITNESS: Repeat the question again.
MR. WINDHAM: Sure. Is it possible to get an ocular status without getting the ocular health of the patient?
MR. SHEALY: Object to form.
MR. MATTHEWS: Object to form.
THE WITNESS: Not that I know of.
BY MR. WINDHAM:
Q. So when you are describing a

comprehensive eye health exam as consisting of an assessment of the ocular health of a patient and individual status, do you mean those to be the same thing?
MR. SHEALY: Object to the form.
MR. MATTHEWS: Same objection.
THE WITNESS: I'm sorry. Repeat that again.
BY MR. WINDHAM:
Q. You described a comprehensive eye health exam as consisting of an assessment of the ocular health of a patient and the visual status. Are those different?
A. They are different. I'm sorry. Yes.
Q. How are they different?
A. Once again, it is an assessment of more of anatomy. And the other is, again, more of an assessment of the visual acuity, accomodation of amplitudes, and occular alignment.
Q. So the latter -- visual acuity, alignment and so forth -- do you need to get an ocular health profile to get those things?
A. Potentially. It depends on whether or not there are any medical reasons for ocular alignment not being, I guess, correct.

Q. How long does a comprehensive eye exam take?
A. It varies depending on the provider providing that care. I can say my office -- we provide a slot of 30 minutes to do that.
Q. Does that exam include a visual status?
A. It does.
Q. Okay. Have you ever renewed or adjusted a patient's corrective lens prescription without conducting a comprehensive eye exam?
A. The only time was in a specific situation where there was patient who was in a nursing home facility who was unable to come to an examination because of her limited mobility and receiving treatment in that facility.
And she had broken her glasses. So we documented the situation and that was the only time I recall of updating a prescription without an examination.
Q. Was that prescription accurate?
A. I can't say for certain because I didn't perform a comprehensive eye examination. But I wanted to be able to provide her with some form of correction since she was unavailable to physically come to the office so that we could, at

a very minimum, improve her quality of life.
Q. Was she a patient of yours?
A. She was.
Q. Is it fair to say that providing that prescription improved her quality of life?
A. I would think so because she had a family member reach out to us asking if we would help in this particular situation.
Q. Did you ever feel like you were putting her health at risk?
A. In that one instance, no.
Q. Did you feel you were violating any standard of care?
A. In that instance, no.
Q. Have you ever been aware of any other South Carolina eye health professional doing anything similar?
A. I do not know.
Q. Still looking at Exhibit 2. Do you see Paragraph 4, on the first page which starts with "Kiosk' means"...
A. Yes, I do.
Q. Could you just read that definition for me?
A. "Kiosk means automated equipment or an

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automated application, which is designed to be used on a phone, computer, or internet-based device that can be used in person or remotely to provide for refractive data or information."

Q. What is your understanding of that provision?

A. Exactly as it defines.

Q. Fair enough. Do you know who came up with the language for this definition?

A. It would have been the AOA.

Q. Is this the same language of the AOA's model legislation?

A. I would have to review that legislative or the model language, but I believe that to be true.

Q. The definition mentions refractive data. What is refractive data?

A. Refractive data would be information needed to improve an individual's eyesight or vision, I should say.

Q. Let me ask you this: What does "refractive" mean?

A. Refraction or refractive is just a physics term that refers to bending light in a certain manner.

Q. So refractive data refers to how light bends in the eye, more or less?

A. Yes.

Q. I forgot to say if you need to take a break just let me know. I know this can be a bit tiresome.

A. Okay.

Q. As an optometrist, can you just walk me through how you go about obtaining that information about how light bends in the eye from a patient? The refractive data.

A. There is a multitude of ways of doing it. One way is using auto refractive -- an auto refractor to give us a starting point to, I guess, finalize what ultimately will become a prescription after other measurements are taken.

Another way is by doing what is called a refraction. And that is when we are basically manually using light, and, I guess, assessing how light bends based on lenses that we put in front of an eye.

Q. What lenses? Are you referring to the lenses in a phoropter?

A. A phoropter, yes.

Q. What is a phoropter?

A. A phoropter is a device we use that has a multitude of lenses that allow us to determine partially what a patient's prescription might ultimately become.

Q. Can you just explain how a phoropter works?

A. There is a number of dials that when you turn will give a different lens. It will put a different lens power in front of the eye.

Q. As an optometrist, do you turn the dials yourself?

A. I do.

Q. And just paint a picture for me.

So when the patient is in your office and you are using a phoropter, where is the patient and what is the patient looking at?

A. The patient is sitting in an exam chair. The phoropter is placed in front of the patient so that are looking through the oculars of the phoropter. They are facing an acuity chart and I am between the patient and the acuity chart and making adjustments to the phoropter based on subjective information that I get from them.

Sometimes, though, I will also use a retina scope and sit just off to the side of the

patient and shine light in through the oculars so I can see how the light bends to help me further assess what the prescription will ultimately become.

Q. Is it fair to say that you use a phoropter every time?

A. Yes.

Q. Okay. What images of the patient are you looking at?

A. It depends on the patient, but the majority of the times it is an acuity chart.

Q. What is an acuity chart?

A. It is chart that has different-sized letters that we use to assess the visual acuity of the patient.

Q. How is that chart displayed?

A. In my office we use an electronic acuity chart that we have on the wall. We also have different types of charts that we use depending on the level of visual acuity the patient may have. Because sometimes the visual acuity might be so great they are unable to see the biggest letter on that chart. In other cases we have to use different charts.

Q. You said it is projected on that wall?

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A. It is not projected. It is on a monitor.
Q. Is that on a computer monitoring screen?
A. It is on a computer monitor screen. We purchased this equipment from a vendor within the eye care field.
Q. How do you switch the images on the screen?
A. With a remote control.
Q. You just click in response to the patient's responses?
A. Correct.
Q. You call those subjective. What does that mean?
A. It is the patient's answer to questions I'm asking.
Q. Okay. What questions are you asking? Can you give me some examples.
A. For example, which image is more clear? Can you give me an idea of the quality of image that you are seeing? You know, are you seeing multiple images? Are you seeing double? These are all the questions that I might ask.
Q. So we are still talking about how to

get refractive data.
How does this process give you the refractive data?
A. It is going to give me information based on what the manifest refraction would be. That's one piece of information. We also take into account the subjective information that the patient gives us and we also look at, you know, eye alignment, accomodation of amplitudes to ultimately determine prescription.
Q. And this is all based on patient responses?
A. Not all.
Q. What's not based on the patient's responses?
A. Manifest refraction.
Q. Can you explain that?
A. Manifest refraction is a refraction that I'm not asking the patient anything. This is based on my training and what I see and how light bends based on a more manual refraction that I need to do.
Q. So you are gathering information at this point. Do you write the information down somewhere?

A. Yes.
Q. What do you write it on?
A. On my computer records.
Q. So you enter the information into like a form on the computer?
A. Yes.
Q. We are still talking about a kiosk. Is a phoropter a kiosk?
A. It is not.
Q. Why not?
A. Because it is not a phone. It is not a computer, and it is not an internet-based device used to help determine a refraction.
Q. Is that the only reason a phoropter is not a kiosk?
MR. SHEALY: Object to form.
MR. MATTHEWS: Object to form.
THE WITNESS: Again, kind of silly. I would have to say based on the definition of a kiosk. That is why a phoropter is not a kiosk.
BY MR. WINDHAM:
Q. Looking back at Page 2 of Exhibit 2. Do you see Paragraph C which starts "A prescription for spectacles"?
A. Yes.

Q. Could you read that provision for me?
A. "A prescription for spectacles or contact lenses may not be based solely on the refractive eye error of the human eye or be generated by a kiosk."
Q. What is your understanding of that language?
A. That a prescription is not entirely based on refractive error of the human eye, and that it can't be generated by a kiosk.
Q. Do you know who came up with that language?
A. I do not. I would assume the AOA.
Q. Is it fair to say it came from the AOA's model legislation?
A. I would say so.
Q. Is it okay if I call it a Kiosk Restriction for short so we know what we are talking about?
A. I assume so, yes.
Q. Does the Kiosk Restriction prevent you from using a phoropter to renew or adjust a patient's previous corrective lens prescription?
MR. SHEALY: Object to the form.
MR. MATTHEWS: Same objection.

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Ophthalmology recommends that an eye examination should first be at the age of 40. I assume that to be if I remember correctly.

Q. Based on your understanding, does the AAO recommend that the patient receive a comprehensive eye exam every single year?

A. I don't recall.

MR. WINDHAM: I'm asking the reporter to mark this as Exhibit 3.

Q. I have just handed the witness what has been marked as Exhibit 3.

Sir, do you recognize this document?

(PLF. EXH. NO. 3, Policy Statement, Frequency of Ocular Examinations, was marked for identification.)

A. I do not.

Q. Do you see at the top there where it says this document is an American Academy of Ophthalmology Policy statement regarding the Frequency of Ocular Examinations?

A. I do see that.

Q. Do you see the paragraph towards the bottom under the section titled "Evaluation," which starts with adults with no signs?

A. I do.

Q. Would you do me a favor and read that paragraph to yourself for me and let me know when you finish?

A. Okay.

Q. Is it fair to say that this paragraph recommends that patients receive a comprehensive eye health exam at different intervals depending on their age and health factors?

A. Yes.

Q. Are some of those intervals longer every single year?

A. Yes.

Q. In fact, are there any of the recommended intervals in that paragraph that are as frequent as every single year?

A. Yes.

Q. Which?

A. For individuals 55 to 64, the recommended intervals for evaluation is one to three years. And for individuals 65 and older, the American Academy of Ophthalmology recommends an examination every one to two years, even if absent of symptoms.

Q. Do you have any reason to doubt that this is an inaccurate statement of the standard of

care among ophthalmologists for the recommended frequency of eye health exams?

A. I do not. I'm not an ophthalmologist.

Q. Does the ECCPL govern ophthalmologists?

MR. MATTHEWS: Object to form. Please answer.

MR. SHEALY: Object to form.

THE WITNESS: The Eye Care Consumer Protection Law is the law in South Carolina which both optometrists and ophthalmologists must abide by.

BY MR. WINDHAM:

Q. So it is fair to say that ophthalmologists have to comply with the ECCPL?

A. Correct.

Q. And you helped to get that law passed?

A. I did.

Q. Earlier we talked about your legislative role on the SCOPA board and we touched on the AOA's SGRC.

Do you recall attending a webinar in 2015 titled "Online Vision Screening, Self-adjusting Glasses, and Kiosk and What ODs Need to Know"?

A. I do.

Q. What do you remember about that webinar?

A. That was probably one of my first real introductions or first time online eye exams and kiosks were becoming, I guess, a thing within the eye care -- in the world of eye care.

Q. When you say "a thing," what do you mean?

A. Well, it is new technology. I previously did not know much about it until I was made aware from this meeting.

Q. After you saw the webinar, did you do anything based on that information?

A. Yes. I guess my initial concern was that we needed to -- as a state organization be aware of this coming technology and express some, I guess, some thoughts or concerns to our SCOPA board at the time that we should discuss this new technology.

Q. Why was it important that the SCOPA board be aware of the technology?

A. There is a number of reasons, but one of the most concerning is we felt it was undermining the standard of care for patient care.

MR. WINDHAM: I'm asking the court

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reporter to mark this as Exhibit 4.
(PLF. EXH. NO. 4, Email Chain, was marked for identification.)
Q. I'll just give you a moment to look through this document, because I know it is big.
MR. MATTHEWS: I'll tell you what. While you are doing that I'm going to take a break.
MR. WINDHAM: Off the record.
(Off the record.)
BY MR. WINDHAM:
Q. So Dr. Zolman, we are looking at Exhibit 4, which I believe you had a chance to look at.
A. Yes.
Q. This is an email chain, correct?
A. It is.
Q. What is this email chain?
A. This is an email chain that, I guess, kind of started the whole idea of us getting together some kind of legislation, particularly as far as the Consumer Protection Eye Care is concerned.
Q. Do you see the first page there that starts at the very top, "From: Michael Zolman"?
A. Yes.

Q. Do you recognize that email?
A. I do.
Q. Did you send that email in response to the SCRG webinar we were just talking about?
A. I did.
Q. Why?
A. For a number of reasons that we had concerns about. Technology and how it potentially lowered the standard of care within our profession. And then I had made some, I guess, hypothetical remarks also within that email.
Q. What were those hypothetical remarks about?
A. Well, you know, just as far as what, I guess, potentially -- how it could potentially affect our profession on, I guess, a business front. You know, looking at -- you know, kind of reading over these remarks now, some are a bit farfetched.
And during this process, you know, I realized, you know, that is not the reason that we drafted the language anyway, because again it was drafted because of our concern for public health and safety.
Q. Is it fair to say in this email you

were concerned with how technology presented in the SGRC webinar might impact the business side of the optometry profession?
MR. MATTHEWS: Object to form.
MR. SHEALY: Object to form.
BY MR. WINDHAM:
Q. Is that a yes?
A. I would say, yes. Just based on my hypothetical.
Q. Do you see the line where you say that AOA's president, David Cockrell, believed 1-800 Contacts to be the single greatest threat to our profession?
A. Yes.
Q. In what sense do you understand him to be saying that 1-800 Contacts was a threat?
A. Because we had learned that they were looking for legislators that would potentially allow venders to change a contact lens prescription.
Q. You are doing some forecasting in this email.
Was it your understanding of President Cockrell's threat comment that it was a threat to the industry itself?

MR. MATTHEWS: Object to the form. Please answer.
MR. SHEALY: Object to the form.
THE WITNESS: It was more of a threat to patient safety.
BY MR. WINDHAM:
Q. When you wrote this email, was it your understanding that President Cockrell's remark referred to the business side of optometry?
A. No.
MR. SHEALY: Object to the form.
BY MR. WINDHAM:
Q. Do you see the line where you say "I feel the issue of kiosks and online eye exams are an even greater threat." It is in the same paragraph in the end.
A. I'm sorry. Yes, I do see that.
Q. What did you mean?
A. I thought that it is more of a threat because that potentially could affect a lot more patients than just a patient who wants to wear contact lenses.
Q. When you wrote this email, did you have any concern that kiosks or online eye exams would impact the business side of optometry?

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A. At the time I had concerns, yes.
Q. When you wrote this email did you have Opternative in mind?
A. At the time Opternative was probably the most well-known of those online internet companies.
Q. Is it fair to say that you had Opternative in mind when you wrote this email?
MR. MATTHEWS: Object to form. Please answer.
THE WITNESS: They were one of them, yes.
BY MR. WINDHAM:
Q. Do you see the second to last paragraph there, the line where you say that "Total eye care is a $35,000,000,000 industry. $23,000,000,000 coming from glasses and CLs"?
A. I do.
Q. What are CLs?
A. Contact lenses.
Q. Based on that comment, is it fair to say when you wrote this email you believed that glasses and contact lens sales made up the majority of the revenue in this industry?
MR. SHEALY: Object to form.

MR. MATTHEWS: Same objection.
THE WITNESS: No.
BY MR. WINDHAM:
Q. Can you explain why?
A. Because not all practices generate their income based on glasses and contact lens sales.
Q. In the sentence we were talking about the $35,000,000,000 sentence. You refer to total eye care.
What is total eye care?
A. That is going to be both the, I guess -- the medical side of optometry as well as the vision side of optometry.
Q. And when you say that total eye care is a $35,000,000,000 industry, does that mean that the $35,000,000,000 is the total revenue of the industry?
A. I'm not certain. This is taken from the AOA presentation from the SGRC presentation.
Q. I'm just trying to make sense of your understanding of the language as you used it in this email.
A. I took that then to just like it says: Total eye care being a $35,000,000,000 industry as

far as, I guess, revenue generated.
Q. The $23,000,000,000 coming from glasses and CL sales in this sentence -- is that the majority of a $35,000,000,000 industry you are referring to?
A. Yes.
Q. In this email, did you forward anything along to the board?
A. I believe I did. It was just a -- I believe it was an actual webinar or the presentation that the SGRC gave us.
Q. And that included the AOA's model legislation, right?
A. Correct.
Q. Did you make any recommendations to the board in this email?
A. That we discussed.
Q. Did the board do anything based on that recommendation?
A. We discussed.
Q. Do you see on the first page the email from Wayne Cannon?
A. Yes, I do.
Q. What is Wayne Cannon saying in that email?

A. He said "The SCOPA board voted to evaluate the passing of a consumer protection legislation. The AOA suggested bill is attached for your review. We will need to meet soon to evaluate our strategy."
Q. So the SCOPA board actually held a vote and as an organization committed to pursuing Consumer Production Legislation?
MR. MATTHEWS: Object to the form.
THE WITNESS: We did.
BY MR. WINDHAM:
Q. Did that happen based on the email that you sent?
MR. SHEALY: Object to form.
THE WITNESS: I don't know if it was solely based on the email I sent.
BY MR. WINDHAM:
Q. Do you think your email inspired your vote to the board?
MR. SHEALY: Object to form.
THE WITNESS: I would hope so.
BY MR. WINDHAM:
Q. Fair enough. Was the ECCPL intended to prevent the use of Opternative to write corrective lens prescriptions?

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MR. MATTHEWS: Object to form.
MR. SHEALY: Object to form.
A. No.
Q. Was the ECCPL intended to prevent the use of online eye exams?
A. No.
Q. All right.
MR. WINDHAM: I'm asking the court reporter to mark this as Exhibit 5.
(PLF. EXH. NO. 5, Email Chain, was marked for identification.)
BY MR. WINDHAM:
Q. Just take a minute to go through that and let me know if you recognize it.
A. I do.
Q. What is this email chain?
A. This is an email chain it looks like that involved myself, our lobbyist at the time, a few other board members, regarding meeting the senate and house staff regarding the Eye Care Consumer Protection Act.
Q. Was this during the legislative process?
A. Yes.
Q. What was being discussed in the email

chain itself?
A. Looks as if this is just us discussing or trying to work on, I guess, language.
Q. When you say "us" do you mean the board and your lobbyist?
A. Yes, I do.
Q. On Page 3 at the bottom right. It says SCOPA 000811?
A. Yes.
Q. Do you see the line that reads -- it is the last paragraph of the email there. Do you see the line that reads "I feel if there are no penalties, then nothing has really been accomplished in preventing online eye exams, which is the main concern for the future"?
A. I'm sorry. I don't see where.
Q. That is fair. So in the middle of SCOPA 000811, there is a paragraph that starts with "Perhaps we would be more successful"?
A. "Working with LLR"?
Q. Yes. Do you see where it says "I feel if there are no penalties, then nothing has really been accomplished in preventing online eye exams, which is the main concern for the future"?
A. I do see that.

Q. Based on that language is it fair to say the ECCPL was intended to prevent the use of online eye exams?
MR. SHEALY: Object to the form.
THE WITNESS: Yes. But the reason for that was because it neglects the ocular health examination. So it puts the public at risk.
BY MR. WINDHAM:
Q. How do online eye exams do that?
A. Because it is not a comprehensive eye exam.
Q. Okay. So just to be clear, an online eye exam that doesn't involve a comprehensive eye exam puts patients at risk?
MR. SHEALY: Object to the form. You may answer.
THE WITNESS: Well, the problem is the term "eye exam." It is online. You are not getting an eye exam. And that is the deception that we are concerned about to the public as it is being marketed as such.
BY MR. WINDHAM:
Q. So are you familiar with the company Opternative?
A. To some degree.

Q. Do you know how Opternative markets its technology?
A. They do it a number of ways. They -- at one point were marketing as that they are able to do a faster eye examination then the, I guess -- the standard eye examination that you get from an optometrist or ophthalmologist.
Q. So this chain of emails, you are working on amended language to the ECCPL and you say that the goal in the paragraph we just discussed is preventing online eye exams. Did Opternative advertise itself at this time as providing an online eye exam?
MR. MATTHEWS: Object to form.
A. I don't recall.
Q. If there was a company that had Opternative's same business model, that did not advertise itself as providing an online exam, would you have tried to prevent that company from operating with this bill?
MR. MATTHEWS: Object to form.
MR. SHEALY: Object to form.
THE WITNESS: If they maintain the same standard of care of what they can get from an eye care professional and what we consider the standard

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of care for eye exams then, no.
BY MR. WINDHAM:
Q. Can you just walk me through that a bit.
How could a company with the same business model of Opternative comply with this law?
MR. SHEALY: Object to the form.
MR. MATTHEWS: Object to the form.
THE WITNESS: They would have to meet the same standard of care of what an eye professional does in his office.
(PLF. EXH. NO. 6, Email Chain, was marked for identification.)
BY MR. WINDHAM:
Q. I'm handing the witness what's been marked as Exhibit 6. Just take a minute to look through that for me and let me know when you have finished.
A. Okay.
Q. Do you recognize this email chain?
A. I do.
Q. Can you just describe generally what it is?
A. This is an email chain that I'm trying to put everything in reference to when it happened.

This is when it looks like we just overrode the governor's veto.
Q. When you say "we," you mean SCOPA?
A. Yes, SCOPA.
Q. Can you turn to the last page of Exhibit 6. Do you see the line in the middle of the page that starts with "It is with the utmost pleasure"?
A. I do.
Q. Do you see where it says "It is with the utmost pleasure to announce that today, Opternative and 'eye exam' kiosks are now PROHIBITED BY LAW in the great state of SC!"
A. I do.
Q. What does that mean?
A. That means that based on the way Opternative conducts their business that they are prohibited by law in South Carolina because they don't meet the standard of care.
Q. Do you see the line in the next paragraph where it says "This is what organized Optometry looks like at it's best! It took grassroots efforts of all of you contacting your legislators to make this happen as well as the tireless of your SCOPA Board of Directors working

in conjunction with AOA to make this possible."
A. I do.
Q. What does that mean?
A. Exactly what it sounds like. We work very hard on a grassroots efforts to get legislation brought about working with AOA in order to ensure public safety in regards to vision and eye care.
Q. Was this email sent out to the SCOPA membership?
A. Yes.
Q. Was this after Governor Haley's veto?
A. Yes.
Q. What does the line above your name at the bottom of the email mean?
A. "Good-bye Opternative."
Q. What does that mean?
A. It means that they are no longer able to conduct their business within our state, which we felt was potentially harmful to the eye care and vision safety of our citizens.
Q. Earlier you testified that patients coming in for corrective lenses constitutes about 50/50 of your daily appointments?
A. In my personal practice.

Q. In a typical day at the office after you test those patients' vision, where do they walk after the appointment?
A. Repeat the question.
Q. After a patient comes in for a corrective lens and you do the testing we talked about earlier, where do they walk out of your office?
A. After the exam is over?
Q. Correct.
A. They are free to purchase glasses if they are so inclined.
Q. Where would they do that?
A. Either in our office or anywhere they choose that sells glasses.
Q. Are the eyeglasses on display in your office?
A. Frames are.
Q. How many?
A. In my office, I think I have roughly 500.
Q. Have you or anyone in your office ever attempted to sell those frames?
A. Yes.
Q. How often do you attempt those sales?

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A. Any time a patient could benefit from either improved vision or if there has not been a change in prescription. They may be scratched or damaged.
Q. Is it fair to say that when you write a prescription for new lenses, whether glasses or contacts or lenses -- is that when you make a sale?
A. Every so often.
Q. I'm just trying to nail down whether you do it every time or not.
A. Not if they already have some place they currently go to purchase their glassware elsewhere.
Q. Do you do it most of the time?
A. I'd say most of the time.
Q. If online eye exams like Opternative's were allowed in South Carolina and became commercially popular, how would they impact those glasses sales?
MR. SHEALY: Object to the form.
THE WITNESS: Well, any time you have increased competition there is a likelihood of sales dropping, but competition is not always bad.
BY MR. WINDHAM:
Q. In that situation where online eye

exams became popular, how would they impact your overall revenue stream at your practice?
MR. SHEALY: Object to the form.
MR. MATTHEWS: Object to the form.
THE WITNESS: Well, initially it would go down, but if there is undiagnosed health concerns that get missed and visual impairments become increased then revenue would go up because now I'm seeing more pathology.
In chronic care patients that have any number of eye diseases that need to be monitored more closely would then cause sales to go up -- revenue to go up.
BY MR. WINDHAM:
Q. I just have a few more questions.
A. Sure.
Q. Do you know the revenue percentage from frame sales at your practice?
A. I do not. I would have to review that information.
Q. Do you have a sense of whether it constitutes a majority of your revenue?
A. It is not a majority in my practice.
Q. So earlier we talked about the actual eye exam process, especially for corrective lenses

and you using an auto refractor and you also taking other measurements.
Can you just explain what those other measurements are?
A. The other measurements are potentially a manifest refraction. One that is not based on an auto refractor. We also measure ocular alignment. We also measure accommodation depending on complaints of the patient.
Q. You said you use a phoropter every time you are writing a prescription for corrective lenses. Do you use a manifest every time?
A. Not every time.
MR. MATTHEWS: Okay. Nothing further.
EXAMINATION
BY MR. MATTHEWS:
Q. Dr. Zolman, did you ever meet with any person from LLR during your advocacy in this bill?
A. We did.
Q. Did you specifically?
A. I don't recall.
Q. Okay. Do you remember who it was?
A. I don't recall the name.
Q. Okay. Right now, you as an optometrist, you are subject to regulation by the

Board of Optometry?
A. That is correct.
Q. Do you know if Opternative is?
A. I do not know.
Q. Well, let me ask you this: If you wanted to use the technology that Opternative offers and conduct a more comprehensive exam to address your concerns about eye care, you could do that, could you?
A. I could.
Q. You could write a prescription using Opternative's technology as long as you conduct an eye exam?
A. That is correct.
Q. So as of this moment, Opternative in your view, can conduct business in South Carolina and still be in compliance with the ECCPL?
A. That would be true.
Q. Okay. Well, Exhibit 4 that these gentleman handed you. On the bottom of the second page. First sentence reads "I don't need to tell any of you that this is potentially a huge threat to our profession but more importantly to the general public. Think of all the glaucoma, ARMD, Diabetic retinopathy, Cataracts, amblyopia, (the

list goes on and on) that would be missed."
I noticed when you -- when I say "you," I mean the SCOPA. When it answered interrogatories it listed as the reason "It believed supported the legislation was as following: The ECCPL protects patients of opthamologists, optometrists, and put in there I helped by obtaining a prescription for corrective lenses without a comprehensive eye examination.
Certain diseases of the eye or the body may go undiagnosed without if patients merely elect to purchase corrective lenses using remote eye refraction eye measurement tools without an in-person comprehensive eye exam."
Do you stand by that answer?
A. I do.
Q. Is that the reason you believe the legislature passed the law and overrode the governor's veto?
A. I do.
Q. Okay. But you didn't vote for it because you're not a legislator?
A. That's right.
Q. Yesterday we determined about 130 some odd legislators voted for that legislation one way

or the other.
Do you know any of them?
A. I do.
Q. Okay. How many?
A. Me, personally, I know -- I would say two relatively well.
Q. Okay. Did they tell you why they voted for the law?
A. They did not.
Q. Okay. So you don't really know why they voted for the law, do you?
A. No.
Q. Okay. You know why they advocated for the law?
A. I know why they advocated for the law. I don't know why they voted for the law.
Q. You advocated the law because you thought it would protect patient health?
A. Correct.
MR. MATTHEWS: Okay. Thank you very much.
MR. SHEALY: I have no questions.
MR. WINDHAM: I think that's all.
(The deposition was concluded at 11:29 a.m.)

STATE OF SOUTH CAROLINA.
COUNTY OF BERKELEY

CERTIFICATE OF REPORTER

I, Jessica R. Dixon and Notary Public for the State of South Carolina at Large, do hereby certify that the foregoing transcript of Michael Zolman, O.D. was taken by me and transcribed by me and is a true, accurate, and complete record.
I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.
In witness whereof, I have hereunto set my hand this 2nd day of August, 2017 at Charleston, South Carolina.

_____
Jessica R. Dixon
Court Reporter
My Commission Expires:
01/27/2027

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AMERICAN ACADEMY® OF OPHTHALMOLOGY
The Eye M.D. Association

POLICY STATEMENT

Frequency of Ocular Examinations

Policy

The frequency of ocular examinations should be based on the presence of visual abnormalities and the probability of visual abnormalities developing. Individuals who have ocular symptoms require prompt examinations. Individuals who do not have symptoms but who are at high risk of developing ocular abnormalities related to systemic diseases, such as diabetes mellitus and hypertension or who have a family history of eye disease, require periodic comprehensive eye examinations to prevent or minimize visual loss. The frequency of examinations depends on an individual's age, specific condition, and the likelihood of finding abnormalities on examination. Adults who have no symptoms, and who are at low risk, should receive an initial comprehensive eye examination by an ophthalmologist and follow a schedule of periodic assessment designed to detect ocular disease.

Background

There are several times in an individual's lifetime when an ocular examination is extremely important. Certain infectious, congenital, and hereditary eye diseases may be manifest at birth, and since they create a risk to vision if undetected, a screening in the newborn is justified. Infants who have detected abnormalities as well as infants with risk factors, such as systemic diseases or a family history of certain conditions, should be referred for a comprehensive eye examination by an ophthalmologist.

Children should receive age-appropriate eye health and vision screenings throughout childhood because different childhood eye problems may be detected at each visit and new problems can arise. The goal is to identify and treat preventable visual impairment at the earliest feasible age. The elements of vision screening vary depending on the age and level of cooperation of the child. Instrument-based screening is first recommended between 6–12 months of age and until a child is able to cooperate for subjective visual acuity testing as stated in the Academy's Pediatric Eye Evaluation, Preferred Practice Pattern® guidelines. The ophthalmologist should be aware there is a trade-off in terms of false positives and false negatives with instrument-based technology as data are analyzed on the basis of preset refractive error criteria to determine whether a child passes or fails.[1] Amblyopia is estimated to occur at a rate of 1–3% in children aged 6–72 months,[2, 3] and may lead to functional blindness if undetected by autorefractors or photoscreening. Therefore any child with an abnormal subjective visual acuity assessment, or one who has not been successfully tested by age 3,[1] should be referred for a comprehensive eye examination by an ophthalmologist.

The major abnormality among school-age children is the unrecognized development and progression of myopic refractive error, and individuals in this age group should be examined during primary health care visits. Myopia can develop in individuals in their 20s, and it can progress in those whose refractive error did not stabilize in the teenage years. In the young adult the rate of development of other significant eye disease is low, but it increases steadily after the age of 40.

Evaluation

Adults with no signs or risk factors for eye disease should receive a comprehensive medical eye evaluation at age 40 if they have not previously received one.[4] Before the onset of

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presbyopia (at approximately age 40), the majority of American adults experience no changing refractive error or significant ocular disease and routine eye examinations are not indicated. For asymptomatic individuals or individuals without risk factors, who are 40 to 54 years old, and who have had a comprehensive eye examination, the recommended interval for evaluations is 2 to 4 years. For individuals aged 55 to 64 years old, the recommended interval for evaluations is 1 to 3 years. For individuals 65 years old or older, the American Academy of Ophthalmology recommends an examination every 1 to 2 years, even in the absence of symptoms.[5]

Note that an eye examination is warranted if ocular symptoms, visual changes, or injury are involved. Also, for individuals at higher risk for certain diseases, such as African-Americans and Hispanics who are at higher risk for glaucoma, comprehensive eye examinations should be considered every 2 to 4 years for those under age 40, every 1 to 3 years for those aged 40 to 54, and every 1 to 2 years for those aged 55 to 64, even in the absence of visual or ocular symptoms.[4, 6, 7, 8, 9, 10, 11]

Recommendations

1. Infants at high risk, such as those with the potential for retinopathy of prematurity and those with a family history of retinoblastoma, childhood cataracts, childhood glaucoma, or metabolic and genetic disease, should have a comprehensive examination by an ophthalmologist as soon as medically feasible.

2. Children should have an assessment for eye problems in the newborn period and then at all subsequent routine health supervision visits. The elements of the assessment vary with the age of the child. Abnormalities present at birth, such as opacities of the ocular media (e.g., congenital cataract) or ptosis, may have profound effects on normal vision development in an infant. By age 3 to 3 1/2 years, the child will generally cooperate enough for fairly accurate assessment of visual acuity and ocular alignment.[1] He or she should have these assessed by a pediatrician or other medical practitioner.[12] Any abnormalities or the inability to test are criteria for referral to an ophthalmologist.

3. School-age children should be evaluated regularly for visual acuity and ocular alignment (approximately every 1 to 2 years) during primary health care visits, in schools, or at public screenings. Note the choice and arrangement of optotypes (letters, numbers, symbols) on an eye chart can significantly affect the visual acuity score obtained. Preferred optoypes are standardized and validated.[1]

4. Individuals who develop diabetes mellitus type 1 should be examined by an ophthalmologist 5 years after disease onset and at least yearly thereafter.[13, 14] Individuals who develop diabetes mellitus type 2 should be examined at the time of diagnosis and at least yearly thereafter.[15] Women with type 1 or type 2 diabetes should receive a comprehensive eye examination before conception and then early in the first trimester of pregnancy. Recommended intervals for subsequent examinations depend upon the level of retinopathy.[16-18]

5. Adults with no signs or risk factors for eye disease should receive a baseline comprehensive eye evaluation at age 40.[4] Individuals without risk factors aged 40 to 54 should be examined by an ophthalmologist every 2 to 4 years. Individuals without risk factors aged 55 to 64 should be examined by an ophthalmologist every 1 to 3 years.[4, 5]

6. Individuals without risk factors 65 years old or older should have an examination performed by an ophthalmologist every 1 to 2 years as the incidence of unrecognized

ocular disease increases with age.[4, 5]

7. The frequency of ocular examinations in the presence of acute or chronic disease will vary widely with intervals ranging from hours to several months, depending on the risks involved, response to treatment, and potential for the disease to progress.

8. Any individual at higher risk for developing disease, based on ocular and medical history, family history, age, or race should have periodic examinations determined by the particular risks, even if no symptoms are present.

9. A routine comprehensive annual adult eye examination in individuals under the age of 40 unnecessarily escalates the cost of eye care and is not indicated except as described above.

Summary

In summary, the frequency of ocular examinations should depend on the individual's age, race, past ocular history, medical history, family history of eye disease, and the types of symptoms or ocular findings encountered. If significant ocular disease is detected, the frequency of examination will depend on the severity of the condition, the response to therapy or surgery, and the potential for detecting progression of the abnormality.

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Approvals
American Academy of Ophthalmology, Board of Directors, February 1983

Revised and Approved by:

American Academy of Ophthalmology, Board of Directors; September 1990, February 2000, February 2005, November 2009, February 2015

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From: Angelia Smith Owens <angelia@kmso.net>
Sent: Monday, June 20, 2016 1:44 PM
To: Jackie Rivers
Subject: FW: FW: Kiosks and Online Eye Exams
Attachments: Consumer Protection in Eye Care Act Final (2).docx; Online Vision Screening Self-adjusting Glasses and Kiosks final (1).pdf

This is the first email I found. Looks like Dr. Zoleman emailed the Board in March, but this wasn't forwarded to me and Mark until May. We worked with Ron Scott over the summer and fall on language. Let me know if you need anything else. Thanks!

From: Wayne Cannon [mailto:wmcannon15@gmail.com]
Sent: Thursday, May 21, 2015 8:30 AM
To: Angelia Smith Owens
Subject: Fwd: FW: Kiosks and Online Eye Exams

The SCOPA board voted to evaluate the passing of a consumer protection leg. The AOA suggested bill is attached for your review. We will need to meet soon to evaluate our strategy.

---------- Forwarded message ----------
From: "Jackie Rivers" <jrivers@sceyedoctors.com>
Date: May 20, 2015 6:49 PM
Subject: FW: Kiosks and Online Eye Exams
To: "Anna Balderson" <abalderson@sceyedoctors.com>, "Bob Branch (jeyes4us@yahoo.com)" <jeyes4us@yahoo.com>, "David McKenzie" <drdavid@mckenzieeyecare.com>, "Jennie Smith Zolman" <jenniesmithod@yahoo.com>, "Johndra McNeely" <uptownnw@yahoo.com>, "Mike Campbell (mcamp16035@aol.com)" <mcamp16035@aol.com>, "Mike Zolman" <focusedeyedoc@yahoo.com>, "Pete Smith" <smithforhouse@gmail.com>, "Ted Newman" <tnewman123@bellsouth.net>, "Wayne Cannon" <wmcannon15@gmail.com>
Cc:

All, below is the e-mail sent out by Dr. Mike Zolman with his thoughts and the info the Consumer Protection in Eye Care Act and another presentation from the AOA.

Passing along so everyone can get reacquainted with the info.

Thanks!!

From: Michael Zolman
Sent: 3/19/2015 12:15 PM
To: Bob Branch; Wayne Cannon; Jennie Smith; Michael Campbell; David McKenzie; Johndra McNeely; Ted Newman
Cc: Jackie Rivers; Anna Balderson
Subject: Kiosks and Online Eye Exams

It was great seeing everyone last weekend at our Spring Convention!

I thought we had a productive board meeting but as ya'll know, we ran short on time and didn't have time to bring up New Business. I wanted to bring up some new business that I feel is of utmost importance to our profession and one that we need to address quickly and attack aggressively. That is the issue of kiosks and online eye exams.

At the HOD at SECO, AOA President David Cockrell stated that the single biggest threat to our profession he feels is 1800 seeking legislation to be able to 'change' a doctor's CL prescription to a proprietary brand of their choosing . He felt this way because this could set a precedent for other retailers to propose similar type legislation on our profession. While this is certainly a big threat, I feel the issue of kiosks and online eye exams are an even greater threat. Here's why:

As of now, Self-Refracting Kiosks currently exist and are being heavily marketed in Europe and Asia. The patient puts in a few dollars, the kiosk 'interacts' with the pt to determine the refraction and a prescription for glasses (or CL) is generated for the pt to take to the nearest optical or the pt can order the glasses or CL online from the kiosk and then have them sent directly to the patient's house. No exam needed, no doctor needed. In the US though, there has to be a doctor's signature in order to have a valid prescription. But what would happen when you combine a Self-Refracting Kiosk with Telemedicine? It would only take one sellout OD or ophthalmologist to approve of countless prescriptions generated from self-refracting kiosks and forego the exam altogether.

Now play this forward when the self-refracting/telemedicine kiosk becomes popular and known to the public. Who would be interested in this technology? I think it is reasonable for every Walmart, Lenscrafters, Costco, Pearl, Sears, JCPenney, America's Best, Eyeglass World.....(the list goes on and would likely include every commercial retail optical) ..... would have great interest in this technology. Our colleagues in commercial practices would be at great risk of becoming irrelevant in that practice model. Why? In the eyes of a commercial retail corporation, which would be more cost effective?.....paying ~$50,000 to $100,00 for this technology that takes up less than 10 square/feet of space and can generate prescription in only a few minutes; or, guaranteeing an Optometrist an annual salary, paying for 1-3 lanes of equipment, paying for the office space, paying for the staff and maintaining a contract with an optometrist to ensure he is there 6 days a week so that he can generate a prescription at the end of a 20 minute eye exam? Both scenarios generate prescriptions for the optical but the kiosk could do it for much much less and more quickly. Plus, theoretically by way of telemedicine, one OD could oversee prescriptions for countless kiosk locations vs these locations needing to hire multiple ODs to generate prescriptions. The savings would be huge. And as much as we like to think that patients would not do this because there is no health evaluation of the eyes by a doctor, how many patients do we see daily who really come in just wanting a new prescription for glasses and/or contacts? This would allow the patient to 'skip going to the doctor' and allow them to get what they want. This holds true for online eye exams as well.

I know this sounds a bit far fetched right now and Im not typically 'the sky is falling' kind of guy but I think there is some real validity to this possibility and could be a reality in the not so distance future. Plus, with total eye care being a 35 BILLION DOLLAR industry, 23 BILLION coming from glasses and CL sales, the financial incentive is certainly there to eliminate the need to have an OD to generate a prescription in the eyes of a retailer.

I don't need to tell any of you that this is potentially a huge threat to our profession but more importantly to the general public. Think of all the glaucoma, ARMD, Diabetic retinopathy, Cataracts, amblyopia, (the list goes on and on) that would be missed. Fortunately, the AOA is on the ball and recently drafted a bill that can be modified on a state-by-state basis to prevent this but it is up to the individual state to modify it and then introduce it to their state legislation. The bill is called The Consumer Protection in Eye Care Act. We will need to go through our current practice act to make sure the two complement each other but I think this is something we definitely want to do.

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I have attached the draft bill from the AOA as well as some information from the AOA that Jackie gathered for us. Please review it.

I would like to open this up for discussion and get everyone's feedback. And provided there is no one on the board outright against this bill, I would like to make a motion that we work together and consult with our lobbyist and attorney to discuss what we need to do to get this bill ready so that we can present this to the SC legislature first thing next January when congress is back in session.

I would like for SC to be one of the first states to make this bill a law instead of one of the last!!! Let's prevent a fire instead of putting out a fire later. Let's be the state that has the legislation that all the other states wish they had!!!

What does everyone think?

Michael W. Zolman, OD

Infinity Eye Care and Low Vision Rehabilitation Center

325 Folly Rd., Suite #109

Charleston, SC 29412

P: 843.795.6464

F: 843.795.6433

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SGRC Webinar

Online Vision Screening, Self-adjusting Glasses and Kiosks and What ODs Need to Know

American Optometric Association

Introduction

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State Government Relations

State Government Relations Committee:

- Deanna S. Alexander, OD, Chair
- Lee Ann Barrett, OD
- Michael Bennett, OD
- Matt Burchett, OD
- Chris Colburn, OD
- Michael G. Horstman
- Steve Langsford, OD
- Gary L. Robbins
- James D. Sandefur, OD
- Roger R. Seelye, OD
- John B. Whitlow, OD
- Paul Zerbinopoulos, OD
- Brian Reuwer, Staff
- Kristen Skiles, Staff

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Agenda for Tonight

- Introduction of Speakers and Topic by Deanna Alexander, SGRC Chair
- Background on the Issue – Drs. Alexander, Zerbinopoulos, Seelye and Steele.
- Recommendations for State Affiliates – Dr. Alexander
- Review of the "Consumer Protection in Eye Care Act" – Mr. Reuwer
- Questions – All Panelists

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Panelists

- Deanna Alexander, OD – Legislative Chair, Colorado and SGRC Chair
- Paul Zerbinopoulos, OD – Legislative Chair, Rhode Island and SGRC Member
- Roger Seelye, OD – Legislative Chair, Michigan and SGRC Member
- Zack Steele, OD – President-Elect, Alabama Optometric Association
- Brian Reuwer – Staff AOA

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BACKGROUND

Kiosks

- A lot of concern among the profession because of a proposed law in Utah that could possibly legalize self-refracting kiosks.
- In addition, Rite-Aid and CVS have tested eyeglass selling kiosks (with existing prescription).
- With online retailors setting up brick and mortar stores and more companies looking to get into eyeglass sales, it's a bet that further technological developments will be made to subvert the eye exam to sell more glasses.

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Direct-to-Consumer Eye Care

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eyeconic.com

glasses.com by 1 800 CONTACTS

Coastal.com
THE BETTER WAY TO BUY EYEWEAR

WARBY PARKER

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Direct-to-Consumer Eye Care

- Rite Aid Pharmacy seeks to build 800 "Wellness Stores" within it's existing pharmacies by 2014
- Vision Center – a new, easy-to-use, interactive kiosk that allows customers to conveniently order prescription glasses and contact lenses online for home delivery and offers eyeglass frames to try on.
- Technology developed by DB Vision

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Direct-to-Consumer Eye Care

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SoloHealth Kiosk

- Measures blood pressure
- Measures visual acuity
- Recommends exam if acuity is below a "standard."
- 1000 units deployed in WalMart and Sam's Club stores
- FDA Approval for measurement of blood pressure.

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What About a Subjective Refraction?

- Automated Subjective Refractors: Do they really exist?

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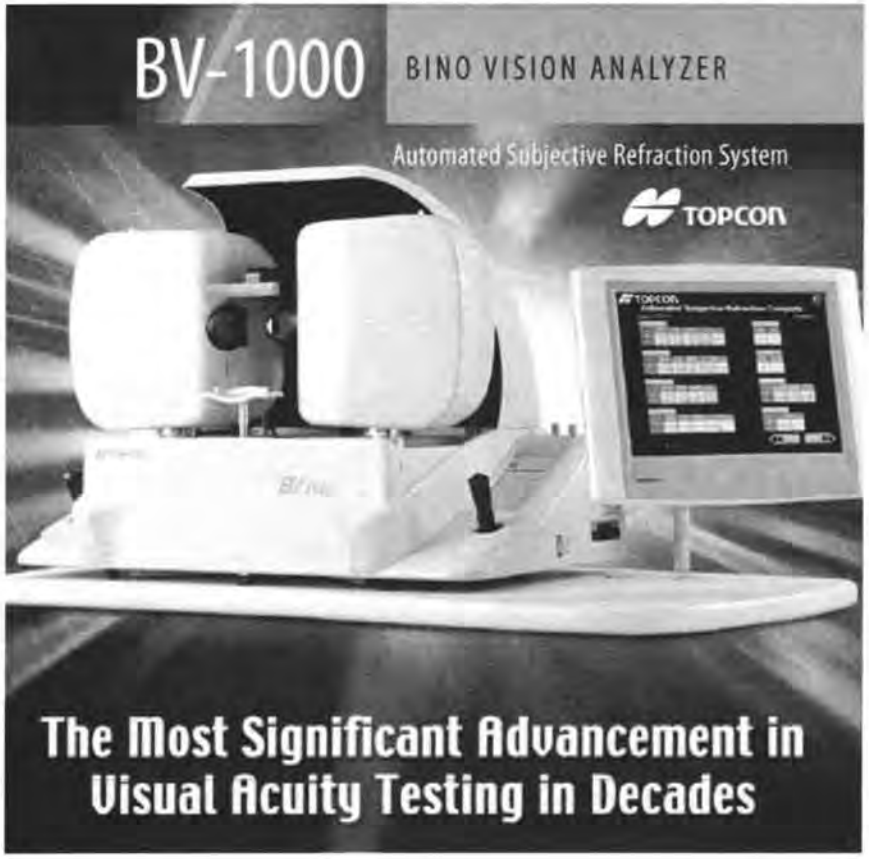
Automated Subjective Refractor



- Topcon BV-1000
- Released in 2002
- Peer reviewed in 2003
- Marketed heavily in Europe and Asia

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Topcon BV-1000

- Uses patient-guided voice prompts to perform complete binocular subjective refraction
- Unit has two joystick controls (for right or left-handed use) and a button for making responses to various questions
- Measures objective refraction, binocularity, **subjective refraction**, alignment, binocular balance, and near addition
- Peer reviewed study in 2003 in *Optometry and Vision Science*

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Online Eye Exams

- Kiosks aren't the only changes coming. Several companies are developing virtual eye exams that will allow people to skip "going to the doctor."

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EyeNetra

October 15, 2010

Cell Phones as Eye Doctors

A prototype device provides access to full-service optometry in your pocket.

Netra is an inexpensive and easy-to-attach add-on for self-testing eyesight quickly, easily, and accurately with a mobile phone.
Credit: Andy Ryan, MIT Media Lab

It won't be long before most people are carrying high-end scientific equipment around in their pockets at all times, said Ramesh Raskar, an associate professor at the MIT Media Lab and the leader of the Camera Culture group there. That equipment comes in the form of smart phones, and Raskar believes this development "will change everything."

Speaking at the 25th anniversary celebration for the Media Lab, Raskar outlined how he wants to take advantage of the increasingly sophisticated power of today's mobile devices. He said it dawned on him that the 300 dpi resolution on a smart phone screen made it the rival of expensive, specialized devices.

One of his group's first experiments is the prototype of Netra, a system that can identify problems with a person's eyesight using only a smartphone, software, and inexpensive optical add-ons. The system, Raskar said, could help people who can't afford or get access to full-service optometry.

- EyeNetra is developing a product called Netra that would allow people to do self-eye exams using their cell phone and a "$2 piece of plastic."
- This is intended for the third world where medical access is an issue but it could easily be deployed in the US

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Opternative

- AOA became aware of an effort by Opternative to market an online eye exam.
- After consulting with the Illinois Optometric Association, the AOA sent a letter to Opternative explaining that their proposed eye exam would not meet the requirements for an eye exam under the Illinois optometric practice act.
  - And the AOA issued a statement calling for people to get an in-person eye exam before getting a prescription.
  - That statement is on the AOA website here: http://www.aoa.org/newsroom/american-optometric-association-cautions-consumers-about-claims-of-online-eye-exams

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OPTERNATIVE

Reinventing Refraction

721

SCOPA 000172

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OPTERNATIVE

Launch Plan

Launching 2014

Direct to consumer solution

Online optical retail solution

$30-40 per exam

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OPTERNATIVE

MENU

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Adjustable Eyeglasses Sold DTC

- Companies are developing products that would allow patients to adjust glasses without a current RX.
- Primarily the technology uses:
  - Alvarez Lens Technology
  - Fluid-Injection, Variable Focus Lens Technology
- Companies maintain that these are simply readers and that they are intended to be a back up pair of glasses
- While many of these products are sold through optometry offices, several of them are sold directly to consumers on the internet.

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PRODUCT OVERVIEW

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- Continuously adjustable for near, intermediate and distance tasks
- One size fits all, a spare pair for whoever is in need
- No tools required
- Complies with all relevant product safety and performance requirements
- Light weight, durable and easy to clean
- Fits easily into a tool kit
- Can be worn indoors and outdoors

Why are We Discussing Any of This???

- The total vision care market, as defined by The Vision Council's VisionWatch survey, reached $35.47 billion in the 12-month period, and includes dollars spent at retail at all retail types at any retail location and spent on the sale of either spectacle lenses (including Rx Sun), frames, contact lenses, plano sunglasses, OTC readers or revenue earned by refractive surgery or eye examinations.
- The report shows an increase in Rx spectacle lens sales of 6.0 percent to **$10.85 billion** in that 12-month period, while frame sales at retail rose 2.7 percent in dollars to **$8.77 billion** during the year ending June. Contact lens sales, in dollars, climbed 5.9 percent to $4.1 billion in that period.

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Can We Fight This and Protect Our Patients?

YES!!!

American Optometric Association

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Suggested Actions For State Affiliates

- Pass the "Consumer Protection in Eye Care Act"
- Add autorefractors to the definition of the practice of optometry
  - Only 7 states specifically have this language
- Give the Board of Optometry (and/or Opticianry) authority to investigate non-licensed professionals
  - About half the state boards have this authority
- A requirement for glasses RX is specifically included in the law to dispense
  - Most states have this requirement but some do not
- ODs should be included in the state telemedicine act
  - Most states have a telemedicine act but not all include ODs

American Optometric Association

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State Responses

- Alabama Experience
- Michigan Experience

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AOA Model Legislation

CONSUMER PROTECTION IN EYE CARE ACT

American Optometric Association

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What Does the Model Bill Do?

- The model language will be written to amend a state's Public Health Act:
- In states without a public health code, the affiliates will have to find a way to enforce the law through the practice act or a standalone law.

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Section 1 - Definitions

- "**Contact Lenses**" means any lens placed directly on the surface of the eye, regardless of whether or not it is intended to correct a visual defect. Contact lens includes, but is not limited to all cosmetic, therapeutic, and corrective lenses.

- "**Department**" means the Department of Health or the department that handles licensure.

- "**Dispense**" means the act of furnishing a pair of spectacles or contact lenses to a patient.

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Definitions

- "**Eye Examination or evaluation**" means an assessment of the ocular health and visual status of a patient that does not consist solely of objective refractive data or information generated by an automated testing device, including an autorefractor, in order to establish a medical diagnosis or for the establishment of a refractive error.

- "**Kiosk**" means automated equipment or application designed to be used on a phone, computer or internet based device that can be used either in-person or remotely to conduct an eye examination or evaluation as defined in this Act.

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Definitions

- "**Online Eye Examination**" means an online vision screening of visual performance measuring visual acuity, contrast, and color vision.

- "**Over the counter spectacles**" means eyeglasses or lenses for the correction of vision that may be sold by any person, firm or corporation at retail without a prescription.

- "**Prescription**" means a provider's handwritten or electronic order as defined in this act, based on an eye examination or evaluation that corrects refractive error.

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Definitions

- "**Provider**" means an individual licensed under the medical or Osteopathic Practice an Act or the Optometric Practice Act.

- "**Spectacles**" means an optical instrument or device worn or used by an individual that has one or more lenses designed to correct or enhance vision addressing the visual needs of the individual wearer and are commonly known as glasses, including spectacles that may be adjusted by the wearer to achieve different types or levels of visual correction or enhancement.

- "**Spectacles**" exclude optical instruments or devices not intended to correct or enhance vision or are sold without consideration of the visual status of the individual who will use the optical instrument or device.

American Optometric Association

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Section 2 – Consumer Protections

Prescription Lenses

- No person in this state may dispense spectacles or contact lenses to a patient without a valid prescription from a provider.
- A prescription for spectacles or contact lens may not be made based on telemedicine services or based solely on the refractive error of the human eye generated by a kiosk.
- An expiration date on spectacles of not less than one year from the date of examination by the licensee or a statement of the reasons why a shorter time is appropriate based on the medical needs of the patient.
- Providers must release a spectacle prescription upon request from a patient and that prescription will include medical findings and any refractive error discovered during the examination.

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Kiosk Language

- The kiosk is approved by the United States Food and Drug Administration for the intended use;
- The kiosk is designed and operated in a manner that provides any accommodation required by the federal Americans with Disabilities Act;
- The kiosk and accompanying technology used for the collection and transmission of information and data, including photographs and scans, gathers and transmits protected health information in compliance with the federal Health Insurance Portability and Accountability Act;
- The procedure for which the kiosk is used has a recognized Current Procedural Terminology (CPT) code;

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Kiosk Language (continued)

- The physical location of the kiosk prominently displays the name and state license number of the individual who will read and interpret the diagnostic information and data, including photographs and scans;

- Diagnostic information and data, including photographs and scans, gathered by the automated equipment is read and interpreted by a provider; and

- The owner or lessee of the automated equipment maintains liability insurance in an amount adequate to cover claims made by individuals diagnosed or treated based on information and data, including photographs and scans, generated by the automated equipment.

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Over the Counter Spectacles

- Over the counter spectacles shall have the following language attached to each pair of spectacles displayed or offered for sale and in at least ten point **bold** type permanently affixed in plain view to the top of any point of sale display or, if there is no display, in the area of sale:

"ATTENTION: READY-TO-WEAR NON-PRESCRIPTION GLASSES ARE NOT INTENDED TO REPLACE PRESCRIBED CORRECTIVE LENSES OR EXAMINATIONS BY AN EYE CARE PROFESSIONAL. CONTINUOUS EYE CHECK-UPS ARE NECESSARY TO DETERMINE YOUR EYE HEALTH STATUS AND VISION NEEDS."

- The lenses in such glasses shall be of uniform focus power in each eye, *shall not be adjustable* and shall not exceed 2.75 diopters.

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Section 3 – Enforcement and Violations

- A person or governmental entity that believes a violation of this part or a rule promulgated under this part has occurred or has been attempted may make an allegation of that fact to the department in writing.

- If, upon reviewing an allegation, the department determines there is a reasonable basis to believe the existence of a violation or attempted violation of this part or a rule promulgated under this part, the department shall investigate.

- The department may hold hearings and administer oaths and order testimony to be taken at a hearing or by deposition conducted pursuant to the administrative procedures act and shall report its findings to the department.

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Enforcement and Violations

- The department may proceed if it is determined that a violation of this law has occurred.

- Nothing in this section shall require the department to wait until human harm has occurred to initiate an investigation.

- The department, upon finding after notice and an opportunity for a hearing that a person has violated or attempted to violate any provision of this part, may impose an administrative fine of not more than $1,000.00 for each violation of this part. If the department finds that a violation or attempted violation occurred and did not result in significant harm to human health, the department may issue a warning instead of imposing an administrative fine.

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Enforcement and Violations

- The department shall advise the attorney general of the failure of a person to pay an administrative fine imposed under this section. The attorney general may bring an action in a court of competent jurisdiction for the failure to pay an administrative fine imposed under this section.

- At the request of the department, the attorney general may file a civil action seeking an injunction or other appropriate relief in the name of the people of the state to enforce this act and the rules promulgated under this act. The court may impose on any person who violates this part or attempts to violate this part a civil fine of not more than $5,000.00 for each violation or attempted violation. In addition, the attorney general may bring an action in circuit court to recover the reasonable costs of the investigation from any person who violated this part or attempted to violate this part.

- The department may promulgate rules under the administrative procedures act that it determines necessary to implement, administer, and enforce this section.

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Questions From the Audience

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American Optometric Association

SCOPA 000195

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From: Michael Zolman <focusedeyedoc@yahoo.com>
Sent: Thursday, May 19, 2016 8:05 AM
To: Jackie Rivers
Subject: Re: URGENT: Senate OVERRIDES Gov. Haley's veto of our bill, 39-3

Can you send it out now? Im getting so many questions from members right now bc they heard about the override in the senate yesterday

Sent from my iPhone

On May 19, 2016, at 6:00 AM, Jackie Rivers <jrivers@sceyedoctors.com> wrote:

> Will do!! I'll have it pushed put before 8:30!! I don't think Anna sent me the video link out il double check. Won't hold the email up for it though. Great message! Super excited about today!!!
>
> Sent from my iPhone
>
> On May 19, 2016, at 2:11 AM, Michael Zolman <focusedeyedoc@yahoo.com> wrote:
>
> > Hi Jackie,
> >
> > Can you please send the following and attach 1. The OD/Congressman spreadsheet (for those who STILL dont know who their legislator is) 2. Our letter of concern and rebuttal 3. our talking points 4. J&J letter 5. Anna's video (if she has it. If not, dont worry about it) 6. Senate score card from yesterday.
> >
> > Let's keep our fingers crossed!
> >
> > Dear Colleagues,
> >
> > Feels good doesn't it?
> >
> > The Senate voted to override Governor Haley's veto of our bill, S1016 yesterday afternoon! All of your calls, emails and faxes to your senators paid off. Senator Cleary proposed the vote and did an EXCELLENT job explaining the importance of the override. Please contact Senator Cleary, as well as your senator, to thank them for their support!
> >
> > Also, as a welcomed surprise and much appreciated showing of industry support, the president of Johnson & Johnson, Peter Menziuso, personally contacted our SCOPA office a few days ago after hearing about Gov. Haley vetoing our bill to prevent online eye exams and 'eye exam' kiosks. He offered Johnson & Johnson's full support to SCOPA to help override the governor's veto. Without question or hesitation, he personally wrote a very powerful advocacy letter from Johnson & Johnson to accompany our Letter of Concern and Veto Rebuttal to the Senate. A big THANK YOU is in order to J&J for their tremendous support of our bill His letter is attached for your review.
> >
> > With yesterday's override in the Senate, our efforts are beginning to attract A LOT of press and is becoming a story of national interest. It is easy to want to celebrate this victory, but now is not the time. With the good comes the bad. We now know that Opternative has stepped up their efforts

and have lobbyists on the hill contacting House members encouraging them to sustain the governor's veto.

We must work quickly as the vote to override Haley's veto will **VERY LIKELY HAPPEN TODAY!!!** Please call your House Representative **NOW!**

We've taken our bill all the way to the finish line once already....only to be punched in the mouth by the governor. We've fought to get it back to the finish line and now this is our opportunity to punch back! Let's send a loud and clear message to the House of Representative letting them know what the sound of passionate, organized Optometry sounds like! Let's show Governor Haley what this 'small group of eye care professionals' can do when we are ignored and she puts the safety of our patients at risk.

Please call your House Representative now!

Fight Optometry Fight!
Michael W. Zolman, OD
SCOPA co-legislative director
Infinity Eye Care and Low Vision Rehabilitation Center
325 Folly Rd., Suite #109
Charleston, SC 29412
P: 843.795.6464
F: 843.795.6433
www.myinfinityeyecare.com

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From: Michael Zolman <scoa@ciclt.net>
Sent: Thursday, May 19, 2016 8:53 AM
To: Jackie Rivers
Subject: S.1016 Update - Success in the Senate - PUSH in the House

May 19, 2016

Dear Colleagues,

Feels good doesn't it?

The Senate voted to override Governor Haley's veto of our bill, S1016 yesterday afternoon! All of your calls, emails and faxes to your senators paid off. Senator Cleary proposed the vote and did an EXCELLENT job explaining the importance of the override. Please contact Senator Cleary, as well as your senator, to thank them for their support!

Also, as a welcomed surprise and much appreciated showing of industry support, the president of Johnson & Johnson, Peter Menziuso, personally contacted our SCOPA office a few days ago after hearing about Gov. Haley vetoing our bill to prevent online eye exams and 'eye exam' kiosks. He offered Johnson & Johnson's full support to SCOPA to help override the governor's veto. Without question or hesitation, he personally wrote a very powerful advocacy letter from Johnson & Johnson to accompany our Letter of Concern and Veto Rebuttal to the Senate. A big THANK YOU is in order to J&J for their tremendous support of our bill **Click here to review his letter.**

With yesterday's override in the Senate, our efforts are beginning to attract A LOT of press and is becoming a story of national interest. It is easy to want to celebrate this victory, but now is not the time. With the good comes the bad. We now know that Opternative has stepped up their efforts and have lobbyists on the hill contacting House members encouraging them to sustain the governor's veto.

We must work quickly as the vote to override Haley's veto will **VERY LIKELY HAPPEN TODAY!!!** Please call your House Representative **NOW! Click here to reveiw a list of legislators, if needed. Also, you can click here for a copy of the revised talking points that were distributed yesterday.**

For your quick reference, **click here for a copy of our letter of concern and rebuttal that has been distributed to all House members**. They will receive another copy of this, including the letter from J&J on the House floor this morning.

We've taken our bill all the way to the finish line once already....only to be punched in the mouth by the governor. We've fought to get it back to the finish line and now this is our opportunity to punch back! Let's send a loud and clear message to the House of Representative letting them know what the sound of passionate, organized Optometry sounds like! Let's show

Governor Haley what this 'small group of eye care professionals' can do when we are ignored and she puts the safety of our patients at risk.

Please call your House Representative now!

Fight Optometry Fight!

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Click Here to OptOut of receiving future emails from this person or organization

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From: Michael Zolman <scoa@ciclt.net>
Sent: Thursday, May 19, 2016 2:20 PM
To: Jackie Rivers
Subject: It's a GREAT day in SC

May 19, 2016

Dear Colleagues,

It's a **GREAT** day in South Carolina!

It's with the utmost pleasure to announce that today, Opternative and 'eye exam' kiosks are now **PROHIBITED BY LAW** in the great state of SC!

Both the SC House and Senate voted to override Governor Haley's veto of our bill S1016. This is what organized Optometry looks like at it's best! It took the grassroots efforts of all of you contacting your legislators to make this happen as well the tireless efforts of your SCOPA Board of Directors working in conjunction with AOA to make this possible. Johnson & Johnson also deserves praise for their full support of our bill by reaching out to our legislators and lobbying with us as well. Call your legislators, tell them you love 'em.....except for Rep. Jonathon Hill. **Click here to see the vote count**.

You should be so proud of your efforts and standing up for what is right in order to ensure the vision, eye health and general health of their patients. It's been a pleasure being a part of this process!

Good-bye Opternative!

Michael W. Zolman, OD
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EXHIBIT 2

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STATE OF SOUTH CAROLINA
COURT OF COMMON PLEAS
COUNTY OF RICHLAND

OPTERNATIVE, INC.,

Plaintiff,

vs. CASE NO. 2016-CP-40-06276

SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS, SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION,

Defendants,

SOUTH CAROLINA OPTOMETRIC PHYSICIANS ASSOCIATION,

Defendant-Intervenor.

DEPOSITION OF: JACKIE RIVERS

DATE: August 1, 2017

TIME: 9:32 AM

LOCATION: Nelson, Mullins, Riley & Scarborough
1320 Main Street, 17th Floor
Columbia, SC

TAKEN BY: Counsel for the Plaintiff

REPORTED BY: AMY R. COPE,
Court Reporter

A. WILLIAM ROBERTS, JR., & ASSOCIATES

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the lawsuit.

Q. Okay. And so it's your understanding that you're here giving a deposition in the course of a lawsuit; is that right?

A. Yes.

Q. And what, if anything, did you do to prepare for this deposition?

A. I reviewed e-mail correspondence.

Q. Okay. Anything else?

A. No.

Q. Did you talk to anyone?

A. There was some discussion that I had with some of the other leadership of the association, just general discussion regarding this.

Q. Okay. Do you remember who in leadership you talked to about the deposition?

A. Mike Zolman.

Q. Anyone else?

A. No.

Q. Okay. When did you talk to Mike Zolman about the deposition?

A. When I found out I was going to be deposed.

Q. Roughly when was that?

A. I'm not sure, two weeks ago, maybe.

Q. Okay. What did you talk to Dr. Zolman about -- actually, I'm sorry, I withdraw that question, this probably makes more sense if I say: And who is Mike Zolman?

A. Mike Zolman is our legislative director and also our vice president on our Board of Directors.

Q. And what did you talk to Dr. Zolman about?

A. Generally about that he and I both were going to be having a discussion regarding questions about the case.

Q. Okay. Do you remember about how long the conversation was?

A. No.

Q. Okay. Was it over the phone or in person?

A. Over the phone.

Q. Okay. Did you talk to anyone about the deposition after Dr. Zolman?

A. No.

Q. Okay. You said you've reviewed some e-mail correspondence, what did you review?

A. Correspondence that I was included in

over the course of preparing for our legislative effort for the passage of our Consumer Eye Care Protection Bill.

Q. And when you say our Consumer Eye Care Protection Bill, who is the our in that sentence?

A. The South Carolina Optometric Physicians Association.

Q. And about how much e-mail correspondence did you review?

A. I'm not sure how to answer that question.

Q. Did you look at more or fewer than 50 e-mails?

A. More.

Q. Okay. Did you look at more or fewer than 100 e-mails?

A. Fewer.

Q. Okay. And roughly what was the time period of the e-mail correspondence you reviewed?

A. As I recall, I believe it was over maybe a two-year period.

Q. How did you chose what e-mails to look at?

A. I just skimmed. I mean, it wasn't anything specific I was looking for, I was just

re-familiarizing myself with some of the correspondence.

Q. Did you just look at all of your e-mail correspondence from a certain time period? Did you search your e-mail for a particular term? How did you choose what to look at?

A. Through a keyword search for anything that had to do with this bill and thereafter once it was passed.

Q. Okay. Do you remember what keywords you used?

A. Not all of them.

Q. Okay, that's fair. Can you give me some examples?

A. Eye care protection, consumer, Opternative.

Q. Okay. What would you say was roughly the earliest e-mail that you reviewed in preparing for this deposition?

A. I don't remember.

Q. Okay. Let's talk just a little bit about your personal background. Are you currently employed?

A. Yes.

Q. And what is your current position?

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A. I'm the executive director for the South Carolina Optometric Physicians Association.

Q. And what is the South Carolina Optometric Physicians Association?

A. We're a membership-based association of licensed optometrists in South Carolina.

Q. Okay. And I've seen in documents that sometimes that's called SCOPA; is that right?

A. Yes.

Q. If I say SCOPA, will we understand that I mean the South Carolina Optometric Physicians Association?

A. Yes, that's a lot easier to say.

Q. It is. With written records sometimes you have to be a little more precise than ordinary conversation.

You said SCOPA is a membership-based organization, about how many members does SCOPA have?

A. About 400.

Q. And are all 400 members practicing optometrists in South Carolina?

A. They are licensed -- the majority of them are licensed in South Carolina, they can be a member and not have a license here, so there are a

small number of out-of-state members.

Q. Okay. So roughly how many of the 400, would you say, hold a South Carolina optometrist's license?

A. About 350.

Q. Okay. And what does your current position at SCOPA require you to do?

A. Recruit and retain members. Work in terms of advocacy, both on the state and federal level. Promote the profession of optometry in the community.

Q. Anything else?

A. Provide continuing education.

Q. And when you say provide continuing education, what do you mean?

A. For our members to -- or optometrists to receive education to meet licensure requirements.

Q. Okay. You say SCOPA has about 400 members, do you know what that represents as a proportion of South Carolina's licensed optometrists?

A. I would say 75 percent.

Q. Okay. 75 percent of South Carolina's licensed optometrists are members of SCOPA?

A. Yes.

Q. Okay. How many employees does SCOPA have?

A. Two.

Q. Who is the other one?

A. Anna Balderson.

Q. And what is Anna Balderson's role at SCOPA?

A. She is the marketing and membership coordinator.

Q. And how does that differ from your position?

A. She is more administrative and processes the admin part of the membership process and then provides support to me.

Q. So is it fair to say you're the only employee of SCOPA that has a substantive as distinct from an administrative role?

A. Can you say that again?

Q. So is it fair to say that you are the only employee of SCOPA who has a role in policy and policymaking as distinct from purely administrative matters?

MR. SHEALY: Object to the form, but you can answer.

THE WITNESS: Yes.

BY MR. MCNAMARA:

Q. Okay. You say one of your roles at SCOPA is to recruit and retain members; what does that look like?

A. Whenever a new licensee comes into the state, we reach out to them and invite them to be a part of the association. If during the course of meetings or being out in the community, we meet someone that may not be a member, but has been here in the state, we talk to them about joining the association.

Q. And how long have you been in your current role at SCOPA?

A. Eight years.

Q. And what did you do before that?

A. I was the executive director for the Alzheimer's Association in North Carolina.

Q. Okay. And how long were you there?

A. About two and a half years.

Q. And what did you do before that?

A. I was an interim executive director for the South Carolina Chapter of the Alzheimer's Association.

Q. Okay. And before that?

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A. I was the director of development for the Alzheimer's Association of South Carolina.

Q. And before that?

A. I was with the March of Dimes.

Q. And before that?

A. I was with the National Association for Campus Activities.

Q. And what is the National Association for Campus Activities?

A. Yeah, it is an association that has both member colleges and universities, and then people that do business in the college market, could be entertainment or promotional products, things like that, so we would hook them together.

Q. What's your educational background?

A. I graduated from the University of South Carolina, bachelor's degree.

Q. In what?

A. Retail management.

Q. This is probably a silly question, but you, yourself, are not an optometrist; is that true?

A. That is true.

Q. Okay. In the course of your role at SCOPA, in any of the four key roles you've

identified, does your job require you to be familiar with South Carolina optometrists, their practices and business models?

MR. MATTHEWS: I'll object to the form, please answer.

THE WITNESS: To some degree, yes.

BY MR. MCNAMARA:

Q. What do you mean to some degree?

A. Well, my job is to recruit and retain members and promote the profession overall. I don't really get involved in the general operation of their practice.

Q. Okay. But as a general proposition, your role at SCOPA requires you to keep tabs on issues of concern to optometrists in South Carolina?

A. Yes.

Q. Okay. You also said your role at SCOPA involves advocacy at the state and federal level?

A. Uh-huh.

(Court reporter seeks clarification).

A. Yes.

Q. What does that mean?

A. We work to establish grassroots relationships with legislators. And we help our

members establish those relationships and maintain those. We also have an legislative day that we do here in South Carolina. And in addition to that we're also a part of the American Optometric Association and they also have a federal advocacy day and we do work to have ongoing relationships with our federal legislators as well for issues that are on a more national level.

Q. Okay. And what is the purpose to maintaining grassroots relationships with South Carolina legislators?

A. To ensure that they stay informed about the type of care and quality of care that optometrists provide to citizens in South Carolina.

Q. Does your role in advocacy at SCOPA ever require you to become involved in legislative activities?

A. Yes.

Q. How so?

A. I attend functions that legislators -- fundraising receptions that legislators have locally. And I accompany our members, typically when they are in town, and may go visit with their legislator just to establish a relationship so they know who we are in the event that there's a

question or some piece of legislation that may come across their desk that has anything to do with the eye, they may have some questions about how that may impact the public.

Q. Okay. And to the extent you can make a fair estimate, what proportion of your job would you say is advocacy as opposed to the other roles you've identified?

A. Maybe 15 percent.

Q. Okay. You say you attend fundraising receptions for South Carolina legislators, is that solely here in Columbia or do you travel across the state?

A. Just in Columbia.

Q. And about how many of those a year would you say you attend?

A. 20.

Q. Okay. In the course of your role at SCOPA, have -- strike that.

Has your role at SCOPA required you to develop personal relationships with government officials whose work intersects with optometry?

MR. SHEALY: Object to the form. You may answer.

THE WITNESS: Can you say that again?

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BY MR. MCNAMARA:

Q. Does your -- has your role at SCOPA required you to develop any kind of relationship with government officials or regulators, such that in your professional capacity you would be able to identify who those people are?

A. Yes.

Q. Okay. Does SCOPA employ any lobbyists?

A. Yes.

Q. How many lobbyists does SCOPA employ?

A. We have one firm and there are two lobbyists.

Q. And who are those lobbyists?

A. Mark Kelly and Angelia Smith Owens.

Q. And is Angelia Smith Owen's first name spelled A-N-G-E-L-I-A?

A. Yes.

Q. Some of what I'm getting at is just identifying who people are whose names show up in e-mails; that's all we're doing.

A. Yes.

Q. And as long as we're -- sorry, going back to SCOPA's lobbyists. Who is responsible for hiring SCOPA's lobbyist firm?

A. Our Board of Directors.

Q. Okay. Is there a particular person the lobbying firm reports to?

A. Mike Zolman, our legislative director.

Q. And is the position of legislative director a volunteer position at SCOPA?

A. Yes.

Q. Do you in your role have any communication with SCOPA's lobbyists?

A. Yes.

Q. How frequently?

A. Well, it depends on what we have going on in the office. So it could be weekly or more often.

Q. Okay. As a general proposition, does your role at SCOPA require you to be aware of all of SCOPA's lobbying activities?

A. Yes.

Q. Okay. And there's just a couple of other identification questions I'd like to ask. Are you familiar with a woman named Holly Beason?

A. Yes.

Q. Who is Holly Beason?

A. Holly Beason is an attorney that works at LLR, I believe.

Q. In what capacity, to the extent you know?

A. I'm not sure.

Q. Okay. Let's try it from this angle: Why do you know who Holly Beason is?

A. Holly Beason was someone who was at the table when we were going for our Consumer Protection Bill, Eye Care Consumer Protection Bill.

Q. Okay. When you say at the table, what do you mean?

A. At meetings that we had at the State House.

Q. Okay. And are you familiar with someone named Peter Candela?

A. Yes.

Q. And who is Peter Candela?

A. Peter Candela is one of our members and is also on the Board of Examiners for the South Carolina Board of Examiners in Optometry.

Q. How many members of the Board of Examiners for the South Carolina Board of Examiners in Optometry are also members of SCOPA?

A. All of the optometrists that are on the Board are members.

Q. Okay. Is anyone else on the Board a member of SCOPA?

A. No.

Q. Okay. You also testified that one of your roles at SCOPA is to promote the profession of optometry; what does that mean?

A. We share information on social media about the importance of eye exams or safety issues and things like that. We also partner with other community organizations to be visible in the community. And we do a lot of activities in providing eye care.

Q. When you say partner with other organizations to be visible in the community, what does that mean?

A. Well, we work with organizations like the Special Olympics and provide vision exams for the athletes that come through. We also work with the United Way of the Midlands and have an eye care clinic that we provide volunteer optometrists to see patients in certain underserved communities.

Q. And we talked at the beginning that you are here testifying pursuant to a lawsuit, right?

A. Yes.

Q. What, if anything, do you know about that lawsuit?

A. I know that it is a lawsuit to

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determine the constitutionality of the Eye Care Consumer Protection Bill that we passed.

Q. Okay.

MR. MCNAMARA: Just so we have something concrete to talk about, I'm going to ask the court reporter to mark this as Exhibit 2.

(PLF. EXH. 2, S.C. Code Ann. 40-24-10, was marked for identification.)

BY MR. MCNAMARA:

Q. All right. Ms. Rivers, I'm handing you a document that's been stamped as Exhibit 2 in this deposition. Do you recognize this document?

A. No.

Q. That's okay, I can do this a different way. So I'll just represent to you that I've handed to you a section of the South Carolina Code taken from what is called the Eye Care Consumer Protection Act, which is Chapter 24 of Title 40 of the South Carolina Code. A couple of times now you've said the Eye Care Consumer Bill or the Eye Care Consumer Bill that we've passed, when you say the Eye Care Consumer Bill that we've passed, do you mean the Eye Care Consumer Protection Act that is encoded in Chapter 24 of Title 40 of the South Carolina Code?

MR. SHEALY: Object to the form, but you may answer.

THE WITNESS: Yes.

BY MR. MCNAMARA:

Q. Okay. Just so we're referring to the same thing when we talk about this, if I talk about the Eye Care Consumer Protection Law or ECCPL, will you understand what I mean?

A. Yes.

Q. And so your understanding of the lawsuit is it's a challenge to the ECCPL?

A. Yes.

Q. And the ECCPL is a bill that SCOPA passed?

A. Yes.

MR. MATTHEWS: Object to the form.

MR. SHEALY: Object to the form.

BY MR. MCNAMARA:

Q. When did you first learn about this lawsuit?

A. I don't recall.

Q. Do you remember how you first learned about this lawsuit?

A. No.

Q. Okay. Do you recall if you first

learned about this lawsuit from the American Optometric Association?

A. No.

Q. No, you don't recall, or no, you did not learn about it from the American Optometric Association?

A. No, I do not recall.

Q. Are you aware that SCOPA is an intervening party in this lawsuit?

A. Yes.

Q. And when did you become aware of that?

A. When our Board voted to intervene.

MR. MCNAMARA: I'm going to go ahead and ask the court reporter to mark this as Exhibit 3.

(PLF. EXH. 3, E-mails between Jackie Rivers, Peter Candela, April Koon and others, dated October 20th, 2016, Bates stamped LLR 00001784 and 1785, was marked for identification.)

BY MR. MCNAMARA:

Q. And the court reporter has handed you a document that's been stamped as Exhibit 3. If you wouldn't mind taking a minute to look at it.

A. Uh-huh.

Q. Do you recognize this document?

A. I recognize that this is an e-mail that I sent, yes.

Q. Okay. And what is the nature of this e-mail?

A. This appears to be an e-mail that I received from the AOA that included a press release about the lawsuit.

Q. Having seen this e-mail, does that refresh your recollection about how you first learned about this lawsuit?

A. This doesn't indicate that this was the first time I'd heard about the lawsuit, this just shows that Daniel Carey was letting me know about it.

Q. I was just asking: Having seen this e-mail, does it refresh your recollection about how you first learned about this lawsuit, whether it was this e-mail or something else?

A. Yes.

Q. Do you remember how you first learned about the lawsuit?

A. No. This doesn't indicate that this was the first time I learned about it, this just indicates that Daniel was letting me know about it.

Q. Okay. So having seen this e-mail, you

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just still don't remember if you had heard --
A. If this was the first time or not, yeah.
Q. That's perfectly fine. And if you see in the bottom third of the page that has the number 1784 in the bottom corner.
A. Uh-huh.
Q. There's a quotation from an e-mail from you saying Dr. Cannon recommended contacting the AG's Office.
A. Uh-huh.
(Court reporter seeks clarification).
A. Yes.
Q. Is that an e-mail you sent as well?
A. Yes.
Q. Okay. Who is Dr. Cannon?
A. Dr. Cannon is a past president of our Board of Directors and a member of our organization and also serves as our PAC Board chair.
Q. Okay. And I see you forwarded this e-mail to Peter Candela and April Koon?
A. (Nods head up and down).
Q. We talked about Peter Candela before; who is April Koon?
A. April is the administrator at LLR that

works with the Board of Examiners.
Q. And what does that mean?
A. She's our administrative person. She's my staff contact for the Board.
Q. Okay. In your role at SCOPA -- strike that.
Has your time at SCOPA given you, for example, any sense of what a South Carolina optometrist usually charges for an eye exam?
A. No.
Q. Do South Carolina optometrists ever give eye exams for free, to your knowledge?
A. Yes.
Q. Is that a common occurrence?
MR. MATTHEWS: Object to the form. Please answer.
THE WITNESS: It's been my experience when I've found that there's someone in need in the community that requires an eye exam that it's not a problem for me to find someone who would be willing to see them.
BY MR. MCNAMARA:
Q. Are you aware of any South Carolina optometrists who give eye exams for free, regardless of whether the person needing the exam

is indigent?
A. I don't know.
Q. Okay. You just don't know either way?
A. I don't know either way.
Q. Are there any optometrists in South Carolina who also sell eyeglass frames in the course of their business?
A. Yes.
Q. Do you have a sense of how many?
A. No.
Q. Do you have a sense of whether that's an unusual business practice?
A. No.
Q. Is it fair to say that many South Carolina optometrists sell eyeglass frames?
MR. SHEALY: Object to the form. You may answer.
THE WITNESS: Yes.
BY MR. MCNAMARA:
Q. Is it fair to say that most South Carolina optometrists sell eyeglass frames?
A. Yes.
Q. To your knowledge, do optometrists conduct a comprehensive eye health exam every single time they write a corrective lens

prescription?
MR. SHEALY: Object to the form. You may answer.
THE WITNESS: Say it one more time, please.
BY MR. MCNAMARA:
Q. To your knowledge, do optometrists conduct a comprehensive eye health exam every single time they write a corrective lens prescription?
MR. SHEALY: Object to the form.
THE WITNESS: Yes.
BY MR. MCNAMARA:
Q. How do you know that?
A. Through my interaction with the members, it's my impression that the majority of them do that. It's just part of their standard of care.
Q. Okay. So it's your impression that a majority of South Carolina optometrists conduct a comprehensive eye health exam every time they write a corrective lens prescription?
A. Yes.
MR. SHEALY: Object to the form.
BY MR. MCNAMARA:

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Q. I know sometimes I'm just restating what you said, I'm just trying to make sure I understand and that we have a clear written record. What steps, if any, does SCOPA take to ensure that optometrists conduct a comprehensive eye health exam every single time they write a corrective lens prescription?

MR. SHEALY: Object to the form. You may answer.

THE WITNESS: Well, again, we -- we promote that as a standard of care for patients.

BY MR. MCNAMARA:

Q. Anything else?

A. Excuse me?

Q. Anything else?

A. No.

Q. Okay. And just to get back to your knowledge of optometrist's behavior, have you or has SCOPA conducted a survey of South Carolina optometrists to determine whether in fact, or how many of them, in fact, conduct a comprehensive eye health exam every single time they write a corrective lens prescription?

MR. SHEALY: Object to the form. You may answer.

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THE WITNESS: No, we have not done a survey.

BY MR. MCNAMARA:

Q. Have you talked to individual optometrists about whether they conduct a comprehensive eye health exam every time they write a corrective lens prescription?

MR. SHEALY: Object to the form. You may answer.

THE WITNESS: Yes.

BY MR. MCNAMARA:

Q. Roughly how many optometrists have you talked to on that subject?

A. I'm not sure.

Q. More than ten or fewer than ten?

A. I would say more than ten.

Q. More than 40 or fewer than 40?

A. More than 40.

Q. More than 100 or fewer than 100?

A. Fewer than 100.

Q. Okay, zeroing in. And so you testified earlier that your impression is that most South Carolina licensed optometrists do a comprehensive eye health exam every time they write a corrective lens prescription, right?

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MR. SHEALY: Object to the form.

THE WITNESS: Yes.

BY MR. MCNAMARA:

Q. Is the basis of that testimony these 40 to 100 conversations you've had on this topic with optometrists?

A. Yes.

Q. Is that sense you have based on anything else in addition to those conversations?

A. Well, again, it's based on the information, and again, the type of quality of care, their code of ethics that we know that they take when they become licensed optometrists. And it's how we communicate with our members, you know, and the type of information that we're sharing with them in terms of how they're providing high-quality care to their patients.

Q. Okay. So your testimony is based on these conversations with optometrists, an optometrist's code of ethics, and on SCOPA's own advocacy; is that a fair summary?

A. Yes. And I may add to that, also the type of continuing education that we provide to them through the association that we do twice a year.

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Q. Is it based on anything else?

A. No.

Q. Okay. It's not, for example, based on firsthand observation of optometrists in their practice?

A. Well, the optometrists that I see, the optometrists that care for me do always provide a comprehensive eye exam when I'm in their office. So I could say it's also based on personal experience.

Q. Have you ever asked your optometrists not to provide a full comprehensive eye health exam and just update your prescription?

A. No.

Q. So we've talked a bit about the Eye Care Consumer Protection Law or the ECCPL, right?

A. Yes.

Q. What do you know about the ECCPL?

A. I know that it's a law that establishes the parameters of in-person eye exams, so that we're putting the patients in the chair in front of the doctor, so that they can be given a comprehensive eye exam.

Q. So I just want to be clear, the ECCPL itself is obviously a law that has been passed by

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the South Carolina legislature as part of the South Carolina Code, but it also had earlier drafts and iterations. So I want to ask at what point did you first become aware of any draft bill that would eventually become the ECCPL?

MR. MATTHEWS: Object to the form.

Please answer.

MR. SHEALY: Object to the form.

THE WITNESS: I don't recall.

BY MR. MCNAMARA:

Q. Okay. Were you involved in the process of drafting the ECCPL?

A. Not the actual language itself, no. I mostly just passed along the drafts to make sure the people that needed to review it got their copies.

Q. Okay. Where did the language of the ECCPL come from?

A. The original draft language came from the American Optometric Association.

Q. Do you know how the language -- so let me get the chain first before I ask how it happened. You say the original draft language that became the ECCPL, came from the American Optometric Association. Did SCOPA then generate a draft based

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on that language?

A. Yes.

Q. Okay. Do you know, if you know, do you know how the language from the American Optometric Association first made its way to SCOPA?

A. I can't remember specifically, other than I'll say that the American Optometric Association, in their role, they identify key issues that states may need to be aware of. So it could have been at one of our national meetings or it could have just been shared via e-mail.

Q. Was there a person or a group of people at SCOPA responsible for drafting the language that became the ECCPL?

A. Yes.

Q. And was that a single person or was it a group?

A. It was a group.

Q. Okay. Who were the members of the group of people at SCOPA responsible for drafting the language of the ECCPL?

A. I recall Phillip Flynn, William Cannon, Bob Branch, there could have been others that I'm not recalling.

Q. Okay. And who are those three people?

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A. Former board members.

Q. Were they former board members at the time they were a member of the group within SCOPA that was drafting the language that became the ECCPL?

MR. MATTHEWS: Object to the form.

Please answer.

MR. SHEALY: Object to the form.

THE WITNESS: I believe all but Phillip Flynn were current board members.

BY MR. MCNAMARA:

Q. Do you know why Phillip Flynn, as a former board member, was active with current board members in drafting legislative language?

A. Because he was involved with -- and still is involved with -- well, he works on third-party areas now, but he was involved with legislative activities at that time.

Q. So even though he was a former SCOPA board member, he was still working with SCOPA on legislative activities?

A. Uh-huh.

(Court reporter seeks clarification).

A. Yes.

Q. And you say at that time, what time do

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you mean?

A. When we started working on and considering going for the legislation.

Q. Roughly when did SCOPA start working on the legislation that became the ECCPL?

A. I don't remember specifically.

Q. Do you remember if it was before or after 2014?

A. It was probably around that time.

Q. Around 2014?

A. Yeah.

Q. Okay. And once SCOPA drafted the language that became the ECCPL, what happened with that language next?

MR. MATTHEWS: Object to the form.

Please answer.

MR. SHEALY: Object to the form.

THE WITNESS: I'm not sure how to answer that question.

BY MR. MCNAMARA:

Q. Let's just -- is it fair to say that the purpose in SCOPA drafting the legislative language that became the ECCPL was that SCOPA wanted the ECCPL to become law?

A. Yeah.

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MR. SHEALY: Object to the form.
MR. MATTHEWS: Same objection. Please answer.
THE WITNESS: Yes.
BY MR. MCNAMARA:
Q. Once SCOPA had drafted legislative language, what steps, if any, did SCOPA take to help ensure that its legislative language would become law?
A. At that point, I would say that we started mobilizing our grassroots efforts so that we could -- our members could begin having dialogue with legislators about what we hope to accomplish with the bill.
Q. And you've testified that there was a group within the scope of drafting legislative language that included Phillip Flynn and others, at what point did that legislative language make its way to you?
A. I don't remember.
Q. Okay. You testified earlier that your role in the ECCPL was primarily passing legislative language on. Between whom were you passing legislative language?
A. Well, depending upon what stage things

were in, it could have been our Board, the group that was working on the legislation, our lobbyists, the AOA.
Q. Anyone else?
A. Not that I can recall.
Q. Okay. At what point in the process was SCOPA's legislative language first sent to a member of the South Carolina legislature, if ever?
A. I don't remember.
Q. Okay. Would you have been the person who shared legislative language with South Carolina legislators or would that have come through SCOPA's lobbyists?
A. That would have gone through our lobbyists.
Q. Okay. Did you have any direct contact with South Carolina legislators about the bill that eventually became the ECCPL?
A. No.
Q. Did you have any direct contact with any South Carolina government official about the bill that eventually became the ECCPL?
A. I'm not sure what might constitute a government official.
Q. Anyone in the employ of the State of

South Carolina?
A. Then I guess I would say yes.
Q. And who were those government officials?
A. I was considering -- I was thinking of the members of the Board of Examiners.
Q. Outside of the members of Board of Examiners, who are also members of SCOPA, as we've learned, did you have contact with any other South Carolina government officials about the bill that eventually became the ECCPL?
A. Would employees of the LLR be considered government officials?
Q. Yes.
A. Then yes.
Q. Who at LLR did you have contact with?
A. Well, April Koon. I believe I had some discussions with Holly Beason at some point.
Q. What was the nature of your discussions with Holly Beason?
A. The -- in one of the versions of the bill, there was some discussion about the role of LLR. And during the course of teasing out what that part of the law might look like, I remember I had some discussions with her about that.

Q. Okay. Do you remember any other discussions with Holly Beason?
A. I don't recall any others.
Q. What was the nature of your discussions with April Koon?
A. Just keeping her in the loop as a -- the administrator for the Board, if I were talking with her board members.
Q. Did you discuss the bill that eventually became the ECCPL with any employees at the LLR, other than April Koon or Holly Beason?
A. I don't believe so, no.
Q. So to the best of your knowledge, the employees at LLR who were involved with and aware of the efforts surrounding the bill that became the ECCPL, were April Koon and Holly Beason?
A. To the best of my knowledge, yes.
Q. Okay. Did you speak with any government employees, outside of your board members and outside of LLR, regarding the bill that eventually became the ECCPL?
A. Not that I can recall.
MR. MATTHEWS: Robert, I need to go feed a meter in about 20 minutes.
(Off-the-record conference.)

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(A recess transpired.)
BY MR. MCNAMARA:
Q. So we've been discussing the legislation that eventually became the ECCPL. Do you know what South Carolina legislator first introduced the ECCPL?
A. I do not remember.
Q. Okay. Are you familiar with the South Carolina legislator named Dr. Long?
A. Yes.
Q. Who is Dr. Long?
A. She is a former member of the House of Representatives and is an optometrist.
Q. Okay. Is Dr. Long a member of SCOPA?
A. Yes.
Q. Do you know roughly how long Dr. Long has been a member of SCOPA?
A. More than 15 years.
Q. Okay. So long before the ECCPL was introduced?
A. Yes.
Q. Okay. We've talked about the drafting of the legislative language that became the ECCPL. Were you involved in any discussions about how best to communicate about the legislative language that

eventually became the ECCPL?
MR. SHEALY: Object to the form.
THE WITNESS: No.
BY MR. MCNAMARA:
Q. Did you ever have discussions about how best to talk about the proposed bill?
A. Yes.
Q. And with whom did you have those discussions?
A. I would say that probably would have been Mike Zolman.
Q. Anyone else?
A. I can't remember, but there could have been others. I know that we did have some talking points that we did develop for the bill.
Q. Okay. You say we had some talking points that we developed for the bill, who is we in that sentence?
A. Well, that would have been me and Mike Zolman. I'm sure there's -- there's a lot of correspondence that went back and forth about this bill. I'm sure at some point we shared with the AOA, there could have been some others.
Q. Okay.
MR. MCNAMARA: I'm going to ask the

court reporter to mark this as Exhibit 4.
(PLF. EXH. 4, E-mails between Jackie Rivers and Mike Zolman and others, dated January 19th, 2016, Bates stamped SCOPA 000667, was marked for identification.)
BY MR. MCNAMARA:
Q. Ms. Rivers, I've handed you a document that's marked as Exhibit 4. This appears to be an e-mail forward, but I want to draw your attention to the bottom half of the document where it says, begin forwarded message; do you recognize that portion of this document?
A. What part of this are you referencing?
Q. I'm referencing everything after, begin forwarded message, where it says from Jackie Rivers.
A. Oh, yes.
Q. Do you recognize that portion of this document?
A. Yes.
Q. What is it?
A. This is -- the bottom half portion would have been an e-mail correspondence to our Board of Directors at that time.
Q. Did you actually send these e-mails?

A. Yes.
Q. Okay. I want to draw your attention to the bottom e-mail on the page that's been marked as Exhibit 4. Do you see where it says: All, Dr. Campbell asked me to let everyone know that it will be very important once our bill gets dropped and we start talking with legislators and encouraging members to do the same, that we refer to bill as the Eye Care Consumer Protection Law?
A. Uh-huh.
(Court reporter seeks clarification).
A. Yes.
Q. Who is Dr. Campbell?
A. That is Dr. Mike Campbell, and he was our board president at the time.
Q. And do you see the last sentence of that e-mail says -- or I guess the second to the last sentence of that e-mail that says: This is also a recommendation from the AOA as well?
A. Yes.
Q. Do you recall who at the AOA made this recommendation?
A. No.
Q. Okay. From your recollection is there a limited universe of people it could have been?

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A. I would say, yes, it would have been, I guess, a limited universe of the group that came up with, don't refer to this bill as a kiosk bill, or any state that's going for legislation like this, it's not just a kiosk bill.

Q. About how many people at the AOA were you in communication with about this bill?

A. I'd say less than ten people.

Q. Okay. Why was it important not to refer to the bill as the kiosk bill?

A. Because it affected -- it would affect more than just a kiosk that might be set up in a mall or another location.

Q. Why did you want this bill to be not about telemedicine?

A. Because it's not a telemedicine bill.

Q. Why is that important?

A. Well, it's my personal opinion that there is a role and a place for telemedicine, especially in a state like ours, with a lot of rural areas.

Q. Okay. Is it a fair statement to say that the bill that eventually became the ECCPL was primarily pushed by the optometrists?

MR. SHEALY: Object to the form. You

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may answer.

THE WITNESS: Yes.

BY MR. MCNAMARA:

Q. Were you involved in any discussions within SCOPA about the substance of the bill that became the ECCPL?

A. I would say I was involved in a capacity of just being looped in so I could be aware of the communication, but I did not have any involvement in drafting the language.

Q. So is it fair to say that you were aware of SCOPA's internal discussions about the substance of the bill that became the ECCPL, even if you, yourself, didn't express any opinions about what that language should be?

A. Yes.

Q. Okay. Why does the ECCPL not simply require a provider to conduct a comprehensive eye health exam before writing a prescription for corrective lenses?

MR. SHEALY: Object to the form.

THE WITNESS: Can you ask that question again?

BY MR. MCNAMARA:

Q. Why doesn't the ECCPL simply require

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providers to conduct a comprehensive eye health exam before writing a prescription for corrective lenses?

MR. SHEALY: Object to the form. You may answer.

THE WITNESS: It is providing for a comprehensive in-person eye exam before a prescription is written.

BY MR. MCNAMARA:

Q. Is it your understanding that the ECCPL mandates, for example, a glaucoma examination before any corrective lens prescription can be written?

MR. SHEALY: Object to the form, but you may answer.

THE WITNESS: It is my understanding, again, I'm not an optometrist, that during the course of providing a comprehensive eye exam, that things of that nature, the overall assessment of the health of the eye, can be assessed, so things like glaucoma could be determined.

BY MR. MCNAMARA:

Q. You say they could be determined, do you know if it's mandatory that they be determined?

MR. SHEALY: Object to the form, but

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you may answer.

THE WITNESS: I don't know, I'm not an optometrist.

BY MR. MCNAMARA:

Q. Okay. Was there ever any discussion regarding the bill that eventually became the ECCPL to the effect that the bill should regulate simply optometrists and not ophthalmologists?

A. No.

Q. No one ever suggested that the bill just regulate optometrists?

A. Not that I can recall.

MR. MCNAMARA: I'm going to ask the court reporter to mark this as Exhibit 5.

(PLF. EXH. 5, E-mail correspondence between Michael Zolman and Jackie Rivers and others, dated March 1, 2016, Bates stamped SCOPA 000469 and 470, was marked for identification.)

BY MR. MCNAMARA:

Q. Ms. Rivers, I have handed you a document that has been stamped as Exhibit 5. Do you recognize this document?

A. Yes.

Q. What is this document?

A. Well, let's see, this appears to be

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regarding some edits to the bill.

Q. And when you say, the bill, you mean the bill that became the ECCPL?

A. Yes.

Q. This appears to be -- this appears to be an e-mail from Michael Zolman between you and several others; did you receive this e-mail?

A. Well, I'm on the distribution, so I assume I did.

Q. And on the face of it, it appears to be quoting an e-mail you sent. Did you send that e-mail?

A. Yes.

Q. Okay. And in your e-mail you seem to be passing along an e-mail from someone named Catherine Hendricks?

A. Yes.

Q. Who is Catherine Hendricks?

A. Catherine Hendricks works for the AOA, the American Optometrics Association.

Q. And what does -- sorry.

A. I was just going to say her official title here, she works for state government relations, she's the manager.

Q. Okay. And to the extent you know, what

is her role as a state government relations manager?

A. I can speak to what my role has been with her and she's one that I consult with if I have a question or need information about legislative issues.

Q. Okay. And it seems from this e-mail that you're passing along feedback from the AOA regarding the proposed amendment from Opternative?

A. It appears to be the case.

Q. What is the proposed bill from Opternative?

A. Yeah, I'm not sure. I don't recall.

Q. So the first full sentence of Ms. Hendricks' e-mail says: Removing MDs basically makes the bill moot?

A. Uh-huh.

(Court reporter seeks clarification).

A. Yes.

Q. Was this an e-mail regarding a proposal to remove MDs from the bill that eventually became the ECCPL?

A. Yes. And I believe that might have been what the proposed edit from Opternative may have been, to remove the MDs.

Q. Why would removing MDs from the bill make it moot?

MR. SHEALY: Object to the form, but you may answer.

THE WITNESS: Because it would still create an avenue potentially for someone to give themselves a refraction utilizing technology that removes them out of the doctor's office.

BY MR. MCNAMARA:

Q. And actually, if I can direct your attention to the second page of this e-mail. Do you mind just reading the last two e-mails before we're done, I think it may refresh your recollection about what Opternative's proposal was.

A. Which part do you think is going to remind me, the e-mail from Robert Adams?

Q. Yes.

A. It looks like they're proposing to delete the South Carolina Board of Medical Examiners.

Q. Okay. So having reviewed that, does that refresh recollection about your earlier testimony about what proposed amendment from Opternative you were talking about in this e-mail?

A. No.

Q. Okay, that's fine. Do you remember when you first learned about the possibility or practice of online-only eye exams?

MR. SHEALY: Object to the form, but you may answer.

THE WITNESS: No.

BY MR. MCNAMARA:

Q. Are you aware, as you sit here today, that there are businesses in the world that purport to provide online-only eye exams?

MR. SHEALY: Object to the form, but you can answer.

THE WITNESS: Yes, I'm aware that there's other technologies out there that can do that, yes.

BY MR. MCNAMARA:

Q. Okay. Are you familiar with a company called Opternative?

A. Yes.

Q. When did you first hear about the company Opternative?

A. I'm not sure.

Q. Do you remember how you first heard about the company Opternative?

A. Not specifically.

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Q. Okay.

MR. MCNAMARA: I'm going to ask the court reporter to mark this as Exhibit 6.

(PLF. EXH. 6, E-mail correspondence between Jackie Rivers and Angelia Smith Owens and others, dated March 13 and 17th, 2016 and April 1, 2016, Bates stamped SCOPA 000501 through 504, was marked for identification.)

BY MR. MCNAMARA:

Q. I've handed you a document that's been marked as Exhibit 6. Do you recognize this document?

A. Yes.

Q. What is this document?

A. This is an original communication that was sent out to all state executive directors from the American Optometric Association.

Q. And when it was sent to state executive directors, are you a member of the e-mail list in the e-mail from Brian Reuwer called state executive directors?

A. Yes.

Q. Okay. So you got this directly?

A. Yes.

Q. What is the nature of this update?

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A. To inform state executive directors about Opternative and online eye exams.

Q. So at least as early at 2014, the AOA was notifying you about developments in the world of online eye exams?

A. Yes.

Q. Was the effort to pass the ECCPL prompted by a desire to ban online eye exams?

MR. SHEALY: Object to the form. You may answer.

THE WITNESS: The purpose of our bill was to protect the consumers, patients in South Carolina to ensure that they get an in-person comprehensive eye exam.

BY MR. MCNAMARA:

Q. Was the effort to pass the ECCPL prompted by the existence of businesses offering online eye exams?

MR. SHEALY: Object to the form.

MR. MATTHEWS: Same objection, please answer.

THE WITNESS: Yes.

BY MR. MCNAMARA:

Q. Did the effort to pass the ECCPL come about before or after SCOPA learned about the

Page 56

existence of online eye exams?

MR. SHEALY: Object to the form. You may answer.

THE WITNESS: After.

BY MR. MCNAMARA:

Q. Were there ever internal discussions at SCOPA about the importance of discussing the ECCPL as if it were not an effort to ban Opternative?

MR. SHEALY: Object to the form. You may answer.

THE WITNESS: Yes.

BY MR. MCNAMARA:

Q. What was the nature of those discussions?

A. The nature of the discussion was what obligations the association or practitioners had to protect consumers to ensure that they have -- receive comprehensive eye exams.

Q. Was that the only reason put forward in internal discussions to talk about the bill that way?

A. I would say that our discussions primarily centered around accomplishing that.

MR. MCNAMARA: I'm going to ask the court reporter to mark this as Exhibit 7.

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(PLF. EXH. 7, E-mail correspondence between Mike Zolman, Jackie Rivers and others, dated May 17th, 2016, Bates stamped SCOPA 001257 through 1259, was marked for identification.)

BY MR. MCNAMARA:

Q. I've handed you a document that the court reporter has labeled as Exhibit 7. Do you recognize this document?

A. Yes.

Q. What is this?

A. This was a document that was sent out to our members after our governor vetoed our bill and asking them to help us with an override.

Q. Okay. And if I can direct your attention to page 2 of this, it has in the bottom right-hand corner SCOPA 1258.

A. Uh-huh. Yes.

Q. Do you see the bolded text that says, what you need to do, in the middle of the page?

A. Yes.

Q. You said this was sent out to SCOPA's members. So is the, you, in this sentence SCOPA's members?

A. Yes.

Q. If you can go to the second paragraph

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after that bolded text, the paragraph that begins, we do not, can you just read that sentence for me, please?

A. Sure. We do not want to make this an anti-Opternative argument as legislators frown upon legislation that singles out and restricts a specific business. We must maintain the argument that this bill protects the consumer from false and misleading claims that an eye exam is as well as that it -- what an eye exam is, as well as that it protects our citizens from unproven technology and that anything less jeopardizes consumer health care.

Q. Thank you very much. When the ECCPL passed, did SCOPA or its members celebrate the passage as a victory over Opternative?

MR. SHEALY: Object to the form. You may answer.

THE WITNESS: We celebrated it as a victory in general for the protection and safety of our citizens.

MR. MCNAMARA: I'm going to ask the court reporter to mark this as Exhibit 8.

(PLF. EXH. 8, E-mail correspondence between Jackie Rivers, Catherine Hendricks, and

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Daniel Carey, dated May 18th and 19th, 2016, Bates stamped SCOPA 000116 and 117, was marked for identification.)

BY MR. MCNAMARA:

Q. Ms. Rivers, I'm handing you a document that has been labeled Exhibit 8 to this deposition. Do you recognize this document?

A. Yes.

Q. What is this document?

A. This is a document -- well, the subject line says, AOA letter of support, so I assume we received a letter from the AOA to support our efforts, it looks like it was distributed to the Senate.

Q. Do you see roughly a little more than a third of the way down the page, it says: On May 18th, 2016 at 5:21 PM Jackie Rivers wrote?

A. Yes, I see that.

Q. What was happening on May 18th, 2016?

A. I believe that was when we got our override in the Senate maybe.

Q. So is this quoting an e-mail you wrote in response to the Senate vote to override Governor Haley's veto?

A. It appears to be.

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Q. And would you mind just reading into the record your May 18th, 2016 e-mail?

A. The one where I said yes?

Q. Yes, ma'am.

A. The Board was here, so we were all able to watch it together. Take that, Opternative.

Q. Thank you, you can set that aside.

MR. MCNAMARA: I'm going to ask the court reporter to mark this as Exhibit 9.

(PLF. EXH. 9, E-mail correspondence from Jackie Rivers to penfields, dated June 27th, 2016, Bates stamped SCOPA 000196 through 203, was marked for identification.)

BY MR. MCNAMARA:

Q. We're almost done. Okay. Ms. Rivers, the court reporter is handing you a document that's been labeled as Exhibit 9. And this appears to be an e-mail with an attachment, so I want to take it in two phases, so we identify everything. Looking just at the first page, do you recognize the first page?

A. Yes.

Q. And what is that?

A. This is an e-mail where I sent Dr. Chris Wroten a presentation that we were asked

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to give at a President's Council of the American Optometrics Association.

Q. And who is Chris Wroten?

A. He is an optometrist in Louisiana and is the moderator for those meetings.

Q. Okay. And what is the nature of the presentation scope you were asked to give?

A. We were asked to give an overview of how we got our law passed, our Consumer Eye Care Protection Bill.

Q. And when you say how we got our law passed, you're referring to the Eye Care Consumer Protection Law --

A. Yes.

Q. -- or the ECCPL?

A. Yes.

Q. At any point you're referring to a different law, please just say that so I can stop breaking it down. And the rest of this exhibit, was that an attachment to this e-mail?

A. Yes.

Q. And what is that attachment?

A. This is the copy of the presentation that we gave.

Q. Okay.

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CERTIFICATE OF REPORTER

I, Amy R. Cope, Court Reporter and Notary Public for the State of South Carolina at Large, do hereby certify that the foregoing transcript is a true, accurate, and complete record.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.

Witness my hand, I have hereunto affixed my official seal this 15th day of August, 2017 at Columbia, Richland County, South Carolina.

Amy R. Cope, Court Reporter
My Commission expires
May 12, 2018

I N D E X

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From: angelia@kmso.net
Sent: Tuesday, January 19, 2016 5:18 PM
To: Angelia Smith Owens
Subject: Fwd: SCOPA's Bill - How to Reference

Angelia Smith Owens
Kelley, McCain & Smith Owens, LLC
803.608.4800 cell
803.254.1110 office
Angelia@kmso.net

Begin forwarded message:

From: Jackie Rivers <jrivers@sceyedoctors.com>
Date: January 19, 2016 at 1:26:43 PM EST
To: "repmkelley@aol.com" <repmkelley@aol.com>, Angelia Smith Owens <angelia@kmso.net>, Philip Flynn <pdflynn@hotmail.com>, Wayne Cannon <wmcannon15@gmail.com>
Cc: Mike Campbell <mcamp16035@aol.com>, Jennie Smith Zolman <jenniesmithod@yahoo.com>
Subject: FW: SCOPA's Bill - How to Reference

Hi all!! Please see message below from Dr. Campbell. Dr. Jennie Zolman asked me to be sure that I sent you this message as well. Wanna try and keep us all on the same page. Thanks!!

From: Jackie Rivers
Sent: Tuesday, January 19, 2016 11:40 AM
To: Anna Balderson <abalderson@sceyedoctors.com>; Bob Branch <jeyes4us@yahoo.com>; David McKenzie <drdavid@mckenzieeyecare.com>; Jennie Smith Zolman <jenniesmithod@yahoo.com>; Johndra McNeely <uptownnw@yahoo.com>; Justine O'Dell <justinejodell@gmail.com>; Mike Campbell <mcamp16035@aol.com>; Mike Zolman <focusedeyedoc@yahoo.com>; Pete Smith <smithforhouse@gmail.com>; Ted Newman <tnewman123@bellsouth.net>
Subject: SCOPA's Bill - How to Reference

All, Dr. Campbell asked me to let everyone know that it will be very important, once our bill gets dropped and we start talking with legislators and encouraging members to do the same that we refer to the bill as the Eye Care Consumer Protection Law. It will be important that we not refer to this bill as the "kiosk" bill. We want this bill to be about ensuring the safety and wellbeing of the public and not telemedicine. This is also a recommendation from the AOA as well.

Thanks!

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From: Michael Zolman <focusedeyedoc@yahoo.com>
Sent: Tuesday, March 01, 2016 11:32 AM
To: Jackie Rivers; Mike Campbell; Philip Flynn; Pete Smith; Kirby D. Shealy III
Cc: Anna Balderson
Subject: Re: Meeting Monday

[redacted]

Michael W. Zolman, OD

Infinity Eye Care and Low Vision Rehabilitation Center
325 Folly Rd., Suite #109
Charleston, SC 29412

P: 843.795.6464
F: 843.795.6433
www.myinfinityeyecare.com

On Tuesday, March 1, 2016 10:51 AM, Jackie Rivers <jrivers@sceyedoctors.com> wrote:

All – wanted to pass along the feedback from the AOA regarding the proposed amendment from Opternative.

Kirby, I neglected to include you in the forward this morning. In case you need it I've attached a copy of the bill from yesterday.

Thanks!

From: Hendricks, Catherine [mailto:CHendricks@AOA.ORG]
Sent: Tuesday, March 01, 2016 10:50 AM
To: Jackie Rivers <jrivers@sceyedoctors.com>; Carey, Daniel <DCarey@AOA.ORG>
Subject: RE: Meeting Monday

Hi Jackie,

Removing MDs basically makes the bill moot. Continue talking about patient safety, the medical device aspects (contacts deprive the cornea of oxygen and must be monitored for signs of wear), and the cost of emergency room treatment (CDC report) for keratitis.

If you sponsor is willing to run with it as is, do it. Give them the ground support and ammo to move it.

Thank you!

Catherine Hendricks
Manager, State Government Relations

703-837-1017 office
703-739-9497 FAX
AMERICAN OPTOMETRIC ASSOCIATION

From: Jackie Rivers [mailto:jrivers@sceyedoctors.com]
Sent: Tuesday, March 01, 2016 10:36 AM
To: Carey, Daniel <DCarey@AOA.ORG>; Hendricks, Catherine <CHendricks@AOA.ORG>
Subject: FW: Meeting Monday

Hi Daniel and Catherine! Wanted to share with you the proposed edit from Opternative. I've attached the latest version of our bill.

From: Angelia Smith Owens [mailto:angelia@kmso.net]
Sent: Tuesday, March 01, 2016 10:30 AM
To: Michael Campbell <mcamp16035@aol.com>; Jackie Rivers <jrivers@sceyedoctors.com>
Cc: 'Mark Kelley' <mark@kmso.net>
Subject: FW: Meeting Monday

FYI from Opternative's lobbyist. His reference isn't clear, but I believe he means they want to revise definition of provider, which is (7) in Julie's amendment from last week and (11) in the bill as introduced. (Jackie please forward)

From: Adams, Robert [mailto:RAdams@mwcllc.com]
Sent: Tuesday, March 01, 2016 10:16 AM
To: Julie Price
Cc: Stokes-Murray, Lynn (LStokes-Murray@MCNAIR.NET); Puhlasky, Jason J. (Jason@parkerpoeconsulting.com); JCNicholson@scmedical.org; kkent@hsbcopperdome.com; 'Bruning, Shannon' (SBruning@mcnair.net); ronscott11@aol.com; Damon Jeter (djeter@jetcorpconsulting.com); benhomeyer@1101publicaffairs.com; Mark Kelley; 'Angelia Smith Owens'; Ron Scott; Boan, William D.; Phillips, Katherine A.; 'rebecca.leach@llr.sc.gov'; Boan, William D.
Subject: RE: Meeting Monday

Group –

I apologize for this, but Billy and I have received new instructions from our client, Opternative, which are different than what I communicated to you in yesterday's meeting.

We would like to make a change to section (11), striking every word after Optometry:

The following would be deleted:

"or the South Carolina Board of Medical Examiners."

Again, we apologize for any confusion this may have caused.

Thanks,
Robert

Robert Adams
SVP Government Relations - State
McGuireWoods Consulting LLC
1301 Gervais Street

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From: Jackie Rivers <jrivers@sceyedoctors.com>
Sent: Tuesday, April 01, 2014 11:59 AM
To: Angelia Smith Owens
Subject: FW: AOA Update on Opternative
Attachments: AOA warns public about online eye exams.pdf

Hey – is this what you were talking about?

From: Jackie Rivers
Sent: Monday, March 17, 2014 3:38 PM
To: 'Angelia Smith Owens'; 'Mark Kelly'
Cc: Wayne Cannon; 'jvaught@vaughteye.com'; 'David McKenzie'
Subject: FW: AOA Update on Opternative

Good afternoon Angelia and Mark. Dr. Cannon asked me to forward you this update on Opternative, just so you all are in the loop on what's going on with this online "eye exam" website that is supposed to be live this summer.

I've attached the article as a pdf. Crazy concept, hard to believe it's being put in place!

From: Reuwer, Brian [mailto:BReuwer@AOA.ORG]
Sent: Thursday, March 13, 2014 2:52 PM
To: State Executive Directors
Cc: Hymes, Jon; Brauns, Renee; Frawley, Jennifer A.; Skiles, Kristen
Subject: AOA Update on Opternative

Good afternoon,

I want to send you a quick update on AOA actions on the Opternative issue, which is the online "eye exam" website that is supposed to be live this summer. The AOA has written an article that was published this morning on aoa.org/news that describes a little more detail on our response which you may want to share with your members. In addition, you might find the article in the Chicago Tribune interesting as well, while Opternative did not comment on our letter, I think the story shows insight into how they will likely respond back to us.

From an SGRC perspective, we are investigating what legal justifications they may use once the program goes live plus the wider issue of the introduction of kiosks in your state. Once we have completed this review, we will make recommendations to state affiliates about suggested strategies to stop this from operating in your state.

If you have any questions about the article or anything else associated with Opternative or kiosks please do not hesitate to contact me.

Brian

http://www.aoa.org/news/advocacy/aoa-warns-public-about-online-eye-exams
http://bluesky.chicagotribune.com/originals/chi-opternative-aoa-warning-dangers-bsi-20140312,0,0.story

Brian Reuwer
Associate Director, State Government Relations
American Optometric Association

SCOPA 000501

1505 Prince St. Suite 300
Alexandria, VA 22314
Phone - 703-837-1343
Cell - 517-290-3532
BReuwer@aoa.org

Click here to view a 99-second video on the historic AOA SUPER ADVOCACY CONFERENCE 2013, and for information on attending next year's meeting.

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AOA warns public about online eye exams

The AOA is warning consumers about possible risks associated with online refractive eye exams.

Such online sites tout convenience. But any alleged advantages come with risks, the AOA cautions. In a statement, AOA President Mitchell T. Munson, O.D., says the association has received an increasing number of questions about the safety and validity of this type of online test.

The AOA contends that such tests are no substitute for an in-person comprehensive eye exam by an optometrist or ophthalmologist.

"We believe that claiming to have performed an eye exam without physically examining a patient is offering misleading information and may contribute to a patient believing—incorrectly—that his or her eye health needs have been met," Dr. Munson says.

The value of in-person exams

One such website says its online refraction test is only available to those between the ages of 18 and 40 who are in good health—meaning people with no history of conditions such as hypertension, cataracts, glaucoma or diabetes.

An online exam has the potential to miss critical, underlying health problems.

But what if patients don't know they have these diseases?

Diabetes, for example, affects more than 8 percent of the U.S. population, but roughly 7 million people are unaware that they have this condition, according to estimates from the Centers for Disease Control and Prevention.

Like diabetes, most systemic conditions are asymptomatic in their earliest and most treatable stages.

These are precisely the types of chronic conditions an OD can diagnose and manage during a comprehensive eye exam, the AOA maintains. A recent study by UnitedHealthcare supports the role ODs play in identifying chronic health issues.

An online exam has the potential to miss critical, underlying health problems, says Beth Kneib, O.D., director of the AOA Clinical Resources Group.

"If you look at refraction only, you're not personally looking in the patient's eye, you're not examining their eye health, you're not looking at their history or observing medical conditions firsthand," she says.

Perhaps a patient is having a shift in vision because of cataracts and isn't aware of it. "And they could be getting better treatment by having the cataract addressed. Maybe they have diabetes and

they have fluctuating vision, and they don't know their glucose is causing their decreased vision if they're just getting lens prescriptions over the Internet," Dr. Kneib says.

Dr. Munson cautions that any delay in intervention in such cases could result in progressive vision damage and more costly and intensive treatments down the road.

"Consumers with chronic conditions such as diabetes or hypertension may be at significant risk regarding proper diagnosis and treatment of potentially sight-threatening diseases if they are not properly evaluated by an eye doctor," Dr. Munson says.

The AOA is calling for a thorough evaluation of online eye-testing sites, and how they might affect patient health. The AOA also plans to monitor these sites and play an active role in fact-checking their claims.

March 13, 2014

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From: Jackie Rivers
Sent: Thursday, May 19, 2016 8:35 AM
To: Hendricks, Catherine; Daniel Carey
Subject: RE: AOA Letter of Support

Importance: High

Hey Catherine...we think the House will take it up this morning at 10:30. Here's a link:
http://www.scstatehouse.gov/video/videopage.php?chamber=H&AUDIO=0

From: Hendricks, Catherine [mailto:CHendricks@AOA.ORG]
Sent: Wednesday, May 18, 2016 5:36 PM
To: Jackie Rivers
Subject: Re: AOA Letter of Support

Let us know when the House will take it up and we'll watch online. This is pretty exciting!
Catherine

Sent from my iPhone

On May 18, 2016, at 5:21 PM, Jackie Rivers <jrivers@sceyedoctors.com> wrote:

> Yes!!!! The board was here so we were all able to watch it together...take that Opternative!!!!!!
>
> ---
>
> **From:** Hendricks, Catherine [mailto:CHendricks@AOA.ORG]
> **Sent:** Wednesday, May 18, 2016 4:54 PM
> **To:** Jackie Rivers <jrivers@sceyedoctors.com>
> **Cc:** Deanna Alexander <deealex1@aol.com>; Carey, Daniel <DCarey@AOA.ORG>; zkloomis@gmail.com
> **Subject:** FW: AOA Letter of Support
>
> So you guys crushed it in the Senate! Do you think you will need/want a letter of support for the House?
>
> Catherine Hendricks
> Manager, State Government Relations
> 703-837-1017 office
> 703-739-9497 FAX
>
> ---
>
> **From:** Hendricks, Catherine
> **Sent:** Wednesday, May 18, 2016 4:51 PM
> **To:** Rivers, Jackie Exec Dir <JRivers@sceyedoctors.com>
> **Cc:** Deanna Alexander <deealex1@aol.com>; Carey, Daniel <DCarey@AOA.ORG>; zkloomis@gmail.com
> **Subject:** AOA Letter of Support
>
> Hi Jackie,

I hope you are doing well. Attached is a letter of support from Dr. Loomis and the AOA for the veto override of S 1016 to South Carolina Senators. The letter reflects the AOA's public health position on eye apps/kiosks/and online tests. Please feel free to distribute to the Senators as they consider the veto override, and let us know if a letter is needed for the House.

Good luck!

Catherine Hendricks
Manager, State Government Relations
703-837-1017 office
703-739-9497 FAX

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From: Jackie Rivers
Sent: Monday, June 27, 2016 1:59 PM
To: penfields@penfields.com
Subject: Fwd: SCOPA - Powerpoint presentation for PC
Attachments: Optometry at its finest!v2.pptx

Sent from my iPhone

Begin forwarded message:

From: "Jackie Rivers" <jrivers@sceyedoctors.com>
To: "penfields10@pensfields.com" <penfields10@pensfields.com>
Subject: Fwd: SCOPA - Powerpoint presentation for PC

Sent from my iPhone

Begin forwarded message:

From: "Jackie Rivers" <jrivers@sceyedoctors.com<mailto:jrivers@sceyedoctors.com>>
To: "Chris Wroten" <cwroten@od.sco.edu<mailto:cwroten@od.sco.edu>>
Subject: SCOPA - Powerpoint presentation for PC

Hi Dr. Wroten! Our presentation is attached. I will also have a copy with me if needed. There shouldn't be any changes made but…☺

Jackie Rivers
Executive Director
SC Optometric Physicians Association
2730 Devine Street
Columbia, SC 29205
803-799-6721 toll free 877-799-6721
fax: 803-799-1064
www.sceyedoctors.com<http://www.sceyedoctors.com><http://www.sceyedoctors.com/>

[cid:16%253aX%253aRgAAAABLMiP7M5b4TqzD7PJzhgdiBwDa0nOsEjiBTqW3srFcjyEbAAAAAAEKAADa0nOsEjiBTqW3srFcjyEbAACaf8UyAAAJ%253aEACPBitetQixT4mR9GeF0c2B]

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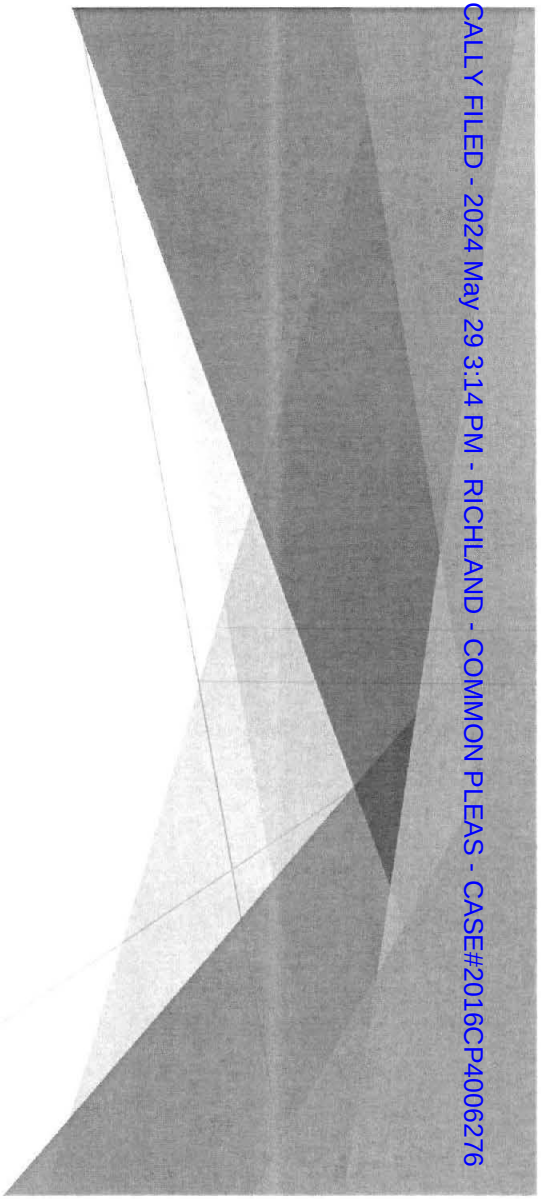
SC(•)PA
South Carolina Optometric Physicians Association

Optometry at its finest!

It was a GREAT day in South Carolina

Our Recipe for Success?

- Great Grassroots
- Great team and a great plan
- Great implementation
- Perseverance!



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What worked for us?

- Being Politically Active.
- Being visible in the community: SC Mission events, Special Olympics, WellPartners Dental and Eye Clinic, numerous community health fair events some of which were at the invitation of legislators for their underserved constituents.
- SCOPA board members were engaged.
- Being an election year where the entire House and Senate are up for re-election.
- SCOPA lobbyist, members and Ophthalmology Executive Director/Lawyer quietly met over the summer and fall to agree on language for the legislation.
- Companion bills were introduced: S.1016 and H.4728.
- Having great primary sponsors.
- Numerous co-sponsors for both bills.
- Several group meetings with House and Senate staff, agency legislative liaisons, ophthalmology representatives.
- A great lobbying team that knew the system, members and procedures and was able to push and get ahead of bill issues.

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Some Highpoints:

- S.1016 was introduced by Senator Cleary on January 21st.
- January - April: worked closely with legislative staff, attended and testified at numerous subcommittee and full committee hearings. Working with state house staff proved to be crucial - having them involved helped us tremendously in being able to move quickly through legislative process and calendar.
- March: Opternative hired a lobbying firm and their efforts to kill our bill began.
- On April 26th the bill was passed out of the Senate by a vote of 40 - 1.
- On April 27th the bill was introduced and had it's first read in the House. It was referred to and recalled from committee on the same day! Due in part to having state house staff involved but also because of Representative (Dr.) Deborah Long being a respected member of the SC House.
- On April 28th the bill received its second reading in the house; had a roll call vote of 100-1 and was given unanimous consent for the third reading the following legislative day.
- The bill was ratified on May 11th - vetoed by Gov. Haley on May 16th

SCOPA members went to work!

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The Veto...

Representative Deborah Long and our lobbying team met with the Governor's Chief of Staff. WE knew the arguments and that we would likely see a veto.

In the words of Governor Nikki Haley

"Today, I am vetoing and returning without my approval, R.178, S.1016, a bill that requires prescription from a licensed optometrist or ophthalmologist to receive glasses or contacts based on an in-person comprehensive eye examination. I am vetoing this bill because it uses health practice mandates to stifle competition for the benefit of a single industry, effectively banning eye care kiosks statewide."

She doesn't stop there...

"...optometrists argue that kiosks create an uneven playing filed because licensed providers cannot take advantage of this technology and charge patients for its use in a medical practice...send a bill to my desk that allows for the expanded use of automatic vision evaluation in all medical settings, and I will sign it.

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The Override!

ready. set. go!

We had our members prepared with a message to contradict the Governor's veto. We asked SCOPA members to again reach out to their legislators explaining why the Governor was wrong and asked them to override.

They listened!

We had a little help from our friends

AMERICAN OPTOMETRIC ASSOCIATION

Johnson & Johnson
VISION CARE, INC.

The Results...

The Senate	The House
39 Yeas	98 Yeas
3 Nays	3 Nays

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EXHIBIT 3

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STATE OF SOUTH CAROLINA
COURT OF COMMON PLEAS
COUNTY OF RICHLAND

OPTERNATIVE, INC.,

Plaintiff,

vs. CASE NO. 2016-CP-40-06276

SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS, and SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION,

Defendants,

and

SOUTH CAROLINA OPTOMETRIC PHYSICIANS ASSOCIATION,

Intervener
Defendant.

30(B)(6) DEPOSITION OF: DARRA COLEMAN, ESQ.

DATE: August 3, 2017

TIME: 9:32 a.m.

LOCATION: Nelson, Mullins, Riley & Scarborough
1320 Main Street
Columbia, SC

TAKEN BY: Counsel for the Plaintiff

REPORTED BY: Janice N. Shepherd, RPR

A. WILLIAM ROBERTS, JR., & ASSOCIATES
Fast, Accurate & Friendly

Charleston, SC (843) 722-8414
Hilton Head, SC (843) 785-3236
Myrtle Beach, SC (843) 839-3376
Columbia, SC (803) 731-5224
Greenville, SC (864) 234-7030
Charlotte, NC (704) 573-3919

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MR. McNAMARA: I'm just going to ask the court reporter to mark this as Exhibit 1.

(PLF. EXH. 1, Five-page 7/11/17 Notices of Deposition, was marked for identification.)

BY MR. McNAMARA:

Q. Ms. Coleman, the court reporter has placed in front of you a document marked as Exhibit 1. Do you recognize this document?

A. Yes.

Q. What is this document?

A. This is the Notice of Deposition for 30(b)(6) Designee for LLR.

Q. And is it your understanding that you're appearing here pursuant to a notice to the Department of Labor, Licensing and Regulation and also to a notice to the South Carolina Board of Medical Examiners?

A. Yes, sir, it is.

Q. And it's your understanding that your testimony today is going to be on behalf of those groups as an entity?

A. Yes.

Q. And so when I ask you questions, I'm not just asking about your personal knowledge; I'm asking about the knowledge of those two entities.

A. I understand.

Q. I think for the most part, we kind of treat those entities as one. If I ask you a question about whether you have any information on a particular topic, I'll be referring to both of them. If necessary, if we need to talk about LLR or about the Board, I'll ask specifically about those. Does that make sense?

A. Yes.

Q. Is it okay if I call them LLR and the Board?

A. Yes.

Q. I want to make sure everyone knows what we're talking about. What, if anything, did you do to prepare for today's deposition?

A. I reviewed some of the documentation that has been previously produced in discovery. I reviewed some of the pleadings, and I also met with counsel.

Q. Did you speak with anyone other than counsel about the deposition?

A. I spoke with our general counsel who participated in the preparatory meeting with our outside counsel.

Q. Okay. I don't want to ask you about anything you said to your attorneys. Outside of a meeting with an attorney, did you talk to anyone?

A. No.

Q. Okay. You say you reviewed some of the documentation that had been produced in discovery?

A. Yes.

Q. Do you remember what that was?

A. Some exhibits that had been marked in the depositions conducted earlier this week. In all honesty, I glanced at them. I did not study them, so I could not identify them by Bates number. But those generally are the documents. I know, I'm falling down on the job already that I can't identify them by Bates number.

Q. The record will reflect laughter.

A. Yes.

Q. Did you look at any documents outside of that?

A. No, not outside the pleadings and those documents identified.

Q. Okay. Are you currently employed?

A. Yes.

Q. And what is your job?

A. I'm chief advice counsel for the South Carolina Department of Labor, Licensing and Regulation.

Q. What does that mean?

A. I am part of the legal services team within the division of administration for the agency, and it is my job to manage the team of attorneys who deliver in-house legal services to all of our 40 boards, plus the additional programs and divisions.

Additionally, I am directly responsible for the conduct of special projects, the development of advisory opinions, position statements, and other special projects as designated by other general counsel or the director of the agency.

Q. And you yourself are an attorney?

A. Yes.

Q. And you're aware that you're appearing here today in the course of a lawsuit; is that right?

A. Yes.

Q. What, if anything, do you know about that lawsuit?

A. Only what's in the pleadings.

Q. And you're testifying today on behalf of the South Carolina Board of Medical Examiners?

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A. Yes.
Q. What is that board?
A. That is the board under South Carolina law with exclusive authority to license and otherwise regulate physicians, physician assistants. We also have the acupuncture committee and respiratory care therapists who fall under the jurisdiction of the Board of Medical Examiners.
Q. When you say the jurisdiction of the Board includes physicians, does the category of physicians include ophthalmologists?
A. Yes, it would include all physicians.
Q. Okay. Does the Board have any role in enforcing the laws and regulations of South Carolina?
A. Yes.
Q. What is that role?
A. We are governed by the statutory authority given to us by the legislature in the Medical Practice Act, which is in Chapter 47 of Title 40. And typically the Board is charged with making licensure decisions as well as disciplinary decisions in cases that are presented to the agency pursuant to the Medical Practice Act.
Q. And how does a case become presented to

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the agency?
A. If it is an application review, that's where someone has applied for licensure, but for whatever reason, it cannot be approved at the staff level. That may be due to disciplinary matters. It may be due to a history of medical malpractice claims. There may be questions about whether the education presented is acceptable. There may be issues regarding their passage of certain tests that are designated in the Medical Practice Act.
For disciplinary matters, we are a complaint-driven process. So the way the complaint process begins is that anyone can file a complaint. That complaint comes in and is reviewed by a complaint analyst. The complaint analyst is not a member of the Medical Board's administrative team but works directly with the Office of Investigations and Enforcement. We have a lot of acronyms. I'll just call that OIE.
So the complaint analyst is the frontline reviewer, and their job is to compare the allegations with the relevant Practice Act and regulations. So if the allegations, if proven true, would constitute a violation of either the Practice Act or the regulations, they would then

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forward that over to the investigative team, and the lead investigator would open a file. They would assign an investigative file number.
From there, the investigator, the chief investigator, assigns an investigator to run with that investigation. It's my understanding they typically initiate contact with the complainant within a number of days to ascertain any additional information or clarification that might be necessary before they reach out to the respondent.
After gathering information from the complainant, they can then identify additional third-party sources of information that they may need to communicate with as well. They follow up with the respondent. They identify for the respondent the core components of the complaint made against them. The respondent has an opportunity to fully respond to the investigation.
Once the investigation is complete, the investigator handling the case prepares a summary that is reviewed by the chief investigator. If the chief investigator is satisfied that the investigation conducted is sufficient, it is then presented to the IRC, which is the Investigative Review Committee.

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The IRC is comprised of the prosecuting attorney, typically, as well as the prosecuting attorney's supervisor, the investigator assigned to the case, the supervising investigator, and most importantly, professional members. The administrator for the Board also usually sits in on the IRC.
The IRC's job is to review all the evidence that's been gathered to date and to determine whether or not, after weighing all the evidence, they believe that a violation of the Practice Act or the regulations has occurred. The IRC then makes a recommendation that is presented anonymously to the Medical Board.
The Medical Board meets quarterly. So the way that it is presented for all of the cases that have been reviewed by the IRC within that period of time, since the last meeting, they are categorized as cases either recommended for dismissal, dismissal with a letter of caution, or issuance of a formal complaint.
The only information that the Board members are provided is the investigative file number, the initial allegations that came in on that informal complaint, as well as the rationale

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for the recommendation. No identifying information is provided. There is no geographical reference, no identification of the practice or employer of the licensee so as to avoid any potential bias or prejudice at that stage.

The Board puts all of those recommendations from the IRC to a vote. If a formal complaint is recommended, then that transfers the case from OIE to the Office of Disciplinary Counsel, which is another division of legal services within the agency charged with prosecuting all of the cases.

And we have within our agency what we would consider a Chinese wall. My team does not participate in the investigative process; and, similarly, ODC does not have the attorney-client relationship that we have with all the boards.

Once a case is turned over to ODC, ODC can either attempt to negotiate stipulations of fact and/or stipulations of a fact constitute a violation of the Medical Practice Act, or they can simply move forward with an evidentiary hearing.

By statute, the Medical Board has a panel that includes a lay member as well as physician licensees who conduct the initial

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evidentiary hearing. That panel is prohibited by statute from recommending sanctions. They only make determinations of fact and determine whether or not in their opinion those facts constitute a violation of the law. They are also charged with identification of any mitigating or escalating factors. That report is then presented to the Medical Board.

Typically where there is a stipulation of fact, you can bypass the evidentiary hearing and come straight to the Board for what we call a final order hearing, at which point, depending upon how the case is postured, the Board will resolve any issues of fact, establish conclusions of law, and if necessary, impose sanctions.

So that is a very long-winded version of the disciplinary process.

Q. I appreciate the thoroughness. So you say it's a complaint-driven process and that anyone can file a complaint?

A. Yes.

Q. So the complaint doesn't have to come from a member of a regulated profession or an injured party. It's literally anyone in the universe?

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A. Correct.

Q. Okay. Do you have a sense of approximately how long the process takes in between the filing of the complaint and when the case reaches the IRC?

A. It's really dependent upon the complexity of the case and also whether there are other complicating factors. For example, if there is a pending criminal investigation, typically we would forbear moving forward in our process until the criminal charges have been resolved.

One source of a number of our healthcare complaints does come from DHEC where the Bureau of Drug Control is housed. So in our diversion cases, it is not uncommon to have a physician who has been arrested, and we would try to coordinate with DHEC and any other law enforcement entities that might be involved.

If, for example, it is a significant case where it's going through either the Court of General Sessions at state court, the state court level, or if it's a federal court matter, we would wait until that matter is totally resolved.

So we could have a case, in theory, that is not complex that could be fully resolved

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within a 12-month span of time. But it's also likely that we could have a case not resolved for a number of years, depending on the other complicating factors.

Q. Just for the record, you used the acronym DHEC?

A. Yes, sir.

Q. Can you tell us what that is?

A. Yes, sir. That's the South Carolina Department of Health and Environmental Control.

Q. And you say it's theoretically possible to have a relatively not complex case be wrapped up in 12 months?

A. In theory, if it's very straightforward, yes, sir. The typical investigative period is 60 to 180 days. We have target investigation cycle goals for each board, and it varies. But within the healthcare boards, I've noticed probably the greatest variability. And, again, if you had a very, very open and shut diversion case where there was no law enforcement involvement, I think it would be -- and the parties stipulated to the facts, stipulated to the violation constituted by the facts, in theory, yes, it could be resolved within 12 months.

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Q. And just to be clear, when you say a case could be resolved in 12 months, you're saying that within 12 months, the case could move from the filing of the complaint to the final determination of sanctions. Is that right?

A. Under those circumstances where there is no question of fact, no question that a violation of law has occurred, and there are no complicating factors, such as a pending criminal investigation or mental health treatment or other issues beyond our control.

Q. And you keep qualifying this as in theory. Is it fair to infer from that that 12 months is about the fastest this process could move between complaint and final determination of sanctions?

MR. MATTHEWS: Object to the form. Please answer.

THE WITNESS: As indicated, it's very difficult, because every case stands on its own merits. The availability of witnesses, the personal circumstances of the licensee involved in the investigation all bear on how long the entire process takes. So in all fairness, it's difficult for me to tell you with any certainty the fastest.

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I'm giving you my best estimate in order to go through the investigative process, the prosecutorial process, and then presentation to the Board at the quarterly meetings.

For example, if you looked at our agenda for the meeting next week, we have three solid days, and the last appearance is scheduled for 6:00 on Wednesday night. We start at 8:00 on Monday morning, and it is not uncommon for us to run until 9:00 or 10:00 at night. So it depends on how quickly the cases can be presented to the Board. But in theory, if there is no dispute, no complicating factors, a case could be presented to the Medical Board for final determination in 12 months.

BY MR. McNAMARA:

Q. In theory, could a case be presented to the Medical Board for final determination in substantially less than 12 months?

A. No, I would not say so. Because of the processes that have to unfold, I would not say that that would be a realistic expectation. But of course anything is possible.

Q. That's fair. Do you have an estimate of what proportion of complaints are actually

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resolved within 12 months?

A. We have that data available. I did not pull that because that wasn't something included in the notice. But we do capture that data. We capture, as I understand it, the average life cycle of a case.

Q. I won't hold you to specific numbers. As you sit here today, could you give a reasonable range of what proportion of complaints are resolved within 12 months?

A. No, I couldn't.

Q. Do you know if it's more than half or less than half?

A. I would say it's not more than half. I would say it would actually probably be a very small percentage of the cases due to the complicating factors that I've already identified.

Q. Okay. Would you say it is less than 10 percent?

A. I can't quantify that. We do have objective data available, and I would certainly defer to that. But I'm not the keeper of that information. We would have to have our department of technology and security glean that information for us. But the agency does keep track.

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Q. But it's fair to say then that you would be very surprised if that data showed that even as many as half of complaints are resolved within 12 months?

A. For the Medical Board?

Q. Yes.

A. Yes, I would be surprised. But, again, I don't manage that data, and I didn't research that prior to today.

Q. Okay. So you say the three recommendations the Medical Board can make are dismissal, dismissal with letter of caution, and a formal complaint. Do I have that right?

A. Yes.

Q. On what basis does the Medical Board make the determination which of the three is appropriate?

A. Well, the IRC is the entity that actually puts forth the recommendation. And as I mentioned earlier, they weigh the evidence that's been gathered as part of the investigative process with the allegations that are presented. And in certain cases, they have the benefit of an expert reviewer's opinion. In some of the more complicated cases, you would expect to have at

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our response when we are contacted by licensees who have a standard of care question. We do not give prospective advice to anyone. We encourage them to confer with counsel. We do, however, provide the law where there is an objective reference available that is responsive to the subject matter of their question.

So a response to an ophthalmologist asking should I do X, Y, or Z would include the disclaimer that we cannot provide legal advice regarding a proposed course of conduct. However, we would refer them to the statute and encourage them to the retain personal legal counsel.

Q. So if an ophthalmologist contacted BME asking whether he should write a prescription based on certain information in light of the ECCPL, he would get back essentially the objective language of the code, but he wouldn't get anything else?

A. Correct. At the staff level, we don't have the ability to bind the Medical Board. Additionally, we've outlined a very detailed disciplinary process, and only the Medical Board has the jurisdiction to measure someone's conduct after all the evidence has been gathered and presented.

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Q. And so the BME and BME staff doesn't provide this kind of advice because it doesn't have any way to short circuit the complaint investigation process and bind the Board to a conclusion?

A. Correct. But we would always provide the law if it's responsive to a question presented. So, for example, we are often presented with questions relating to supervision. Since the Telemedicine Act passed, we've received a number of questions relating to the implementation of telemedicine policies, and we follow that same practice.

Q. If an ophthalmologist refrained from violating the ECCPL out of concern that he would receive a complaint or potentially draw penalties, would that be unreasonable?

MR. MATTHEWS: Object to the form.

THE WITNESS: I don't think that I can answer that question. I'm not sure that I understand how either the agency or the BME would be able to dictate what's reasonable or unreasonable for an ophthalmologist or any other practitioner.

BY MR. McNAMARA:

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Q. I'm not asking for a legal conclusion. Do you just as a human being have a sense of what the words reasonable and unreasonable mean?

A. Of course.

MR. MATTHEWS: Object to form. Please answer.

THE WITNESS: Yes, I understand those words.

BY MR. McNAMARA:

Q. Do you believe that a practitioner who refrains from violating a law out of concern that he will be penalized for violating that law is acting unreasonably in your sense of that term?

MR. MATTHEWS: Object to form.

THE WITNESS: I do not believe that it is ever unreasonable to forbear against violating a law. That is what we would expect of law abiding citizens and licensees. And actually adherence to state and federal law is required. Failure to do so is identified as a grounds for finding misconduct.

However, there are a number of considerations that individual practitioners must weigh when they're deciding whether to engage in a particular practice or not.

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So using your example, an ophthalmologist may choose to use the Opternative tools as part of their practice, or they may choose not to without regard to this law. But that determination would be outside of the scope or knowledge of either the agency or the Board of Medical Examiners.

BY MR. McNAMARA:

Q. Does either LLR or the Board provide input on draft legislation in South Carolina?

A. When asked, yes.

Q. When asked by whom?

A. Either legislative staff or individual legislators. As a general rule, we do not provide testimony unless we are invited to appear. It is very common that we are asked to provide a statement of economic impact from legislative staff relating to proposed legislation. It is also not uncommon for us to be to offer guidance regarding potential regulatory burdens that may flow from a legislative initiative.

Q. And you say you provide input when asked. Does that refer to both LLR and the Board?

A. Yes. We are prohibited from lobbying, and only a handful of our boards have statutory

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authority to make recommendations regarding legislation. The Medical Board is not one of those boards. And so we are very careful to remember what our role is. We are a regulatory administrative agency. So we are charged with taking the law that's given to us. If either a legislator or staff asks us for factual information, we are certainly happy to provide that.

Q. And that's actually my question. If a legislator has a question and directs it to the Board of Medicine, does the Board of Medicine provide the information, or does that have to go through LLR because of restrictions on the Board?

A. Typically that request would come through LLR. But if it is something that requires feedback from the Board -- so, for example, the agency is an administrative agency, but we do not have clinical expertise. And so a really good example that I can provide to you did not come to the Medical Board, but it came to the Board of Pharmacy relating to medical marijuana. The legislature asked for the Board of Pharmacy to prepare a letter stating its position on the proposed medical marijuana legislation. And that

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request would have been coordinated internally between our legislative liaison, who is Rebecca Leach, the administrator for the Board, and then the Board itself.

It's not common that that happen, but it does happen where a specific response is requested from the Board itself.

Q. And just so I'm clear how the example fits in, you said earlier that some boards are authorized to make legislative proposals and that the Medical Board is not one of those?

A. Correct.

Q. Is the Pharmacy Board one of those?

A. No.

Q. Okay. So the example is analogous in that sense?

A. Yes, yes. But an example of one of our boards having that statutory authority independently of an invitation from the legislature is our Real Estate Commission. So if you wanted to look at our practice acts in comparison to see the difference for yourself, that is one example that I can identify for you.

Q. Okay. Great. Thank you. Do staffers at either LLR or the Board monitor proposed or

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pending legislation that would affect the areas they regulate?

A. Yes. The Office of Communications is directly responsible for monitoring all legislation that affects regulated professions, and that is under the supervision of Holly Beeson. Ms. Leach, who I referred to a few moments ago, works on Ms. Beeson's team. They are responsible for reporting out to the boards the status of legislation as it goes through the process. If there are committee meetings that are coming up where either testimony has been requested or where they are planning to attend to observe, they will usually let either the Board president, or if the Board has a designated contact person for legislative purposes, that person would be notified.

Q. Okay. And you mentioned Holly Beeson?

A. Yes, sir.

Q. What's her job title?

A. She is special counsel to the Office of the Director, and she is an attorney. She is responsible for the supervision of the Office of Communications, which includes our legislative affairs.

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Q. So would Holly Beeson be the person within LLR most knowledgeable about pending legislation and the legislative process with respect to any particular bill?

A. Yes, she and Ms. Leach typically.

Q. Okay. Anyone else?

A. They provide that information. Also my team monitors legislative initiatives that are directly impacting our boards. For example, one of the attorneys who previously worked on my team, Donnell Jennings, was the advice counsel for the Board of Nursing, and we've had the Enhanced Nurse Licensure Compact going through the legislative process. So both Donnell and Rebecca and Holly would all be monitoring that legislative.

From the advice counsel perspective, we are monitoring the legislative process if there is an anticipation that we're going to have to change regulations or if it's something that will immediately impact some aspect of the Practice Act so that the boards are not given a nasty surprise at the end of a legislative session. But the Office of Communications is responsible on behalf of the agency for tracking all legislation.

Did that make sense?

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Q. That did make sense. I was trying to think if we need to clarify the record the fact that it's called the Office of Communications doesn't mean it's solely concerned with public relations. But --

A. No, but that is part of what they do. They also handle all the Freedom of Information requests that come in. Our ombudsman is within the Office of Communications. So if reporters have inquiries, if other governmental entities have questions, we try to funnel all of those through the Office of Communications, and then they ferret out aspects of the matter as appropriate to other parts of the agency.

Q. Okay. So you've discussed your relationship with the legislative process as it relates to the legislature and individual legislators. Is there anything different about your relationship to the legislative process as it relates to the Governor's Office?

A. No, sir. If we are given a request by the Governor's Office to provide information or feedback, whether it's anticipated regulatory impact or something specific, I mean, either the legislature or the Governor's Office could receive

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a call from a constituent who has a concern, and then they call LLR for clarification.

Q. Does staffers at LLR or the Board ever have meetings with outside groups about pending legislature?

A. Yes.

Q. When would that occur?

A. When invited.

Q. Are there any rules governing meetings with outside groups about pending legislation?

A. Not that I'm aware of. As public employees, we are all governed by the code of conduct and also by the State Ethics Act. We are absolutely not to engage in any lobbying activity. But other than those guidelines, I'm unaware of any rules or other policies that might be responsive to your question.

Q. Is it true as a general proposition that an outside group that asked for a meeting with LLR staff about pending legislation would get such a meeting?

MR. MATTHEWS: Object to form. Please answer.

THE WITNESS: I would say, typically, yes. And I just want to clarify, for the reasons

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previously identified. So if an outside entity reached out to LLR and said we would like to talk to you about the regulatory impact of this proposed legislation, we would always say yes to that, because part of our mission is education. If an outside entity contacted us and said we would like for LLR to lobby or to advocate for a particular position, that request would be met with greater scrutiny, obviously.

BY MR. McNAMARA:

Q. I'm not suggesting any impropriety. I'm asking, as for example at the federal level, if a group requests a meeting with the OMB about a pending regulation, by executive order, the OMB has to have that meeting. I'm trying to explore whether there is a similar policy, or it sounds like just as general proposition, the meetings are taken as a matter of unwritten policy. Is that fair?

A. Yes, but we are in the South, so I would say it's probably a matter of courtesy, but also in furtherance of our mission, which is to educate and to be transparent and to make sure that folks understand what it is that we do.

As a regulatory entity, we do have a

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unique insight. We have an ability through our disciplinary cases to identify weaknesses and temptations and considerations that folks outside of that process probably do not have the benefit of.

Q. Do LLR or the Board ever take positions on pending legislation?

MR. MATTHEWS: Object to form. Please answer.

THE WITNESS: The agency, if asked, might take a position. But, typically, no. The Board of Medical Examiners, as I mentioned earlier, does not have the statutory authority to either endorse or oppose pending legislation. However, they -- if they're called to testify and they're asked to identify concerns or identify potential regulatory burdens, certainly they would do that.

BY MR. McNAMARA:

Q. One more for the terminology, when you say the agency, are you referring to LLR?

A. Yes, sir. The one and only, yes, sir.

Q. I've had many situations where the whole deposition is actually talking about a noun we never defined.

A. No, sir.

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Q. Did LLR take a position on the ECCPL?
A. To the best of my knowledge, no.
Q. Was LLR asked to take a position on the ECCPL?
A. To the best of my knowledge, no.
MR. McNAMARA: I'm going to ask the court reporter to mark this as Exhibit 3.
(PLF. EXH. 3, Two-page 5/16/16 E-mail String, Bates Stamp LLR 00002621 and 00002622, was marked for identification.)
BY MR. McNAMARA:
Q. I've handed you a document that's been marked as Exhibit 3. Have you ever seen this document before?
A. If I have, I don't remember it. This was not one of the documents that I reviewed in preparation for today.
Q. Okay. This appears to be an e-mail from someone named Peter Candela?
A. Yes, sir.
Q. Can you tell me who that is?
A. Yes, sir, he's an optometrist licensed in South Carolina. And in 2016, he would have been president of the Board of Examiners of Optometry.
Q. And it appears to be sent to someone

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named Donnell Jennings, who I think you mentioned earlier?
A. Yes, sir, he's an advice attorney, and at this time he was the advice attorney assigned to the Board of Optometry.
Q. And there are three people in the CC line. One is Holly Beeson. Is that the Holly Beeson we discussed earlier?
A. Yes, sir.
Q. And one is Rebecca Leach?
A. Yes, sir.
Q. Who is Rebecca Leach?
A. She is the legislative liaison who works under Ms. Beeson's supervision.
Q. And April Koon?
A. Yes, sir, she is the administrator for the Board of Optometry.
Q. So this then is an e-mail from the then president of the Board of Examiners in Optometry to attorneys and staff members within LLR. Is that true?
A. Yes.
Q. Can you just look at the operative text of Dr. Candela's e-mail where it says: Although I have sent a letter from the Optometry Board to

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Governor Haley in support of her hopeful signature, if someone has a direct contact with the governor, please pass along that we strongly support this bill and hope that she signs it into law.
Do you see that?
A. Yes.
Q. I assume from your testimony that the Board of Medicine didn't send a similar letter to the governor?
A. That's correct.
Q. Is it unusual for boards to send letters to the governor in support of her signing bills?
MR. MATTHEWS: Object to form. Please answer.
THE WITNESS: Again, I would have to go back to my earlier testimony, which is feedback is solicited occasionally. In this instance, I don't know the background regarding the preparation of the letter. I simply don't have that information. If the Governor's Office asked for feedback, it would not be atypical for a board to generate that. Is that something that happens frequently? Probably not.
BY MR. McNAMARA:

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Q. Do you know if LLR staff or attorneys complied with Dr. Candela's request?
A. Meaning to identify a direct contact in the Governor's Office?
Q. To please pass along that we strongly support this bill and hope that she signs it into law.
A. Yes, sir. I don't have that knowledge.
Q. Okay. Would it have been inappropriate had one of them done so?
A. Again, I don't know the context. I don't know the background. I think if the Governor's Office had asked for the Board's feedback regarding the impact of pending legislation, it would have been proper for that information to have been communicated. But without having the benefit of the context, I really can't answer that question.
Q. Okay. So as you sit here today, you have no way of knowing whether Dr. Candela's request was complied with or not?
A. No, sir, I don't.
Q. Okay. You can set Exhibit 3 aside.
A. Thank you.
MR. McNAMARA: I'm going to ask the

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court reporter to mark this as Exhibit 4.
(PLF. EXH. 4, Four-page E-mail String, Bates Stamp LLR 00002777 Through 00002780, was marked for identification.)
THE WITNESS: Thank you.
BY MR. McNAMARA:
Q. And I've placed in front of you a document the court reporter has labeled as Exhibit 4.
A. Yes, sir.
Q. Do you recognize this document?
A. Yes, sir. This is an e-mail that I did review prior to today's deposition.
Q. What is this document?
A. This appears to be an e-mail -- let me -- it looks like an e-mail thread that began on February 3rd of 2016 between the Governor's Office and Richele Taylor, who was then our director, and continuing through February 16th of 2016, and at that point, the e-mail that's on the first page is actually from Holly Beeson responding to David Glaccum with CC Josh Baker and Richele Taylor.
Q. Who is David Glaccum?
A. I don't know him personally, but I understand that he was employed in the Governor's

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Office at that time.
Q. Do you know in what capacity?
A. No, sir.
MR. MATTHEWS: Well, no offense, but it says Policy Advisor.
BY MR. McNAMARA:
Q. That's where I was going.
A. Well, I'm sorry. I can read.
Q. On page 4 of this document, if you look at his e-mail signature, it says: Policy Advisor, Office of Nikki R. Haley?
A. Yes.
Q. Is that true, to the best of your recollection?
A. I have no independent knowledge to contradict that, so I would assume he is the policy advisor.
Q. Fair enough. Referring to the e-mail on the first page, the e-mail from Holly Beeson --
A. Yes, sir.
Q. -- why would an e-mail like this be sent?
MR. MATTHEWS: Object to the form. Please answer.
THE WITNESS: Yes, sir. Where the

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Governor's Office or a legislator asked for background or context on pending legislation, this is the type of e-mail that would be generated. And it looks like there are three separate pieces of legislation that Ms. Beeson is discussing, one related to mobile barbershops, two relating to the Eye Care Consumer Protection Act, and then finally to a bill concerning hearing aids.
BY MR. McNAMARA:
Q. So when you testified earlier that in response to inquiries from the Governor's Office, LLR would generate information and commentary, is this an example of that process?
A. Yes, sir. And if you go to Mr. Glaccum's e-mail of February 9th, it says: If passed, would any of the below bills restrict the practice that is not currently regulated (such as mobile barbershops), or protect a specific constituency (like eye doctors prescribing glasses)? Could you also please provide feedback on Senate 167 regarding hearing aids?
So that inquiry was presented to the director. She then asked Ms. Beeson to provide the background, which is what her e-mail does or attempts to do.

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Q. Okay. Great. I just want to direct your attention to the paragraph in the middle of the page beginning: Both sides of the anti-competition argument are clearer.
A. Yes, sir.
Q. If you want to take a moment just to read that to yourself.
A. Yes, sir.
Q. Okay. Is it fair to summarize this paragraph by saying that Ms. Beeson believed that the ECCPL could be construed as economic protectionism, but that the advocates for the bill argued that there was a health and safety justification for the bill?
A. Those were the two perspectives identified, yes.
Q. Okay. I didn't want to read the whole thing into the record.
A. Thank you.
Q. So that's a fair summary. Did LLR take any steps to verify the health and safety arguments of the proponents of the bill?
A. To my knowledge, no. We would not have been charged with that.
Q. So you would not expect Ms. Beeson to

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have investigated the truth of those assertions before writing this e-mail?

A. No. And to be candid with you, I'm not sure how much of an investigation would be necessary to verify the public safety consideration identified.

Q. Are defendants aware of any factual evidence that the Eye Car Consumer Protection Law protects the public health or safety?

MR. MATTHEWS: Objection. Do you mean these defendants? We're not SCOPA.

BY MR. McNAMARA:

Q. Sorry, the named defendants as distinct from intervenor defendants, the parties you're testifying on behalf of.

A. Neither the agency nor the Medical Board have been presented an opportunity to evaluate the statute as implemented in any way. So I don't think that either the agency or the Medical Board is in a position to articulate an opinion on that.

Q. I'm not asking for the Board's opinion. I'm asking if there is evidence in the Board's possession tending to show that the ECCPL actually protects the public health or safety.

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MR. MATTHEWS: Object to the form.

THE WITNESS: As indicated -- and I apologize if my response was inartful -- if we have not been presented with an opportunity to evaluate the implementation of any law, we would not have evidence regarding that impact on the public safety.

BY MR. McNAMARA:

Q. So part of what I'm doing in this deposition is trying to determine what the entities know to see if there needs to be further investigation, as, for example, if Ms. Beeson conducted a six-month study that perhaps we need to know about. So I'm not suggesting that the Board should and ought to have evidence. I'm trying to determine what exists.

A. I understand. And I want to be perfectly clear. We have had no disciplinary matters, to my knowledge, we have had no complaints, even at the beginning of that disciplinary process, relating to the implementation or enforcement of this statutory provision. So to the best of my knowledge, we would have no evidence within our possession relating to the impact on public safety of the

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ECCPL.

Q. All right. You say you haven't received any complaints under the ECCPL. Prior to the passage of the ECCPL, had the Board received any complaints about online eye exams, kiosks, or other matters regulated by the ECCPL?

A. To the best of my knowledge, no. I've been with the agency since 2012, and I don't sit in on every disciplinary proceeding conducted, but I'm unaware of any such issue coming before the Medical Board.

Q. Okay. Prior to the passage of the ECCPL, was the Board of Medical Examiners aware of a company called Opternative, Incorporated?

A. Yes.

Q. How so?

A. I have to tell you, I am not sure. In reviewing the documentation, there was an e-mail that I sent to Dr. Stephen Gardner, who is the president of the Medical Board, that had what appeared to be a press release regarding Opternative attached. And that was immediately prior to the August 2015 Medical Board meeting. I don't remember the context in which the Opternative press release came into my possession. But that

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was at the same time that we were developing an advisory opinion regarding telemedicine. We had already issued an advisory opinion regarding the establishment of the physician-patient relationship as a prerequisite for prescribing, which a lot of people had viewed as the Medical Board's guidance on telepractice in South Carolina.

So prior to that August meeting, we were developing a separate policy that was explicitly entitled Telemedicine. And the e-mail that I sent to Dr. Gardner had a telemedicine piece, and it also had the press release attached. But there is nothing in the e-mail to indicate where it came from or how that was in my possession, and I don't have an independent recollection.

Q. Just because I hate to do things in the abstract, we'll just mark that e-mail.

A. Sure.

MR. McNAMARA: It's unfair to make people testify about things not in front of them. I'm going to ask the court reporter to mark this document as Exhibit 5.

(PLF. EXH. 5, One-page 8/2/15 E-mail From Darra Coleman to Stephen R. Gardner MD, Bates

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that time. Teladoc was invited to return, and they did not. So the Medical Board did not pursue any action against Teladoc. We assumed that they had abandoned the pursuit of telepractice in South Carolina. And we knew that they were very engaged in other parts of the country.

In 2015, toward the end, we were put on notice that Teladoc had made some changes internally, and they were interested in pursuing legislation. So Teladoc retained lobbyists who were driving the Telemedicine Act. And once that was filed, the Medical Board had this policy. We had this history of three years at that time of working with telemedicine issues. And so the legislature essentially adopted and codified what the Medical Board had been utilizing.

They did add some additional restrictions. So, for example, they added the restriction that a licensee may not prescribe a C2 or C3 without express prior authorization by the Medical Board. They added a prohibition on agents that can induce abortion. And then they clarified the Medical Board's prior prohibition against the use of telemedicine for the prescription of lifestyle drugs to exclude birth control, which the

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Medical Board felt should also be excluded. I think there was some objection regarding the characterization of birth control as a lifestyle medication. The legislature retained the specific examples of ED drugs and hormone replacement therapy.

So with those few tweaks, what essentially became the law, or the Telemedicine Act, was what the Medical Board had already developed.

Q. In 2015? Beginning in 2015?

A. Well, actually, beginning with the advisory opinions relating to the establishment of the physician-patient relationship in 2012, and then the clear separate telemedicine policy in 2015.

Q. Okay. Just to return quickly to your August 2nd, 2015, e-mail, if you'll look at your last paragraph, it says: Please let me know your thoughts on the telemedicine policy which is basically cut and pasted from the NC policy. We agree the Opternative and county detention facility compliance challenges are best discussed in executive session only.

A. Yes, sir.

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Q. It sounds from your testimony that the fact that those are phrased in independent sentences should not be taken as an implication that the telemedicine policy was not being discussed in executive session?

A. Oh, absolutely not, right, because we were discussing that in executive session. And under the Freedom of Information Act, as you're aware, there are very few reasons why we can go into executive session. One is for the benefit of legal counsel, which was the purpose of the executive session discussion.

Q. Okay. I appreciate that. You can set that e-mail aside.

A. Thank you.

Q. Does the ECCPL require an ophthalmologist to conduct any particular tests before writing a corrective lens prescription?

MR. MATTHEWS: Object to form. Please answer.

THE WITNESS: It refers to medical findings and refractive error. So it does require an eye exam, but I'm not sure what other diagnostic methodologies might be relied upon to develop the medical findings. There is no explicit

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requirement, other than at least the refractive error, because that's specifically called out.

BY MR. McNAMARA:

Q. Okay. So the ECCPL doesn't require the ophthalmologist to find any specific information other than refractive error before writing a corrective lens prescription?

A. Well, it does. I mean, it requires them to consider medical findings. But what I'm saying is, on the face of the statute itself, it doesn't identify diagnostic methodologies that have to be employed in order to develop the medical findings.

Q. Does it specify what those medical findings must be?

A. No, sir.

Q. Okay. So is it fair to say that the ECCPL leaves it to an ophthalmologist's professional judgment exactly what diagnostic methodologies and exactly what medical information he needs before writing a prescription?

A. That would be my understanding, yes, sir.

Q. Is that generally in keeping with how South Carolina regulates medical doctors?

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MR. MATTHEWS: Object to the form.
THE WITNESS: If your question is asking whether great deference is given to the clinical expertise of the physician based upon the patient and the comprehensive evidence presented, I would say, yes, that there is considerable deference given to the clinical judgment of the physician who is evaluating the patient, so long as the conduct of that physician comports with general standards of care.
BY MR. McNAMARA:
Q. Does the ECCPL require an ophthalmologist to physically examine a patient before prescribing a corrective lens?
A. It refers to an eye examination. But it doesn't say how the eye examination is to be conducted.
Q. So nothing in the ECCPL prevents an ophthalmologist from having a nurse or another assistant gather the visual information he needs to write the prescription?
A. I don't see that prohibition here. But in complete candor, I'm not familiar with what an ophthalmologist would typically do.
Q. But at least as far as the ECCPL goes,

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that's not part of it?
A. No, sir, it's not.
Q. Does the ECCPL prohibit an ophthalmologist from writing a prescription if all of the information he's basing it on is collected by a computer rather than being collected by a nurse or a human assistant?
MR. MATTHEWS: Object to the form. Please answer.
THE WITNESS: It doesn't appear to restrict it in that way. It does say that you can't base the prescription solely on the refractive eye error of the human eye or be generated by a kiosk. So there is, at least in my reading, some expectation that there will be some type of human involvement. It doesn't specify by whom. And in South Carolina, we do use a number of physician extenders.
BY MR. McNAMARA:
Q. What is a physician extender?
A. A physician extender can be a midlevel, such as a nurse practitioner or a physician assistant. It can be another licensed professional, such as an RN or an LPN, or in some instances, it can actually be unlicensed

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professionals, such as a medical assistant or a certified nurse assistant.
Q. Is the use of medical extenders left to the discretion of the physician, or are there specific areas in which extenders are allowed to practice or not practice?
A. No, typically, the delegation authority is within the physician's determination, so long as it comports with the scope of practice identified for those physician extenders.
So, for example, the practice of licensed practical nursing is defined. The practice of registered nursing is defined. A prn practice is also defined. And although there are not specific tasks or duties that are identified in statute, certainly I think the general parameters are there. There are minimal educational requirements and credentialing requirements for PAs. We also have specificity requiring supervision by the physician.
And so I think that so long as the physician complies with the statutory and regulatory guidance governing the scope of practice, it is well within his or her discretion to delegate tasks.

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Q. Has either LLR or the Board adopted any policies of any kind regarding the enforcement of the ECCPL?
A. No, sir.
Q. So it follows from that that neither the agency nor the Board have adopted the policy that it will not enforce the ECCPL?
A. We don't have the luxury of not enforcing law, and so we would not need a policy to support that proposition. But we have not had any issues providing an opportunity for interpretation or application of the law.
Q. So neither LLR nor the Board has the authority to refrain from enforcing a South Carolina statute?
A. No.
MR. McNAMARA: Okay. Off the record.
(A recess transpired.)
MR. McNAMARA: Back on the record. Thank you very much for your time, ma'am. I have no further questions. Any cross from anyone?
EXAMINATION
BY MR. MATTHEWS:
Q. Yeah, just one or two. If you look at Exhibit 2, you received some questions about eye

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examinations and kiosks?
A. Yes, sir.
Q. Okay. Is it fair to say that those are defined in the act itself?
A. Yes, sir, in 40-24-10, subparagraph (4), the word kiosk is defined.
Q. And in (3), what an eye examination means?
A. Yes, sir.
Q. Okay. So the Board and LLR would rely on those definitions to determine what a kiosk was and what an eye examination meant?
A. Yes, sir.
MR. MATTHEWS: Thanks so much. Nothing further.

EXAMINATION

BY MR. McNAMARA:
Q. And just so I'm clear, just so the record is clear, when you were answering questions about the ECCPL earlier in the deposition, you had the ECCPL in front of you; is that right?
A. Yes, sir.
Q. I understood you were referring to it when you answered those questions?
A. Yes, sir. And if I may, if there is

any question, medical findings, which is what I spoke to earlier, is not one of the defined terms. So eye examination and kiosk and all the other defined terms were certainly intended to be included as defined by the legislature. But when I expressed that medical findings was not quantified or spelled out, that's independent, obviously, of the defined terms.
MR. McNAMARA: Right. Nothing further from us.
MS. TATE: Nothing further.
MR. McNAMARA: Thank you very much, ma'am.
THE WITNESS: Okay. Thank you.
(The witness, after having been advised of her right to read and sign this transcript, waives that right.)
(The deposition was concluded at 11:03 a.m.)

CERTIFICATE OF REPORTER

I, Janice N. Shepherd, Registered Professional Reporter and Notary Public for the State of South Carolina at Large, do hereby certify that the foregoing transcript is a true, accurate, and complete record.
I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.
Witness my hand, I have hereunto affixed my official seal this 9th day of August, 2017, at Charleston, Charleston County, South Carolina.

Janice N. Shepherd, RPR, CSR
My Commission expires
October 10, 2024

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(No Information Requested)

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From: Peter Candela <pkcandela@gmail.com>
Sent: Monday, May 16, 2016 2:59 PM
To: Donnell Jennings
Cc: Holly Beeson; Rebecca Leach; April Koon
Subject: Re: S.1016 "EYE CARE CONSUMER PROTECTION LAW"

***** SCDLLR NOTICE *** This email is from an external email address. Please use caution when deciding whether to open any attachments or when clicking links inside the email.**

Although I have sent a letter from the Optometry board to Gov Haley in support of her hopeful signature, if someone has a direct contact to the Gov, please pass a long that we strongly support this bill and hope that she signs it in to law.
Sincerely,
Dr. Candela

Sent from my iPhone

On May 16, 2016, at 2:13 PM, Donnell Jennings <Donnell.Jennings@llr.sc.gov> wrote:

> Holly:
>
> At your earliest convenience, please provide a status update on Senate bill 1016 aka the "EYE **CARE CONSUMER PROTECTION LAW**". It has passed both houses and awaits a final decision by the governor.
>
> Thank you.
>
> Donnell G. Jennings
> Assistant Advice Counsel
> Office of Advice Counsel
> SC Department of Labor, Licensing and Regulation
> 110 Centerview Dr.
> P.O. Box 11329
> Columbia, SC 29211-1329
> 803-896-4199 (direct dial)
> donnell.jennings@llr.sc.gov
>
> <image001.png>
> *Website: www.llr.state.sc.us*
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> *Confidentiality Note: This e-mail message, including any attachments, contains privileged and confidential information intended only for the use of the individual or entity named above. If the reader of this e-mail message is not the intended recipient or the employee or agent responsible for delivering it to the intended recipient, you are hereby notified that any dissemination or copying of this e-mail message, including attachments, is strictly prohibited. If you have received this e-mail message in error, please notify us immediately by telephone and return the original e-mail message,*

including attachments, to LLR Office of Advice Counsel, Post Office Box 11329, Columbia, SC 29211, via the US Postal Service. Thank you.

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Opternative, Inc. v. S.C. Board of Medical Examiners, et al.
(Civil Action No. 2016-CP-40-06276)

AFFIDAVIT OF JOSHUA WINDHAM
PART 2
(APP 229A-APP 363)

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EXHIBIT 4

IN THE COURT OF COMMON PLEAS FOR THE FIFTH JUDICIAL CIRCUIT
STATE OF SOUTH CAROLINA
COUNTY OF RICHLAND

Opternative, Inc.,
Plaintiff,
v.
South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation,
Defendants,
South Carolina Optometric Physicians Association,
Defendant-Intervenor.

Civil Action No. 2016-CP-40-06276

VIDEOCONFERENCE DEPOSITION OF
MELVIN SHIPP, O.D.

DATE: Wednesday, March 1, 2023
TIME: 8:03 a.m. MST/10:03 EST
LOCATION: Remote Proceeding
Phoenix, AZ 85001
REPORTED BY: Richard Livengood, Notary Public
JOB NO.: 5771794

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At this time will everyone in attendance please identify yourself for the record.

MR. WINDHAM: Josh Windham, attorney for the plaintiff.

MR. MCNAMARA: Robert McNamara, also counsel for the plaintiff.

DR. SHIPP: Melvin Shipp, S-H-I-P-P. I guess I'm the -- what am I?

THE REPORTER: You're the deponent.

DR. SHIPP: I am the witness. Thank you.

THE REPORTER: Thank you, sir. Anybody else speaking that needs to identify themselves?

MR. SHEALY: I'm Kirby Shealy. I'm the attorney for the intervenor, the South Carolina Optometric Physicians Association.

THE REPORTER: Okay. Thank you. Hearing no objection, I will now swear in the witness.

Please raise your right hand, sir.

WHEREUPON,

MELVIN SHIPP, O.D.,

called as a witness, and having been first duly sworn to tell the truth, the whole truth, and nothing but the truth, was examined and testified as follows:

THE REPORTER: Thank you.

You may begin.

EXAMINATION

BY MR. WINDHAM:

Q Good morning, Dr. Shipp. My name is Josh Windham, as I just mentioned off the record, and I represent Visibly, Incorporated, formerly called Opternative, Incorporated, the plaintiff in this matter. How are you doing today?

A I am well, sir. How are you?

Q I'm good. It's earlier for you today than it is for me.

A It is.

Q Would you please state your full name and maybe your current job title for the record?

A My full name is Melvin Douglas Shipp. I am currently retired, fully retired. I am a former dean of the Ohio State University College of Optometry and an emeritus professor from that institution.

Q And do you understand, sir, that you're here today to testify regarding the litigation between Opternative, Incorporated, currently called Visibly, Incorporated, and the defendants listed earlier?

A I do.

Q And have you been deposed before?

A No. This is a first time for me.

Q Well, let me just ask, you know, is there anything that would prevent you from testifying truthfully today and without impairment?

A No. There is not.

Q So since you haven't been deposed before, I just want to cover kind of basic procedural ground rules. The way this will work is that I will ask a question, you'll provide an answer, and the court reporter will try to record everything down. Does that make sense?

A That makes sense.

Q And please try to speak up clearly and be clear for the court reporter. You've done a great job of that so far, but it's common in ordinary conversation to say things like "Mm-hmm" or "Uh-huh," non-verbal answers. Please try to give full, clear, verbal answers if that works for you.

A Thank you.

Q And kind of in the same vein, let's try to make sure that when we're talking, we let each other finish. So when I ask a question, try to let me finish my question. And when you're giving an answer, I'll try to extend the same courtesy to you. Does that make sense?

A That makes sense.

Q And Mr. Shealy might object at some point. Please still answer the question. Does that make sense?

A Yes. It does.

Q And let me know if you need a break at all. I'm not sure how long this will go on, but you know, it's up to you if you want to break. I'm certainly to take a bathroom break, or if it goes through lunch, we can take a lunch break.

A Okay. Thank you.

Q So did you do anything to prepare for today's deposition?

A I basically reviewed the affidavit that I submitted to you before, and some other materials that I received from Mr. Shealy. I also went over some other materials at the request for this deposition that would support the -- the issues that I raised in my affidavit. I was unaware at the time that I wrote the affidavit that there was a need for documentation, etcetera, which was five years ago, seven years ago. So I had to resurrect as best I could comparable references to support those statements. So yes, those are the preparations that I've done.

Q So it's fair to say you can't recall precisely what materials you might have relied on when

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writing the affidavit back in 2017?
A Not -- not exactly. But also, they're of course my personal experiences as either a clinician or a public health person. I drew on those experiences as well, which are not documentable other than the fact that I can say I have that experience.
Q Fair enough. I think just to kind of make things clearer, let me just try to introduce an exhibit and get the affidavit in front of everybody. And I haven't done this in a little while, so let's see how it works out. Give me one moment. I'm introducing what's been marked digitally as Plaintiff's Exhibit 1, and that should show up in the shared exhibit folder.
(Plaintiff Exhibit 1 was marked for identification.)
So please let me know if you see it there. Dr. Shipp, do you see the exhibit that I've put into the marked exhibits folder? It should pop up on your side of the Ignite portal.
A I do not see it. No.
Q Well, let me just ask you this, and if you can't figure it out, we'll go off the record. Do you -- yeah. I can just share my screen. Let's do it that way. Okay. So I'm now sharing my screen.

Dr. Shipp, do you see the exhibit on the screen?
A I do.
Q Great. Okay. So maybe we'll use this as a solution. All right. So what is this document that I've got here on the screen? And let me know if you want me to scroll down for you.
A Okay. That is the affidavit that I provided to Mr. Shealy.
Q Now I'm going to take that down, and we'll probably revisit that at some point. Okay. So when writing this affidavit, or prior to writing this affidavit rather, did you talk to anybody?
A Mr. Shealy.
Q What were those conversations like?
A Mr. Shealy informed me that he was representing, I think it's called SCOPA, and an individual in that organization had recommended or suggested me as a person that might provide information helpful to this case. He mentioned the person's name at that time, and I recognized the name vaguely, but didn't -- I can't place his face with it, but he's a former student of mine, purportedly from UAB. So that was my contact with Mr. Shealy, and the only contact that I've had with anyone thus far regarding this case.

Q Did you say you do or do not recall the name of the person who referred Mr. Shealy to you?
A I vaguely recall. I think I recalled the name, but I don't remember the person. No.
Q So if I asked you to tell me the name right now, you wouldn't be able to do that?
A I have no idea. I was there for all of 20 years, and I saw a lot of people. Not to mention a number of students and graduate students and residents, so no. I don't recall.
Q And what was the university you mentioned? You used an acronym.
A I'm sorry. University of Alabama at Birmingham School of Optometry.
Q Got it. Okay. And when you talked to Mr. Shealy about potentially putting this affidavit together, did he tell you what to say?
A No. He basically shared with me the issues and asked me if I would be interested or willing to make comments regarding it. I thought, "Yes. With my background experience, I should be able to help not only from optometry's perspective but also public health."
Q Were you offered any sort of compensation to put together the affidavit?

A There was a reference of a potential compensation, but I did not -- I have not requested anything. No. this is purely something I'm doing because I think it's the right thing to do.
Q So you haven't been paid at all for this?
A No.
Q What about the drafting process of the affidavit? Who drafted it?
A I did myself, and then I submitted the information to Mr. Shealy for review to make sure that it was comprehensible. And he made the final draft and submitted the papers. I sent them directly.
Q So how many drafts of this document were there?
A I think maybe one or two at best. It was pretty straightforward.
Q Did that work by -- so you said you drafted it, you sent it to Mr. Shealy, and then he provided some notes. Did he then send it back to you?
A I did approve the final document. Yes.
Q So there were maybe a couple rounds of edits, but you approved the final?
A At best.
Q I'm sorry. At best?
A At best. At best, there were a couple of

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measurement or alignment of the lenses.
And I think that pretty much covers what's in item 21.
Q And to be clear, item 21 lists the elements of a comprehensive eye health exam. Right?
A Basically, yes. And there are other things that I may not have listed, but those are the things that I thought of at the time. And if you asked me, I might say, "Oh, yeah. That too." But those are the things that I listed.
Q I mean, is there any --
A There are other tests that would be prompted, of course, if in fact you found something errant or unexpected during the course of the other examinations. Comprehensive examinations -- comprehensive eye examinations have a core process in terms of eliciting whether or not there is a problem. And then that might lead to you doing more tests to determine how important the problem is or how extensive the problem is and whether or not there's a need for additional testing.
Q So it's fair to say that all the things listed in paragraph 21 here are not necessarily always performed during every comprehensive eye health exam?
A In some version, there is an evaluation of

the eye health, the motility of the eye, refractive corrections, yes. Those are pretty routinely done. Yes. But of course, again, it depends on the patient's age, condition, etcetera, etcetera, how extensive those tests are done.
Q That's what I'm asking. So it sounds like because it depends on the patient's age, condition, and so forth, that not all of these tests are performed every single time a patient necessarily sees an optometrist. Right?
A I didn't say that. All of the areas that are assessed by these tests are evaluated by the clinician as part of the comprehensive eye examination. Yes.
Q But let me go back to my question before. You said you didn't say that. What I'm asking is, it's not necessarily the case that every time a patient sees his or her optometrist that they will receive all of these tests. Right?
A A version of these tests would have -- something would have been done to reinforce that either nothing has changed from the previous examination -- this is for a follow-up exam. And I'm sorry, you did ask initially for that first eye exam. So let's say "yes." All of these would have been

evaluated during that first comprehensive eye examination. Yes.
Q And you mentioned that might be different for a follow-up. So what things would impact whether it's different for a follow-up?
A Let's try an example that's not comical. Are you experiencing any other problems other than the ones that you mentioned when you were here before? In other words, if a person came in initially saying, "I had itchy burning. I had other things," for that first initial comprehensive eye exam, and you say, "Are you still having the eye itchy burnies?" Well, now you won't be -- if the patient says "no," you're not as concerned about that as an issue, so you don't spend an inordinate amount of time trying to investigate that.
By the same token, if you have basic data on other issues and the patient says, "No, there's been no change," and you assess that, again clinically. You have the ability to do that, sometimes without actually using a particular instrument, you can confirm that things are as they were before. If the pupils appear to react the same as they did before, you don't have to do extensive pupil testing at this time.

The ability of the patient to do versions and ductions, you've done already before. You do a quick preliminary assessment and you find out they're unchanged. So in essence, you would consider the fact that those conditions are nominal at that point in time and not pursue extensive testing, but yes, you would assess whether or not there is a need for further testing.
So in essence, I guess what I'm trying to say, and it's kind of tough if you're not a clinician. It would make sense to you if you were a clinician. If you have already done the test before and you have someone sitting before you who is telling you that they're not having any differences, and from your clinical observations there's not a need for extensive testing, you move on to the next item. In most cases, yes, you would do some evaluation of each of the things that I've mentioned on this list during a comprehensive eye examination.
Q Can a patient in practice opt out of any part of the comprehensive eye exam?
A Of course.
Q It's always up to the patient's choice then?
A Of course.
Q Have you ever in your clinical practice had

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a patient opt out of any portion of the comprehensive eye health exam?

A Yes.

Q For example, a dilation? The patient says, "I don't really want to have dilation today, Dr. Shipp." Has that ever happened?

A That has happened, and of course I accept the patient's wishes, but I make sure the patient understands that I would not be able to accurately assess those things that I would need to assess -- or could assess, could evaluate with a dilated examination.

Q So you're telling the patient in essence, "You're missing out on a portion of the comprehensive eye health exam." Right?

A Yes, but I would not force anything on the patient. No.

Q And if you tell the patient that and they choose to proceed with whatever care you provide after that, that patient is aware they're not receiving the full scope of what the eye exam could be. Right?

A I would hope that they are. I would like to think, though, that I was able to articulate the concern well enough that they would understand that, "No, I don't want to take that risk."

Q I mean, have you ever felt that -- is it common for you to feel in your clinical practice that patients are not aware of the care they're getting?

A I am not seeing patients, like I said, and have not for some time, but at the time that I did see patients, I was very comfortable that I did the best that I could to inform the patient. And if the patient, again, insisted on not having something done, I would not do it for them. An example of a case in which -- not a matter of being belligerent, but a patient says for example, "I have an examination coming up. If you dilate my pupils, I won't be able to do the examination." Then fine. "Why don't we schedule you back during a time when that will not be a problem"? And I've done that before.

Q Well, is this a specific example of the patient with the exam?

A That's one that I recall off the top of my head. A student. I've been in a student environment for most of my professional career. That has happened to me once that a person said that they really did not want to be dilated at the time because they had an examination.

Q And in that situation, obviously don't tell me anything about the patient's identity, but I just

want to know what was the patient coming in for?

A A routine eye exam.

Q Had they seen you before?

A I think they had. Yes.

Q And after not receiving the dilation, what sort of care did you provide for the patient?

A The patient came back and I dilated the patient, completed the exam.

Q Well, what I'm asking is about the appointment before he came back for the dilation. So during that appointment, what was the ultimate outcome?

A The outcome were the things that I was able to detect and record I did. The tests, the results I recorded. The things that I could not, I left a note that the patient would return for that procedure. And he did, and we completed the examination. And the record reflected that.

Q Did the patient have glasses?

A I don't recall.

Q Did the patient have any corrective vision problems?

A Again, I don't recall. This is over 20 years ago.

Q That's okay. I'm just trying to get at

whether the patient received any care other than the testing that you performed.

A If -- well, and I don't -- I suppose would have, could have, had of, should have, ought have, but I would think that if in fact there was something that the patient needed and I could ascertain that was something that they could have, I would have given them a prescription. However, if I was not certain, I would say, "Let's hold off on this prescription until you return and we've completed your exam" because that finding could be important for this prescription. And I think that's something that any clinician would do.

Q Understood. Okay. Let me ask about a few of the items in paragraph 21, just because even thought as you've noted I have glasses, I don't necessarily have the clinical understanding of what all these terms mean. Let's start with visual acuity. Can you just explain again what that is?

A It is, like I said, an end point. It's a very end point that you establish on how well a patient can see, either with or without corrective devices. And that's a reference that you use both for that particular exam. Can you improve that if you in fact have a refraction, and if so, does the patient appreciate that change such that they are willing or

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interested in making a change in their prescription? That's a very precise -- ideally a very precise measure because it's important to document going forward whether there has or has not been a change.

If in fact you don't measure the acuities properly, if the target is not properly illuminated, the test is not accurate, you mis-record information about the actual performance of the eye, that reference is sort of like garbage in, garbage out. It doesn't matter. It doesn't help.

One of the things that happens in an exam room is that you measure very specifically and precisely the distance that the patient will be from the optotype or the testing chart. That's relevant to the -- it's called the angular subtense of the putter or the optotype. And that has to be a certain amount so that it -- you can if you don't have the proper distance misrepresent the person's acuity.

If they're too close, they will "see better" than they actually see according to that measure. If they're farther away from the chart then they should be, they will see worse. So the distance is extremely important.

Q Let me make sure I understand. So when you talk to optotype, are you talking about an eye chart?

A Yes. The actual letter or symbol on the chart. I'm not doing a very adequate job of this, and I apologize. The -- the terminology is laborious, but angular subtense of the gaps for the optotype have to be certain size for certain distance. And if you have the wrong size at the wrong distance, the acuity measurement is invalid I guess is the best way to say that.

Q So let's try to sum this up. I don't mean to dwell on this too long. But if the chart is properly calibrated for lack of a better term, the patient is standing the appropriate distance away from the chart, the chart is a useful aid in determining the patient's visual acuity?

A The term "calibration" is the one that I was looking for. Thank you. And it is -- that's one of the factors. The other -- and I didn't get there, so let me get there now, is the contrast between the actual -- the background of the chart and the actual symbol. So if in fact you -- for example, next time you have your eyes evaluated at the -- during a driver's license exam, you'll notice that the charts, some of them are nice and white with black symbols, others are somewhat yellowed with black symbols.

And of course, the difference in contrast

can in fact affect a person's ability to discern the sizes or the objects, even at the appropriate test distance. So that's important as well.

Q If everything is set up correctly, running a patient through this test, looking at an eye chart is an accurate way of measuring visual acuity?

A It is. But again, it's the environment, the lighting in the room, the test distance, and again the contrast between the actual symbol and its background.

Q Caveats are well taken. With regard to aided, so that'll be a patient wearing their glasses or contacts while looking at the chart and getting responses?

A Correct.

Q So just unpack that a little bit for me. If I'm looking at a chart, wearing my existing prescription for glasses or contacts, what are you learning about the patient? And by "you," I mean an optometrist, based on their responses?

A When I'm testing aided acuities, I'm trying to determine how that person -- how well that person is able to see with their current prescription. And again, that's a reference now. When I look to what's going to happen during the actual examination, the refraction is going to follow. And if in fact I find

that the acuity can be improved by changing the prescription, then the patient would be so informed.

And especially after the patient had told or had an opportunity to observe the difference in their acuity with and without the new prescription, and decided, "I think I'd like a copy of that prescription" or "I'd like to obtain a new pair of spectacles or contact lenses based on the fact that I see -- I discern that there is a significant difference in that." So again --

Q If there's a patient, you know, wearing their glasses or contacts and they rattle off every single letter on the chart with precision and everything seems great, does that mean their existing prescription is good?

A It could, yes. It could.

Q Why would it not?

A If they rattled off the letters on the chart, and very few people can do that. In fact, you get down to the extreme sizes, below 20/20 for example. 20/15, 20/10, 20/8. Most folks cannot see that well. I had the good fortune of being roughly 20/10 at one time in my life, but I can't do that anymore.

So if in fact you exhaust the letters on the

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chart, well number 1 you're pretty good because it's below the threshold of human vision in most cases. You could test that. I would argue that most optometrists do not. I didn't. I typically would have a standard in mind and would get down to that level. And when the patient started having difficulty, as opposed to frustrating them, I would stop and say, "That's fine."

Q What I'm trying to get here, it sounds like some people can see very well, and that reading the entire chart means that they have better than normal human vision.

A Yes.

Q What I'm trying to get at is if a patient gives satisfactory answers to the chart wearing their existing prescription, you wouldn't be inclined to change the strength of their prescription?

A It's not up to me. If the patient says, "I prefer seeing as best as I possibly can, then fine." We'll change your prescription. That choice is the patient's as far as when I practice.

Q I understand. If a patient says they like their prescription and you're satisfied by the answers to the vision chart test, would you be inclined just to change the strength of their prescription then?

A I would give them a copy of the new prescription and tell them that it's at their option. If they should lose or break their glasses, they then don't have to go through another refraction. Here is their current prescription, and we would be able to fill that out at such time.

Q Suppose during this examination we've been talking about, the patient gets a routine comprehensive eye health examination. They come out with a pair of glasses, and the next day they say, "Dr. Shipp, I don't know that I quite like my prescription that I got. Can I come back and seek an adjustment to it?" What would you say?

A Come in.

Q And that's consistent with the optometric standard of care?

A The way that I practice and the way that I taught, yes.

Q But the way you taught and the way you practice was consistent with the AOA's standard of care. Right?

A It was not outside of the bounds of that. No.

Q And if the patient came in just with this desire to change their prescription, how would that

appointment go?

A There would be another re-assessment of the prescription just in case there was an error made or in case the lenses that were manufactured and delivered by the optical company were not accurate. Yes, I would change them. That has happened more than once, that I've written a prescription that I've had sent to the ophthalmic lab, had the lenses fabricated, come back to the clinic, and then find out that no, that wasn't what I wrote or what I prescribed. And they have to send it back to have a change of prescription, or some other minor modifications like that.

So yes, that does happen. It is not terribly common, but it does happen. It's one of the reasons why you allow for the patient to return and re-evaluate, just in case there was an error.

Q But the patient coming back for the adjustment for the lenses or, you know, to find out if there's an error in the lenses, how extensive would that appointment be? What would you go through?

A That would not be a comprehensive eye exam. That would be a very problem-focused exam or problem-focused examination. Yes.

Q You wouldn't perform, like, a dilation for

example?

A No.

Q Or a slit lamp examination?

A Not for a glasses prescription.

Q By the way, the lamp --

A And again, you're asking questions that would -- that have other possible -- and I'm trying to think through those very quickly, so I apologize. And I apologize for interrupting you. But again, this would be a clinical perspective. It would depend on how the patient was complaining. If for example the patient said, "I don't see as well with these glasses as I did the other day and I think there's a problem." And I say, "What's happened between now and the time you got the glasses."

And if they tell me, "I wore my contact lenses too long," or "I had an eye injury," or "I had itchy burnies," then the problem with the glasses may not be the problem with the glasses. It may be something else. And so that may prompt me to do something different using a slit lamp to determine whether or not there was a problem with the cornea. Or perhaps even a dilated eye examination if in fact there was a suggestion that something had happened inside of the eye, retinal detachment, ocular

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hemorrhage, that you would have to dilate the eye for.

So again, I'm trying to answer your questions as best I can, but there's always the possibility that there's something other than glasses that might -- a patient might say, "I can't see well with these, and I need to have my prescription changed."

Q I certainly understand that. And if the patient comes to you following this comprehensive eye health exam and they're seeking this adjustment to their prescription because they're not comfortable with it, and they're totally asymptomatic in the sense that they don't have any other complaints to present to you, there's no other problems, that's when you would just focus on the problem they're presenting for, which is the strength of the prescription. Right?

A Correct.

Q I did have a question about, I asked about a slit lamp. What is a slit lamp?

A Let's see. How do I describe this? It's called a slit lamp because the lighting on the device are such that you can do what are called optical sections of the cornea. The cornea is the clear structure within the eye that light goes through in

order for you to be able to see, focus, etcetera. It is subject to changing. It is subject to disease. It is subject to a whole host of things. And the term "slit lamp" describes that device, but it is basically a device that's used for looking at external structures, and with the aid of other lenses, you can use it to look inside of the eye as well.

Q You mentioned the cornea. I think there's a paragraph -- let me scroll down a little bit, if you can still see it. Can you still see Plaintiff's Exhibit 1?

A I have one here in front of me. Yes.

Q Is it on the screen though, just so that I'm clear?

A Your -- yeah. Your version is on the screen. Yes.

Q Let me see if I can find it here. Here we go. Okay. I just wanted to ask about paragraph 14 here. Let me know when you see it.

A Okay.

Q You do see it?

A Yes.

Q And there's a reference to "corneal examination and evaluation." Do you see that?

A Yes.

Q What does a corneal examination and evaluation entail?

A Let's see. I was trying to do that just now, and I apologize for not doing a good job. A corneal examination is basically taking a look at the cornea. That's, again, the clear structure in front of the colored portion of your eye. It should be optically clear. Sometimes it is not. It can have opacities or obstructions that can block light, but with certain assessments, with clinical dyes, etcetera, you can determine whether not the tissue there is healthy, the external tissue is healthy.

And by lighting adjustments, you can determine whether or not there are any opacities within the cornea that would impede vision. You can determine corneal swelling. And again, without having a device right here in front of us for me to show you these things, I'm waving my hands. It's hard to describe a clinical device that is very specific for activities that people normally don't see or have an exposure to.

Q That's okay. I just wanted to lay a little bit of groundwork for my next question. So there's a reference later on in the paragraph to a "contact lens fit." Can you see that?

A Yes.

Q So what lens is a contact lens fit?

A That's how the contact lens rests on the cornea.

Q So how does -- assume I know nothing about it. How does an optometrist determine the proper contact lens fit?

A Again, by using this device, aligning it and putting the lighting such that you can determine exactly how the contact lens approximates the surface of the cornea. Whether it's sitting improperly, there are no gaps, it's not too tight, it's not too loose. Is it moving properly to allow for tears to exchange properly, to allow the cornea to be oxygenated.

Those are the things that are determined, again, with respect to the fit or the -- how that contact lens fits on the eye, whether it's in the appropriate place and is stable, or stable enough to be comfortable and also provide good acuity.

Q So tell me about how that fit works over time. Does a patient's cornea shape change in a way that would require a different fit over time?

A The cornea shape can change in certain conditions -- certain circumstances, that's purposefully done to adjust or change the shape of the

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cornea. But that's not typically the way contact lenses are fit. They're designed to fit properly without being uncomfortable. Sort of like if you were to have a pair of shoes that were fit improperly, you would be uncomfortable trying to wear them. And that's not a good analogy, but it's the closest I can come to.

The patient may or may not have any symptoms, but it's important for the person who's doing the fitting to make sure that it fits properly because that could lead to symptoms, and or could lead to changes in the cornea that are not healthy.

Q I don't know that I fully understand the answer to my question, so I'm going to ask it a different way. If I have a contact lens prescription that I like, and both myself and my optometrist when it's prescribed feel that it's appropriately fit, can I, the patient expect that fit to change in the next six months?

A It should not.

Q What about the next year?

A It should not.

Q Does it change at all in old age? Is that when you would expect the change to occur, or does it just generally never change?

A Since -- since the body changes, and that happens, it may very well be that a fit that was proper at one time may over time not be appropriate. In fact, it may be appropriate not to have contact lenses at all because physiologically, the LPI is unable to support or sustain that contact lens being in place and having normal physiology.

Q Is there a particular age at which you expect fit changes to occur with more frequency, or is it just very patient specific?

A I would not be able to give you a specific age, no. And you're right, it does depend on a patient.

Q Just to give you one more example, if I'm somebody who got contact lenses at age 23 and I have them for a decade, and I love them, and I see my optometrist every two years, and he feels that the fit is good. And I'm 33, so it's been a decade, is there any reason to think that the fit has changed?

A The fit may not have changed, but the technology may have changed. Contact lenses may have been improved to allow for better oxygenation, a healthier cornea, a healthier eye. And at that time, the clinician might say, "You know, you've been wearing this lens and wearing it well, but there's a

new one on the market. I think you'll find it as good, and physiologically it's better for your eye because it will allow your eye to breathe more -- or your cornea to have better access to oxygenation."

Q But the fit --

A The fit then might be different because the technology is different. Right? If it's a thinner lens and not -- the actual parameters of the lenses may change too over time. So I'm trying to answer your question. I'm not trying to be cute, but yes. It could change. It could change, and it's not something that I could say, "If you're fit one time, you can wear that for the rest of your life and never have to change that lens again." That would be wrong.

Q What I'm getting at, and it sounds like I get your answer, but let me ask it this way. In this example of the guy who has the contacts he likes from 23 to 33, it sounds like the cornea itself is not changing in shape, but the technology for a lens might have changed, and so there be a better lens for him. Right?

A Either or both. The shape of the cornea could change over ten years.

Q But at least for the patient that we talked about earlier who got a fit, you said from six months

to a year it's unlikely that it would change. Right?

A Unlikely. Yes.

Q In the course of performing a comprehensive eye health exam, and let's go back to paragraph 21 as a reference point for that. Let me know when you're there.

A Okay.

Q In the course of performing a comprehensive eye health exam and collecting the information listed here and performing these tests, do optometrists ever use assistants to help collect information?

A Yes.

Q Can you tell me more about that?

A Depends on the procedure, but yes. There are certain instruments that lend themselves to allowing someone to simply position the patient and then obtain data. Data that does not require clinical judgement, I should say.

Q Can you give examples of the most common ones?

A Well, if you've been to the eye doctor recently and they performed tonometry with the eye puff where you sit in a line and the patient is asked to hold their eyes open and the technician presses the open when the eye is properly aligned, the technology

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of the instrument allows the puff of air to blow and to reflect a particular measurement. So it doesn't require any more -- it doesn't require clinical judgement. It requires familiarity with the technology and the ability to perform the test.

Q That's helpful. What other examples do you have in mind?

A Let me see. What do I have here? The same would be true of perimetry. That's having the patient sit in front of a device that's designed to measure one's peripheral vision, asking the patient to fixate in a certain direction and asking the patient to press a button when they see various images appear. And they press the start button, and the machine goes through and again, does the process, and at the end of that process, a result -- a readout or a printout is providing data for that particular test.

Q I just want to go through all the examples you can think of, so do you have any more?

A Goodness. Well, again, after not having done this for several years, let me think. Those are the two that come readily to mind. I'm sorry. Refractive error is another one. They're autorefractors where again, you have the patient sit, look inside the device at a target, and meanwhile the

machine whirs and burs, and finally it spits out data about the refractive correction. Those are the ones that immediately come to mind. And there are others I'm sure, and again, I can't immediately think of them right now.

Q But in the course of technicians or -- you said they were technicians. Is that what you mean by, like, an assistant who's unlicensed, or maybe even licensed? Sorry. I'm going to scratch all of that. I'm asking you a bunch of questions. What do you mean by "technician"?

A This is someone who has been trained to use a particular device. Often the ones I've had experience with in the past at the University of Alabama Birmingham and Ohio State University were actually trained in programs specifically designed for optometric assistants or technicians. They were taught to collect those pieces of data uses those instrumentation. Yes.

Q And they're collection data, and then how does the optometrist get that data?

A Well, there is a printout of the information typically, and it's made part of the record and or transcribed from the machine. But more often than not, there is a printout. And the data is there for

the clinician to review and make an assessment of what it is and what it means and how to proceed best from there or next from there. Whether or not the findings are nominal, or whether or not additional tests need to be performed, or reaching a conclusion about a diagnosis.

Q The optometrist would have accessible to them all the results of the technician's tests to the extent they were performed, and then would consider that when deciding what to do with the patient?

A Correct.

Q In terms of this, you mentioned autorefractor, is there a type of technician who works on eye charts, for example?

A The autorefractor sometimes has a -- well, yes. There is a possibility that technicians would be involved in taking visual acuities. Yes.

Q And is that common?

A I can't speak for it being common. I know that it does happen.

Q Can I just go back to the example of a patient with pinkeye for a second? Do you remember when we were talking about pinkeye?

A Yes.

Q So let's suppose that I'm the patient,

you're the optometrist. Right? Let's suppose that I see you for a comprehensive eye health exam. Everything seems great. Follow me so far?

A Sure.

Q And a week later, I come to you and say, "Dr. Shipp, I've got the itchy burnies. I think I have pinkeye. Can you start to evaluate me for that?" Still with me?

A Yes.

Q What is the approach you would take for a patient who presents with a discrete issue like pinkeye? How would you proceed with the appointment?

A I would initially take acuities so that I would be able to compare that with the reference acuity to determine the effect -- what the effect on the visual acuity is of the condition that the patient has presented with, and then proceed to do testing to determine the actual cause of the pinkeye. Whether it is bacterial or viral, allergic, chemical exposure, whatever the case may be. And then proceed to make the diagnosis and then do whatever is appropriate for the patient.

Q At the time of the appointment, it's been about a week since you did the comprehensive eye health exam, during that exam let's suppose you didn't

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think there was any reason to suppose they had an issue with macular degeneration or glaucoma or cataracts. Would you test for those things during the pinkeye appointment a week later?

A If in fact there was an acuity problem, in other words they were not seeing as well as they saw the last time, I would look at all the structures between the front of the eye and the back of the eye where the actual light has to focus to see to determine whether or not there was something different than there was last time.

So if a person had itchy burnies only, symptoms only, their acuities were the same, it would be different than someone having itchy burnies and they didn't see well. No, I wouldn't. Those would be two very, very different circumstances. In the latter, I would do much more extensive testing because there are many more explanations for why that initial acuity is not the same.

Q In the form where you would not do the testing if the acuity checked out?

A Not necessarily.

Q Well, I'm trying to -- you drew a distinction, so I'm trying to understand the distinction.

A I understand. But I would never commit to say -- these are hypotheticals. I would never commit to you right now to say if a person had these symptoms that I would not pick up the ophthalmoscope to look at their eye. I might very well do that because, "You know, I think I see something there. Let me see if I can check that out." No, I wouldn't just have the person -- I wouldn't just address the chief complaint if I as a clinician thought there might be something additional that I needed to pursue. I would treat the patient like I would like a clinician to treat me.

Q I understand. But if you didn't have reason to think there was any other problem, the patient was coming in just for the pinkeye issue, you had recently done a comprehensive eye health exam, you had no reason to think there were any other issues, at that point you wouldn't go through this whole modality of other tests. Right? You would just focus on the problem before you?

A Yes. As a hypothetical, that's probably true. Yes.

Q As you understand it, that would be consistent with the standard of care?

A Is that a question?

Q Yes.

A That basically would be. I'm trying to do due diligence for a problem-focused exam, determine the cause of the problem. I've found a solution for the problem to be remediated. I might even schedule a follow-up exam of that exam to make sure that that evaluation was accurate and that problem was resolved. So this might be a list of further examinations, perhaps up to and including a referral for additional testing by someone else if in fact I felt that that was indicated.

Q Understood. But if you --

A Getting a patient into the -- the potential for making sure that you avoid a clinical disaster is extremely important. Making sure that they're there and can be managed either by the clinician or by others if the need arises.

Q I understand. What I'm asking is, if the patient is in for a discrete issue like pinkeye and they've recently had a comprehensive eye health exam and you have no reason to think there were other issues, it's within the standard of care to just treat the discrete issue, even if you later schedule a follow-up appointment. Right?

A For that hypothetical, yes.

Q Do you know what the American Academy of

Ophthalmology is?

A I do.

Q What is it?

A It is similar to the American Medical Association, but it's a subset. It's a sub-group of medicine that's comprised of ophthalmologists. People who have that training and that classification.

Q Are they similar to the AOA, or are they different?

A I have no idea.

Q Oh. Are you familiar with them?

A I don't know their structure. I don't know how they operate. I don't know their policies. You would better -- be better asking that of an ophthalmologist.

Q Okay. Let me ask you a question about something then. Let me pull up another exhibit. It's going to take me just a moment. Okay. I'm introducing what's been marked as Plaintiff's Exhibit 2.

(Plaintiff Exhibit 2 was marked for identification.)

I'm going to share my screen so that you can see it. Okay, sir. Do you see Plaintiff's Exhibit 2?

A Yes.

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Q Do you recognize this document?
A Yes. I do.
Q What is it?
A It's my response to the deposition. They asked for documentation of references that I had used in developing my affidavit.
Q Let me scroll down.
A And --
Q I'm sorry. Go ahead.
A Sorry. And I think if you scroll back up to the top, as the note says, "On September 28, 2017, "Dr. Shipp was not aware," etcetera, etcetera. So these are documents I did not use initially, but they're used to try to support some of the information that I shared.
Q I'm going to scroll down to the very bottom here on page 5. Do you see page 5?
A Yes.
Q And there's a reference here. It looks to me, and you can correct me if I'm wrong, that this is a looks or other publications that you have been involved in. But am I reading that wrong?
A No. I have not been involved in that.
Q So these are just sources that you were referring us to?

A Yes.
Q And one of these at the very bottom is a source by the American Academy of Ophthalmology. Right?
A Well, it's by -- yes. By Dr. Trobe.
Q Correct. In affiliation with the AAO. Right?
A Yes.
Q Let me see if I got this right. Do you think of the AOA as a reliable source?
A This is the AAO you mean? The American --
Q Let me ask about both. Do you think of the AOA as a reliable source?
A Yes.
Q And that's a reliable source of information on the optometric professional standard of care?
A Yes.
Q And is the same true of the AAO with regard to ophthalmologists?
A Well, I don't know Dr. Trobe and I don't know what the American Academy of Ophthalmology would think, but I assume that -- I assume or would like to assume that the American Academy of Ophthalmology would think that Dr. Trobe would be a reliable source.
Q I'm not asking about Dr. Trobe. I'm asking

about the American Academy of Ophthalmology, and whether you consider them a reliable source of information.
A I would -- until proven otherwise, yes.
Q I'm going to give you an example. I'm going to share a different exhibit with you. As I'm pulling this up, just let me know if you need a break or anything. I'm introducing what's been marked as Plaintiff's Exhibit 3, and I'm going to share my screen.
(Plaintiff Exhibit 3 was marked for identification.)
All right. Dr. Shipp, do you see Plaintiff's Exhibit 3?
A I do.
Q Have you ever seen this document before?
A I have not.
Q It's not very long, so what I'd like to do is give you a chance to read it through. And I don't want to pressure you, so you're very welcome to take your time. I'm going to put it on page 1. And once you've read page 1, tell me when you need me to scroll. It should be about three and a half pages.
A Okay. Move forward.
Q All right. Thank you. Scrolling to page 2.

A You cut off the top.
Q There we go.
A There we go. Okay.
Q All right. Nearly there. This is the last section.
A Okay.
Q All right. So you have read the whole document at this point, setting aside the footnoted references. Correct?
A Yes.
Q General question. Do you have any reason to think that anything in this document is incorrect?
A In general, I think it's consistent with what I understand to be reasonable. Yes.
Q And would that be true for optometrists as well?
A I don't have their document right here in front of me to compare side by side, but they're pretty close.
Q Fair enough. If an optometrist followed the recommendations in this document, would that violate any standard of care that you're aware of?
A I didn't see anything in there that would be inappropriate.
MR. WINDHAM: I'm going to pull this

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down. Maybe we'll come back to it. I'm not sure. Let me take a quick break, Dr. Shipp. I'm going to use the restroom, and then we can come back on the record. Okay?

THE WITNESS: Okay.

THE REPORTER: Let's go off the record at 11:33 a.m.

(Off the record.)

THE REPORTER: We are now back on the record at 11:41 a.m.

BY MR. WINDHAM:

Q All right, Dr. Shipp. Do you recognize that you're still under oath?

A I do.

Q Great. I think we're nearing the end here, but I have a few more questions for you. I want to ask just as a general matter, you're familiar with the COVID-19 pandemic. Right?

A I guess I am.

Q What did optometrists do during the pandemic?

A If I'm perfectly honest, I could not answer that question. I do not know what optometrists did. I do know that my wife was able to access some services with the optometrist that we use here, and I

would assume that that would be consistent with other optometrists in other locales. However, I understand too that it may very well be that some folks could not practice at all, or practice the same. I don't know.

Q How did your wife access those services?

A She needed a new frame, and at the time they had all the activities occurring outdoors, outside of the building. They had a technician come and meet with her, masked, and requested that she be masked as well. And they did the adjustment or frame replacement or whatever it was that she needed, and she came home. So yeah. I imagine, and I don't know, but I imagine that other services were provided in addition to what she required, but I don't know for a fact.

Q Understood. Have you yourself -- well, actually, let me back up. Do you know what telemedicine is?

A Yes.

Q And what is it?

A It's an opportunity to have a health evaluation by a clinician or by a professional clinician remotely via telephone and or telephone and -- as we are today.

Q Have you ever had a telemedicine appointment

yourself?

A Yes, I have.

Q In what context?

A I had prostate cancer and prostate surgery, and I was able to access my neurologist via telephone.

Q Well, I'm sorry to hear that you went through that. How was your experience with telemedicine in that situation?

A I don't -- I don't care for it particularly, but it was okay.

Q Let me switch gears a little bit and bring back up Plaintiff's Exhibit 1. And I'm sharing my screen. All right. Do you see Plaintiff's Exhibit 1 again?

A Yes.

Q And in this first paragraph, before the first numbered paragraph, that starts with "Personally," do you see where it says that "Dr. Melvin Douglas Shipp, who deposes and states that the following is based upon his personal knowledge, except those matters stated upon information and belief"? Do you see that?

A Yes. Yes, I do.

Q I just have a few questions about the references throughout this affidavit to Opternative.

Have you ever been to the Opternative website?

A I accessed it just two days ago. I just opened it up just to see what it was like, and yeah, so I have.

Q And we're referring now to Visibly because the company has changed names. Correct?

A Correct.

Q So you've been to the Visibly website? That's correct?

A That's correct. Yes.

Q Aside from having visited the website, do you have any other personal knowledge of Visibly, or previously Opternative?

A Only that information I acquired or received from Mr. Shealy.

Q And what information is that, if you can list that for me?

A I think he sent some court documents related to the case that he has been handling for the optometry association in South Carolina. Beyond that, nothing.

Q Do you know if those documents are titled, or could you list them for me?

A I think Mr. Shealy might be able to do that better than I, but let's see if I can --

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Q Take your time.
A Do you want me to go through this, or should I --
Q No. Take your time going through the documents if you have them in front of you. And just if you could read the titles of them for me, that would be great.
A Okay. Here's one. "In the Court of Common Pleas for the 5th Judicial Circuit, Civil Action Number 2016-CP-40-06276. State of South Carolina, County of Richmond -- Richland." Sorry. "Opternative, Incorporated, Plaintiff, versus South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation, Defendants, South Carolina Optometric Physicians Association, Defendant-Intervenor." Should I read more?
Q Is that the --
A Oh, I'm sorry. That's the one that you sent to me, so you knew that. The other would be the document that you've been posting or sharing with us. My affidavit. And another would be, let's see. Another court document "Civil Action Number 2016-CP-40-0627. Plaintiff Responses to Defendant-Intervenor's First Set of Requests for Admission." Is

that sufficient, or do you need more?
MR. WINDHAM: Here's what we'll do. Kirby, do you have a list of documents that you sent to Dr. Shipp that we can see? That way we don't need to have him read a bunch of titles on the record.
MR. SHEALY: I think so. Let me dig that up. I mean, I had forgotten that I sent him the request for admissions responses, but let me dig through my e-mails, and I can just read them off as soon as I get to them.
MR. WINDHAM: Okay. Let me ask it this way. I know that we're trying to do something a little weird here, so let me know if you have a problem with it. But what I'm thinking is, can you just say on the record that you did not send him anything that was not already in the record in this case or not already filed in this case?
MR. SHEALY: I believe I can say that, but let me confirm, because that was five years ago.
MR. WINDHAM: Sure. I just want to make sure that there's not a document that Dr. Shipp considered that we have not seen.
MR. SHEALY: Right. Of course. If you want to just keep moving, and I'll raise my hand or something just to confirm. But I'm almost positive

that you're correct.
MR. WINDHAM: I have no further questions at this time, so you know, it's your witness. But let's wrap that up at the end, if you can.
MR. SHEALY: Okay.

EXAMINATION

BY MR. SHEALY:
Q Dr. Shipp, I may just ask you a few other questions. And you may have been asked some of this earlier. In addition to being an optometrist, you also have a doctorate in public health. Correct?
A That's correct.
Q And your teaching has been sort of in both fields, both in optometry and in public health. Correct?
A That's correct.
Q And describe for me if you will sort of the thrust of that discipline, of the discipline of public health. If one studies public health, what are you studying?
A Again, I think I mentioned this earlier, so I apologize if I'm repeating myself. But public health is a very diverse group of professions and disciplines, some of which are related to patient

care, most of which are not. And any and all factors -- these groups represent any and all factors that could affect the health of individuals and or groups. So you have epidemiologists, you have sanitarians, you have psychologists and clinicians, etcetera. There are even lawyer who are health policy experts who are involved in public health.
So it is an extremely diverse group of folks, and the difference -- I guess the way of trying to characterize the differences between clinical science and public health science. Clinical science is all about trying to deal with things that are preeminent, and typically individual-focused. Public health is more community focused, like the atmosphere, like environmental issues, etcetera.
But perhaps the other way of thinking of public health is that public health has an emphasis on preventing things from happening, whereas clinicians are concentrated on trying to take care of things that have happened, to remediate and or prevent something from occurring, and ideally reversing the process so the person regains their activities and facilities.
So a good example is if you have two people standing by a river, one of whom is a clinician. And as they're standing by the river, they notice that

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respect -- Mr. Matthews? Dr. Matthews? I'm sorry.
BY MR. MATTHEWS:
Q Mr. Matthews, please.
A Mr. Matthews' role.
Q I'm not a doctor anyway.
A I respect your role, and your very important role, frankly, in trying to do the best that you can to protect the health and welfare of those in the state of South Carolina. That's -- well, that's the state's responsibility, frankly. And obviously, trying to balance the needs of patients and populations versus business or other activities. But in this particular case, I think -- and I keep emphasizing, and I can't emphasize enough the fact that it's not glasses. It's not contact lenses, which is what refraction is all about. It's about the patient's health. Because you can have the best pair of glasses you want, but if you died of something preventable, that's not protecting the public's health.

And if in fact the potential for people either misunderstanding or using an alternate route to get something that they should have gotten in the course of a very straightforward examination, frankly, I think care should be exercised. I feel very

uncomfortable saying, "Go full roll with the technology, that's a wonderful thing," when I feel that the risks are there for -- for harm. I don't know if that helps.
Q Well, let me be more direct. There's a provision of the law that's in question here that states as follows. "A prescription for spectacles or contact lenses will not be based solely on the refractive eye error of the human eye, or be generated by a kiosk." And that's one of the provisions of law that's at issue here. And again, the department I'm here for has defended the constitutionality of this law. However, it is considering its position.

And one of the things that I'm interested in your opinion is, do you believe that there's a rational basis for that law to exist?

MR. WINDHAM: Objection. Calls for a legal conclusion.

You can answer.
BY MR. MATTHEWS:
Q Please answer.
A I do. A refractive correction is a prescription. And just like any other prescription you receive for a pharmacology-type intervention, health intervention, you don't write that prescription

pro forma or on the basis of the fact that you have an approximation of what you think the problem is without fully assessing it. So I see the refraction as being a part of the eye health, and again, the prescription as being indicative of the fact that something significant has happened, that an actual examination, comprehensive examination has happened.

A diagnosis has been made, and a formulated prescription has been developed to assess that person's eye circumstance of which in this case the refraction is only part. A blood pressure medication might be sufficient for blood pressure, but you might also have other medications as well. But you would not prescribe that in the absence of appropriate testing to determine that everything was okay. Because -- again, because of the consequence.

Blood pressure in and of itself won't kill you. It's what happens as a result of having that circumstance in a prolonged fashion over a period of time. That's when heart disease happens. That's when strokes develop. So I guess the analogy I would use in the comfort of writing a prescription and implying to the patient for all intents and purposes that that's all you need for your eye health and your health.

MR. MATTHEWS: Okay, Doctor. Thank you so much for your testimony. I have no further questions.

MR. WINDHAM: I have a few follow-up questions.

EXAMINATION

BY MR. WINDHAM:
Q So I want to follow-up on a few things Mr. Matthews asked you about. First of all, you had a few moments where you were describing the way that Visibly works. And I want to ask how you know how Visibly works.
A I think I said -- I think I said, I don't know. I'm going by what I think I read, and that is how the process is done. That it takes a limited period of time. That questions are asked of the patient. That the patient self-administers a visual acuity test, and that some form of a refraction is done. And it's an objective refraction. Clearly, the patient can't do a subjective refraction, which is what happens when one has an comprehensive eye exam.
Q So you --
A That's what I --
Q You're making statements about Visibly and how it operates, and you just testified that you don't

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know how it operates. Is that right?
A I said that before. I don't know exactly how it operates. No. I read how Visibly describes it operates, and that's what I'm telling you.
Q You're telling me you read that from the website?
A I read that from documentation I have and from the website. Yes. Those are the references I have. I've not -- again, I've not had the Visibly test, but I have documents that I've read related to how Visibly works written by Visibly.
Q Would your assessment of the technology differ at all, as you've described it, differ at all if it was a subjective refraction instead of an objective refraction?
A It would be a different level of accuracy for refraction. Yes.
Q In what way?
A Well, with a subjective refraction, and that's where the provider asks you, "Better 1 or 2? Better 1 or 2?" along with a host of other things, including proper alignment of the lenses so that the prescription is specifically designed to have lenses in the appropriate position for the patient. Assessing both near and distance vision, refining

cylinder, axis. Yeah. All of those things, those are part of a subjective refraction, which is a bit more comprehensive than sitting in front of a machine and having the machine spit out numbers.
Q So a subjective refraction is in your estimation better than an objective refraction?
A Yes.
Q I want to ask about what you were saying earlier about optometrists, or maybe the eyecare industry generally. I couldn't tell. You mentioned there being newer online technologies that are useful in expanding access to care. Do I have that right?
A I don't recall having said that.
Q You mentioned online technologies. Do you remember that at all?
A I don't recall in what context. No.
Q That's okay. If you don't remember, then I won't ask about it. You were talking earlier about the patient providing their own information. Right? And you expressed some concern about that. Do I have that right?
A You mean Visibly providing their information or requesting that they do that?
Q When patients are providing information to visibly, you had a concern about that. Correct?

A Not a concern, but simply that that was what I understood Visibly processed to do, that patients have to answer specific questions. I have no idea what those questions are.
Q Let me ask you this way. Do you have any concern generally speaking with optometrists of ophthalmologists relying on information provided to them by patients?
A I don't have any problem at all. In fact, I think that conversation with patients is extremely important. But it's interactive. You ask a question, you have the ability to ask follow-up questions to make sure that you understand exactly, or as best you can, what is what.
Q When you were talking earlier about technicians collecting certain data using machines and providing that data to optometrists, is that interactive?
A Yes, I suppose. Yeah. You have to give instructions to the patient on how to position themselves. You make sure that they're appropriately comfortable, and what they understand, and that they do the process so that the information is as valid as it can be.
Q Fair enough. But the data itself that is

provided to the provider, the optometrist, is not itself interactive. Right?
A That's data. And you're exactly right. It is data that then is incorporated in part of the process of determining what is in the best interest of the patient.
Q And consideration of that data is ultimately up to the optometrist's professional judgement. Right?
A Yes.
Q And they get to decide, you know, based on the circumstances, whether it's useful data for them or not. Right?
A Correct. Or if they need to repeat the test or do a different test because the data was inconclusive. Yes.
Q Got it. Are you aware at all of South Carolina -- and maybe you're not. Are you aware if South Carolina requires a comprehensive eye health exam every single time patients receive a prescription for corrective lenses?
A I am not aware of that.
Q I mean, prescriptions for corrective lenses. Let's talk about that a little bit for a second. They're not always written because a patient comes in

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for a specific problem. Are they?
A Could you rephrase that, please?
Q Yeah. I mean, if a patient comes in seeking a prescription for corrective lenses to an optometrist's office, they don't always walk out with a prescription because they came in with another health problem they were complaining about. Right?
A I think we've kind of talked about the problem-focused exam. So if a patient came in with itchy burnies, no, they wouldn't necessarily have a refraction.
Q You used the phrase "something significant happened" in the sense of saying that patients receive a prescription because something significant happened. I'm trying to understand what you meant by that.
A Well, I don't recall that phrasing, but maybe I meant by that there was a significant change in the prescription, and or the patient was having -- was unable to see as clearly with their old prescription as they were able to see with the new one.
Q If a patient has seen you, they've gotten a comprehensive eye health exam, they're healthy, they're asymptomatic, they're not in an older age group, so they don't have the risk factors that come

with that, and it's been a year for example since their last examination, but their glasses broke. So they come in and say, "Dr. Shipp, my glasses broke. I'd like a new prescription." How would you approach that situation?
A If a patient came to me with broken glasses and they would like a new prescription, I would make sure that the prescription that -- I would make sure the prescription I gave them was the best prescription I could.
Q But it would be okay for them to receive a prescription without going through the litany of all the different tests we talked about earlier. Right?
A And what -- it would depend. And I'm sorry, but -- and I'm sorry to be evasive, but clinical care is not cookie cutter. You do as much as is necessary, but you don't do any less than you should, if that makes sense.
Q But you said earlier --
A If in fact I felt -- I'm sorry to interrupt you. But if in fact I felt the need to confirm something that I had that there was a question about, yes. I would do something to make sure that what I offered was the best I could. I wouldn't cut corners. I wouldn't try to take the easy way out and -- no. I

would do -- again, I try, and I can't generalize and say every clinician, but I would like to hope so. I try to treat the patient as I would like to be treated, and or any other loved one in my family. I give them as much as is necessary, but no more than is necessary.
Q When you say, like, care is not cookie cutter, I think that's a helpful principle here. So, you know, when a patient comes in to you, you're not doing the same thing for them every time. Right?
A Indeed.
Q And what --
A Do I do the exact same thing for every patient every time they come in? No.
Q Correct. And what you said earlier is that care depends on things like the patient's age, the patient's history, the patient's history with you, that sort of stuff. Right?
A Yes.
Q And those things can inform the scope of the examination necessary on any given occasion. Right?
A Correct.
Q And sometimes, that examination can be less extensive than others. Right?
A Correct.

Q And what would be a reason why it would be less extensive?
A There are a variety of reasons. Those that I can think of off the top of my head, and others that are common sense and clearly would be appropriate.
Q Off the top of your head --
A Yeah. And again, all that is written here and all that you see on the documents that you've shared with me from ophthalmology, optometry, and any other health discipline, they're all going to be the same. They'll have a basis from which to move, but it's not locked in stone in that you can't do more than that as necessary, or as indicated. That's part of the professional training.
And it's the responsibility of the individual provider to make sure that they do the best that they possibly can to address that particular patient's needs at that particular time under those particular circumstances, and they change. All of those are different each time. There's no one way of predicting what a patient is going to need in the future or even in the past. That's just not the way it works. As a clinician I can tell you that, and I hope you understand I'm not trying ot blow smoke at you. I'm trying to be honest with you, but I can't

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CERTIFICATE OF TRANSCRIBER

I, ADAM ZACHARIA, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

ADAM ZACHARIA

Melvin Shipp, O.D.

March 17, 2023

RE: Opternative Inc. v. SC Board Of Medical Examiners Et Al.
3/1/2023, Melvin Shipp , OD (#5771794)

The above-referenced transcript is available for review.

Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at cs-midatlantic@veritext.com.

Return completed errata within 30 days from receipt of testimony.

If the witness fails to do so within the time allotted, the transcript may be used as if signed.

Yours,
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Opternative Inc. v. SC Board Of Medical Examiners Et Al.
Melvin Shipp , OD (#5771794)

ERRATA SHEET

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Melvin Shipp , OD Date

Opternative Inc. v. SC Board Of Medical Examiners Et Al.
Melvin Shipp , OD (#5771794)

ACKNOWLEDGEMENT OF DEPONENT

I, Melvin Shipp , OD, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

_____ _____
Melvin Shipp , OD Date
*If notary is required

SUBSCRIBED AND SWORN TO BEFORE ME THIS
_____ DAY OF _____, 20___.

_____
NOTARY PUBLIC

Exhibit
PL 0001
Melvin Shipp

ELECTRONICALLY FILED - 2024 May 29 3:14 PM - RICHLAND - COMMON PLEAS - CASE#2016CP4006276

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FIFTH JUDICIAL CIRCUIT
COUNTY OF RICHLAND	)	
	)	Civil Action No. 2016-CP-40-06276
Opternative, Inc.,	)	
Plaintiff,	)	
v.	)	**AFFIDAVIT OF DR. MELVIN DOUGLAS SHIPP**
	)	
South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation,	)	
	)	
Defendants,	)	
and	)	
	)	
South Carolina Optometric Physicians Association,	)	
	)	
Defendant-Intervenor.	)	

PERSONALLY appeared before me Dr. Melvin Douglas Shipp, who deposes and states that the following is based upon his own personal knowledge, except those matters stated upon information and belief, and as to those matters he believes them to be true:

1. My name is Dr. Melvin Douglas Shipp, OD, MPH, DrPH. I am over the age of 21 years, of sound mind, and have personal knowledge of matters set forth herein. I am authorized to make this Affidavit and have reviewed the allegations of the Plaintiff's Complaint, the Answer filed South Carolina Board of Medical Examiners ("BME") and South Carolina Department of Labor, Licensing and Regulation ("LLR") (collectively, "Defendants"), the Answer filed by Defendant-Intervenor South Carolina Optometric Physicians Association ("SCOPA") in the above-captioned action.

EXHIBIT
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2. I received my Bachelor of Science degree from Indiana University in May of 1970 and my Doctor of Optometry in May of 1972. I received my Master of Public Health degree from Harvard University in June of 1980 and my Doctor of Public Health at the University of Michigan in 1996. I have been licensed to practice Optometry since 1972. I have been teaching since 1976.

3. I was the Dean of The Ohio State University College of Optometry from 2004 to 2014. Prior to this appointment, I was a member of the faculty at the University of Alabama at Birmingham School of Optometry. While at UAB, I also served as Assistant Dean of Clinical Services and Director of Clinics.

4. I have served as a consultant, panelist, and reviewer for several federal institutions—notably, the Food and Drug Administration, the Health Resources and Services Administration, and the National Eye Institute (NEI) of the National Institutes of Health. I was a member of the NEI National Advisory Eye Council (1989-1993), and from 1990 to 1995, a member of the NEI Planning Committee for the National Eye Health Education Project (NEHEP), a nationwide program with the goal of preventing blindness through public and professional education programs. From 2011 to 2012, I served as President of the American Public Health Association, the world's largest and oldest public health association.

5. Presently, I am a Former Dean and Professor Emeritus. I have held this position since retiring from The Ohio State University College of Optometry in July of 2014.

6. Doctors of optometry are known as "optometrists." Optometrists are independent primary health care professionals for the eye. Optometrists examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures as well as identify related systemic conditions affecting the eye.

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7. It is my understanding that Opternative is a healthcare technology company that has produced certain technology which allows ophthalmologists and optometrists to collect refractive data and other information from patients using a computer ("Technology"). The Technology is designed to be used by a patient without having an ophthalmologist or optometrist in the room.

8. It is my understanding that Opternative's Technology can be accessed by individuals through Opternative's website.

9. It is my understanding that Opternative's Technology relies on an individual's subjective self-reporting to collect refractive data using a computer.

10. Per the website, it is my understanding that the use of Opternative's Technology does not constitute a comprehensive eye examination.

11. It is my understanding that Opternative's Technology generates a set of data about a user and the user's ocular refractive error. This set of data is sent to a licensed ophthalmologist, who determines if a corrective-lens prescription is appropriate.

12. It is my understanding that Opternative's Technology collects information by soliciting a user's responses to questions and visual stimuli; it does not measure objective data about the user's eyes or eye health.

13. It is my understanding that Opternative's Technology cannot detect or aid in diagnosing diseases of the eye or systemic diseases.

14. It is my understanding that Opternative's Technology does not perform a corneal examination and evaluation. A contact lens is considered a medical device that can be used to correct vision, or for cosmetic or therapeutic reasons. A contact lens evaluation is a set of diagnostic tests and procedures performed in addition to a comprehensive eye examination.

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These tests and procedures include a measurement of the corneal curvature (keratometry or corneal topography) and an evaluation of the anterior segment and tear layer of the eye in relation to the contact lens fit. A poorly fit contact lens can cause irritation to the eyes. Continuing to wear the irritating contact lens for a prolonged time can create pain and cause scarring and vision loss for a patient. A patient may not have any symptoms from a poorly fit contact lens, but scarring and vision loss can develop nonetheless. Such consequences of a poorly fit contact lens can only be detected by a corneal evaluation.

15. Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination. There is a risk that individuals may mistakenly believe that they have received an eye examination after receiving a prescription for spectacles or contact lenses from an ophthalmologist or optometrist following an Opternative examination. It is possible that some of those individuals may have an asymptomatic eye or systemic disease.

16. In addition to assessing eye and vision problems, an eye examination may be the first opportunity to detect diabetes and other health conditions. Examples include, high blood pressure, hypercholesterolemia, and certain inflammatory diseases.

17. Diabetes is currently the nation's 7th leading cause of death in the United States. Diabetes is also a risk factor for heart disease and stroke, and a leading cause of kidney disease and blindness in adults. Early detection can allow early treatment and management of both systemic and eye related diabetic changes.

18. One of the more debilitating eye related outcomes associated with type 2 diabetes in adults is vision impairment, including blindness. Diabetes related eye conditions include, but

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are not limited to, refractive changes, cataracts, diabetic retinopathy, and glaucoma. Diabetic retinopathy is among the leading causes of preventable blindness in the United States.

19. Most symptoms associated with diabetic eye disease progress slowly, and unnoticeably, therefore, comprehensive dilated eye examinations are necessary to diagnose, prevent and manage these conditions.

20. Importantly, diabetic eye disease can be detected and diagnosed during a routine comprehensive dilated eye examination.

21. Optometrists are qualified to (and do) conduct comprehensive eye examinations. Comprehensive eye examinations consist of, but are not limited to, the following: a review of the patient's health history; measuring visual acuity, both aided and unaided; performing an examination with a slit lamp of the anterior segments of the eyes and eyelids; performing an internal ophthalmoscopic examination through a dilated pupil, including evaluation of the optic nerve head, macular and peripheral retina; performing a subjective refraction; performing tonometry; evaluating pupils; assessing ocular motility and eye alignment; performing confrontation visual field or similar screening field; performing other tests and procedures as indicated by the patient's chief complaint, case history or objective signs and symptoms discovered during the course of the eye examination; making a diagnosis and formulating a treatment plan; seeking consultation and/or making referrals for assessment/treatment to other health providers as appropriate.

22. Optometrists are under an affirmative obligation to look after the health and safety of their patients, which requires them to use their optometric judgment to determine whether their patients' complaints or symptoms pertaining to their eyesight or eye health are indicators of

systemic or body-wide disease processes or pathologies. They are likewise obliged to make such determinations even when the disease processes or pathologies are asymptomatic.

23. An optometrist that conducts a comprehensive eye exam can detect and diagnose certain diseases of the eye, such as glaucoma, cataracts, macular degeneration, binocular vision disorders and corneal dystrophy. They can also detect diabetes, hypertension, hypercholesterolemia, auto-immune disorders and other systemic diseases.

24. The American Optometric Association is a national organization of optometrists that, among other things, helps set the standard of care for optometrists nationwide.

25. The American Optometric Association recommends that adults between the ages of 18 and 64 who are asymptomatic and who are not considered "at risk" should have comprehensive eye examination every two years. Such patients who are 61 years old or older should have comprehensive eye examinations annually. Patients who are "at risk" meet one or more of the following conditions: (1) have diabetes, hypertension, or a family history of ocular disease; (2) work in occupations that are highly demanding visually or are particularly hazardous to the eye; (3) wear contact lenses; (4) have had eye surgery; or (5) have other health concerns or conditions. "At risk" patients between the ages of 18 and 60 years should have comprehensive eye examinations every one to two years, as recommended. Such "at risk" patients who are 61 years old or older should have comprehensive eye examinations annually, or as recommended.

26. It is my opinion, to a reasonable degree of certainty as an optometrist and a public health professional, that the South Carolina Eye Care Consumer Protection Law appropriately addresses the risk to public health that is created when members of the public are allowed to obtain corrective lenses merely by undergoing a refractive examination.

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FURTHER AFFIANT SAYETH NAUGHT.

Dr. Melvin Douglas Shipp

SWORN BEFORE ME THIS
28th of September 2017.

(Seal)
Notary Public for Arizona
My Commission Expires:

BRANDON REISH
NOTARY PUBLIC - ARIZONA
MARICOPA COUNTY
My Commission Expires
April 16, 2018

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Exhibit
PL 0003
Melvin Shipp

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AMERICAN ACADEMY® OF OPHTHALMOLOGY
The Eye M.D. Association

POLICY STATEMENT

Frequency of Ocular Examinations

Policy

The frequency of ocular examinations should be based on the presence of visual abnormalities and the probability of visual abnormalities developing. Individuals who have ocular symptoms require prompt examinations. Individuals who do not have symptoms but who are at high risk of developing ocular abnormalities related to systemic diseases, such as diabetes mellitus and hypertension or who have a family history of eye disease, require periodic comprehensive eye examinations to prevent or minimize visual loss. The frequency of examinations depends on an individual's age, specific condition, and the likelihood of finding abnormalities on examination. Adults who have no symptoms, and who are at low risk, should receive an initial comprehensive eye examination by an ophthalmologist and follow a schedule of periodic assessment designed to detect ocular disease.

Background

There are several times in an individual's lifetime when an ocular examination is extremely important. Certain infectious, congenital, and hereditary eye diseases may be manifest at birth, and since they create a risk to vision if undetected, a screening in the newborn is justified. Infants who have detected abnormalities as well as infants with risk factors, such as systemic diseases or a family history of certain conditions, should be referred for a comprehensive eye examination by an ophthalmologist.

Children should receive age-appropriate eye health and vision screenings throughout childhood because different childhood eye problems may be detected at each visit and new problems can arise. The goal is to identify and treat preventable visual impairment at the earliest feasible age. The elements of vision screening vary depending on the age and level of cooperation of the child. Instrument-based screening is first recommended between 6–12 months of age and until a child is able to cooperate for subjective visual acuity testing as stated in the Academy's Pediatric Eye Evaluation, Preferred Practice Pattern® guidelines. The ophthalmologist should be aware there is a trade-off in terms of false positives and false negatives with instrument-based technology as data are analyzed on the basis of preset refractive error criteria to determine whether a child passes or fails.[1] Amblyopia is estimated to occur at a rate of 1–3% in children aged 6–72 months,[2, 3] and may lead to functional blindness if undetected by autorefractors or photoscreening. Therefore any child with an abnormal subjective visual acuity assessment, or one who has not been successfully tested by age 3,[1] should be referred for a comprehensive eye examination by an ophthalmologist.

The major abnormality among school-age children is the unrecognized development and progression of myopic refractive error, and individuals in this age group should be examined during primary health care visits. Myopia can develop in individuals in their 20s, and it can progress in those whose refractive error did not stabilize in the teenage years. In the young adult the rate of development of other significant eye disease is low, but it increases steadily after the age of 40.

Evaluation

Adults with no signs or risk factors for eye disease should receive a comprehensive medical eye evaluation at age 40 if they have not previously received one.[4] Before the onset of

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presbyopia (at approximately age 40), the majority of American adults experience no changing refractive error or significant ocular disease and routine eye examinations are not indicated. For asymptomatic individuals or individuals without risk factors, who are 40 to 54 years old, and who have had a comprehensive eye examination, the recommended interval for evaluations is 2 to 4 years. For individuals aged 55 to 64 years old, the recommended interval for evaluations is 1 to 3 years. For individuals 65 years old or older, the American Academy of Ophthalmology recommends an examination every 1 to 2 years, even in the absence of symptoms.[5]

Note that an eye examination is warranted if ocular symptoms, visual changes, or injury are involved. Also, for individuals at higher risk for certain diseases, such as African-Americans and Hispanics who are at higher risk for glaucoma, comprehensive eye examinations should be considered every 2 to 4 years for those under age 40, every 1 to 3 years for those aged 40 to 54, and every 1 to 2 years for those aged 55 to 64, even in the absence of visual or ocular symptoms.[4, 6, 7, 8, 9, 10, 11]

Recommendations

1. Infants at high risk, such as those with the potential for retinopathy of prematurity and those with a family history of retinoblastoma, childhood cataracts, childhood glaucoma, or metabolic and genetic disease, should have a comprehensive examination by an ophthalmologist as soon as medically feasible.

2. Children should have an assessment for eye problems in the newborn period and then at all subsequent routine health supervision visits. The elements of the assessment vary with the age of the child. Abnormalities present at birth, such as opacities of the ocular media (e.g., congenital cataract) or ptosis, may have profound effects on normal vision development in an infant. By age 3 to 3 1/2 years, the child will generally cooperate enough for fairly accurate assessment of visual acuity and ocular alignment.[1] He or she should have these assessed by a pediatrician or other medical practitioner.[12] Any abnormalities or the inability to test are criteria for referral to an ophthalmologist.

3. School-age children should be evaluated regularly for visual acuity and ocular alignment (approximately every 1 to 2 years) during primary health care visits, in schools, or at public screenings. Note the choice and arrangement of optotypes (letters, numbers, symbols) on an eye chart can significantly affect the visual acuity score obtained. Preferred optoypes are standardized and validated.[1]

4. Individuals who develop diabetes mellitus type 1 should be examined by an ophthalmologist 5 years after disease onset and at least yearly thereafter.[13, 14] Individuals who develop diabetes mellitus type 2 should be examined at the time of diagnosis and at least yearly thereafter.[15] Women with type 1 or type 2 diabetes should receive a comprehensive eye examination before conception and then early in the first trimester of pregnancy. Recommended intervals for subsequent examinations depend upon the level of retinopathy.[16-18]

5. Adults with no signs or risk factors for eye disease should receive a baseline comprehensive eye evaluation at age 40.[4] Individuals without risk factors aged 40 to 54 should be examined by an ophthalmologist every 2 to 4 years. Individuals without risk factors aged 55 to 64 should be examined by an ophthalmologist every 1 to 3 years.[4, 5]

6. Individuals without risk factors 65 years old or older should have an examination performed by an ophthalmologist every 1 to 2 years as the incidence of unrecognized

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ocular disease increases with age.[4, 5]

7. The frequency of ocular examinations in the presence of acute or chronic disease will vary widely with intervals ranging from hours to several months, depending on the risks involved, response to treatment, and potential for the disease to progress.

8. Any individual at higher risk for developing disease, based on ocular and medical history, family history, age, or race should have periodic examinations determined by the particular risks, even if no symptoms are present.

9. A routine comprehensive annual adult eye examination in individuals under the age of 40 unnecessarily escalates the cost of eye care and is not indicated except as described above.

Summary

In summary, the frequency of ocular examinations should depend on the individual's age, race, past ocular history, medical history, family history of eye disease, and the types of symptoms or ocular findings encountered. If significant ocular disease is detected, the frequency of examination will depend on the severity of the condition, the response to therapy or surgery, and the potential for detecting progression of the abnormality.

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Approvals
American Academy of Ophthalmology, Board of Directors, February 1983

Revised and Approved by:

American Academy of Ophthalmology, Board of Directors; September 1990, February 2000, February 2005, November 2009, February 2015

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EXHIBIT 5

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From: Mark Kelley <mark@kmso.net>
Sent: Wednesday, May 18, 2016 9:33 AM
To: Jackie Rivers
Subject: Re: S 1016

Got it

Sent from my iPhone

On May 18, 2016, at 8:50 AM, Jackie Rivers <jrivers@sceyedoctors.com> wrote:

> Dr. Zolman, Angelia and Mark...response from Senator Scott below
>
> **From:** Peter Candela [mailto:pkcandela@gmail.com]
> **Sent:** Wednesday, May 18, 2016 8:48 AM
> **To:** Jackie Rivers <jrivers@sceyedoctors.com>
> **Subject:** Fwd: S 1016
>
> Just a heads up. I forwarded this email to Dr Campbell also.
> Thanks.
> Dr C
>
> Sent from my iPhone
>
> Begin forwarded message:
>
> > **From:** <jscottbyos@aol.com>
> > **Date:** May 17, 2016 at 10:17:07 PM EDT
> > **To:** Peter and Kari Candela <pkcandela@gmail.com>
> > **Subject: Re: S 1016**
> >
> > Hi Peter,
> >
> > So sorry to miss your call. Left floor of Senate and went straight to Finance. I will work tomorrow to get support to override S1016.
> >
> > Be well with the healing of your eye.
> >
> > John
> >
> > **From:** Peter and Kari Candela
> > **Sent:** Tuesday, May 17, 2016 4:54 PM
> > **To:** Senator John Scot/M
> >
> > Hi John. Sorry for the phone tag today. Just got back from Cincinnati for my eye surgery. It's been a process.

I am deeply concerned with Governor Haley's veto of this bill. When she speaks of stifling new technology to benefit a single industry, it shows she just does not truly understand the danger to the public allowing internet/kiosk refractions and the sale of glasses/contact lenses from them. Ophthalmology and optometry are NOT looking to "block new technologies" as we are on the forefront of creating new technologies that help our patients. Buying cheap glasses over the internet or at kiosks is not "new technology", it's a recipe for public injury.
The public's perception will be they will not need to get their eyes examined in person by a licensed physician, optometrist or ophthalmologist. I do not sell product in my practice so there is no financial reason why I am supporting this bill. I truly believe as we have seen with the sale of contact lenses in beauty shops and the like, the public will ultimately be harmed.
Both ophthalmology and optometry were together in full support for this bill. Both the House and Senate voted unanimously in support of this bill. I as current president of the South Carolina Board of Examiners in Optometry sent the Governor a letter from the board stating our unanimous support for this bill and how it would protect the citizens of our great state.
I ask that you continue to encourage your colleagues in the House and Senate to override the Governors veto.

Sincerely,
Peter

Peter V. Candela, OD, LTC, BSC, SCANG

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From: Jackie Rivers
Sent: Thursday, May 19, 2016 8:35 AM
To: Hendricks, Catherine; Daniel Carey
Subject: RE: AOA Letter of Support

Importance: High

Hey Catherine...we think the House will take it up this morning at 10:30. Here's a link:
http://www.scstatehouse.gov/video/videopage.php?chamber=H&AUDIO=0

From: Hendricks, Catherine [mailto:CHendricks@AOA.ORG]
Sent: Wednesday, May 18, 2016 5:36 PM
To: Jackie Rivers
Subject: Re: AOA Letter of Support

Let us know when the House will take it up and we'll watch online. This is pretty exciting!
Catherine

Sent from my iPhone

On May 18, 2016, at 5:21 PM, Jackie Rivers <jrivers@sceyedoctors.com> wrote:

> Yes!!!! The board was here so we were all able to watch it together...take that Opternative!!!!!!
>
> **From:** Hendricks, Catherine [mailto:CHendricks@AOA.ORG]
> **Sent:** Wednesday, May 18, 2016 4:54 PM
> **To:** Jackie Rivers <jrivers@sceyedoctors.com>
> **Cc:** Deanna Alexander <deealex1@aol.com>; Carey, Daniel <DCarey@AOA.ORG>; zkloomis@gmail.com
> **Subject:** FW: AOA Letter of Support
>
> So you guys crushed it in the Senate! Do you think you will need/want a letter of support for the House?
>
> Catherine Hendricks
> Manager, State Government Relations
> 703-837-1017 office
> 703-739-9497 FAX
>
> **From:** Hendricks, Catherine
> **Sent:** Wednesday, May 18, 2016 4:51 PM
> **To:** Rivers, Jackie Exec Dir <JRivers@sceyedoctors.com>
> **Cc:** Deanna Alexander <deealex1@aol.com>; Carey, Daniel <DCarey@AOA.ORG>; zkloomis@gmail.com
> **Subject:** AOA Letter of Support
>
> Hi Jackie,

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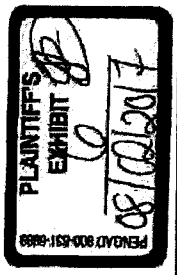
From: Michael Zolman <focusedeyedoc@yahoo.com>
Sent: Thursday, May 19, 2016 8:05 AM
To: Jackie Rivers
Subject: Re: URGENT: Senate OVERRIDES Gov. Haley's veto of our bill, 39-3

Can you send it out now? Im getting so many questions from members right now bc they heard about the override in the senate yesterday

Sent from my iPhone

On May 19, 2016, at 6:00 AM, Jackie Rivers <jrivers@sceyedoctors.com> wrote:

> Will do!! I'll have it pushed put before 8:30!! I don't think Anna sent me the video link out il double check. Won't hold the email up for it though. Great message! Super excited about today!!!
>
> Sent from my iPhone
>
> On May 19, 2016, at 2:11 AM, Michael Zolman <focusedeyedoc@yahoo.com> wrote:
>
> > Hi Jackie,
> >
> > Can you please send the following and attach 1. The OD/Congressman spreadsheet (for those who STILL dont know who their legislator is) 2. Our letter of concern and rebuttal 3. our talking points 4. J&J letter 5. Anna's video (if she has it. If not, dont worry about it) 6. Senate score card from yesterday.
> >
> > Let's keep our fingers crossed!
> >
> > Dear Colleagues,
> >
> > Feels good doesn't it?
> >
> > The Senate voted to override Governor Haley's veto of our bill, S1016 yesterday afternoon! All of your calls, emails and faxes to your senators paid off. Senator Cleary proposed the vote and did an EXCELLENT job explaining the importance of the override. Please contact Senator Cleary, as well as your senator, to thank them for their support!
> >
> > Also, as a welcomed surprise and much appreciated showing of industry support, the president of Johnson & Johnson, Peter Menziuso, personally contacted our SCOPA office a few days ago after hearing about Gov. Haley vetoing our bill to prevent online eye exams and 'eye exam' kiosks. He offered Johnson & Johnson's full support to SCOPA to help override the governor's veto. Without question or hesitation, he personally wrote a very powerful advocacy letter from Johnson & Johnson to accompany our Letter of Concern and Veto Rebuttal to the Senate. A big THANK YOU is in order to J&J for their tremendous support of our bill His letter is attached for your review.
> >
> > With yesterday's override in the Senate, our efforts are beginning to attract A LOT of press and is becoming a story of national interest. It is easy to want to celebrate this victory, but now is not the time. With the good comes the bad. We now know that Opternative has stepped up their efforts



and have lobbyists on the hill contacting House members encouraging them to sustain the governor's veto.

We must work quickly as the vote to override Haley's veto will **VERY LIKELY HAPPEN TODAY!!!** Please call your House Representative **NOW!**

We've taken our bill all the way to the finish line once already....only to be punched in the mouth by the governor. We've fought to get it back to the finish line and now this is our opportunity to punch back! Let's send a loud and clear message to the House of Representative letting them know what the sound of passionate, organized Optometry sounds like! Let's show Governor Haley what this 'small group of eye care professionals' can do when we are ignored and she puts the safety of our patients at risk.

Please call your House Representative now!

Fight Optometry Fight!
Michael W. Zolman, OD
SCOPA co-legislative director
Infinity Eye Care and Low Vision Rehabilitation Center
325 Folly Rd., Suite #109
Charleston, SC 29412
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From: Michael Zolman <scoa@cicit.net>
Sent: Thursday, May 19, 2016 8:53 AM
To: Jackie Rivers
Subject: S.1016 Update - Success in the Senate - PUSH in the House

SC(•)PA
South Carolina Optometric Physicians Association

May 19, 2016

Dear Colleagues,

Feels good doesn't it?

The Senate voted to override Governor Haley's veto of our bill, S1016 yesterday afternoon! All of your calls, emails and faxes to your senators paid off. Senator Cleary proposed the vote and did an EXCELLENT job explaining the importance of the override. Please contact Senator Cleary, as well as your senator, to thank them for their support!

Also, as a welcomed surprise and much appreciated showing of industry support, the president of Johnson & Johnson, Peter Menziuso, personally contacted our SCOPA office a few days ago after hearing about Gov. Haley vetoing our bill to prevent online eye exams and 'eye exam' kiosks. He offered Johnson & Johnson's full support to SCOPA to help override the governor's veto. Without question or hesitation, he personally wrote a very powerful advocacy letter from Johnson & Johnson to accompany our Letter of Concern and Veto Rebuttal to the Senate. A big THANK YOU is in order to J&J for their tremendous support of our bill **Click here to review his letter.**

With yesterday's override in the Senate, our efforts are beginning to attract A LOT of press and is becoming a story of national interest. It is easy to want to celebrate this victory, but now is not the time. With the good comes the bad. We now know that Opternative has stepped up their efforts and have lobbyists on the hill contacting House members encouraging them to sustain the governor's veto.

We must work quickly as the vote to override Haley's veto will **VERY LIKELY HAPPEN TODAY!!!** Please call your House Representative **NOW! Click here to reveiw a list of legislators, if needed. Also, you can click here for a copy of the revised talking points that were distributed yesterday.**

For your quick reference, **click here for a copy of our letter of concern and rebuttal that has been distributed to all House members**. They will receive another copy of this, including the letter from J&J on the House floor this morning.

We've taken our bill all the way to the finish line once already....only to be punched in the mouth by the governor. We've fought to get it back to the finish line and now this is our opportunity to punch back! Let's send a loud and clear message to the House of Representative letting them know what the sound of passionate, organized Optometry sounds like! Let's show

Governor Haley what this 'small group of eye care professionals' can do when we are ignored and she puts the safety of our patients at risk.

Please call your House Representative now!

Fight Optometry Fight!

Michael W. Zolman, OD
SCOPA co-legislative director
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From: Michael Zolman <scoa@ciclt.net>
Sent: Thursday, May 19, 2016 2:20 PM
To: Jackie Rivers
Subject: It's a GREAT day in SC

SC(•)PA
South Carolina Optometric Physicians Association

May 19, 2016

Dear Colleagues,

It's a **GREAT** day in South Carolina!

It's with the utmost pleasure to announce that today, Opternative and 'eye exam' kiosks are now **PROHIBITED BY LAW** in the great state of SC!

Both the SC House and Senate voted to override Governor Haley's veto of our bill S1016. This is what organized Optometry looks like at it's best! It took the grassroots efforts of all of you contacting your legislators to make this happen as well the tireless efforts of your SCOPA Board of Directors working in conjunction with AOA to make this possible. Johnson & Johnson also deserves praise for their full support of our bill by reaching out to our legislators and lobbying with us as well. Call your legislators, tell them you love 'em.....except for Rep. Jonathon Hill. **Click here to see the vote count**.

You should be so proud of your efforts and standing up for what is right in order to ensure the vision, eye health and general health of their patients. It's been a pleasure being a part of this process!

Good-bye Opternative!

Michael W. Zolman, OD
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From: Angelia Smith Owens <angelia@kmso.net>
Sent: Monday, June 20, 2016 1:44 PM
To: Jackie Rivers
Subject: FW: FW: Kiosks and Online Eye Exams
Attachments: Consumer Protection in Eye Care Act Final (2).docx; Online Vision Screening Self-adjusting Glasses and Kiosks final (1).pdf

This is the first email I found. Looks like Dr. Zoleman emailed the Board in March, but this wasn't forwarded to me and Mark until May. We worked with Ron Scott over the summer and fall on language. Let me know if you need anything else. Thanks!

From: Wayne Cannon [mailto:wmcannon15@gmail.com]
Sent: Thursday, May 21, 2015 8:30 AM
To: Angelia Smith Owens
Subject: Fwd: FW: Kiosks and Online Eye Exams

The SCOPA board voted to evaluate the passing of a consumer protection leg. The AOA suggested bill is attached for your review. We will need to meet soon to evaluate our strategy.

---------- Forwarded message ----------
From: "Jackie Rivers" <jrivers@sceyedoctors.com>
Date: May 20, 2015 6:49 PM
Subject: FW: Kiosks and Online Eye Exams
To: "Anna Balderson" <abalderson@sceyedoctors.com>, "Bob Branch (jeyes4us@yahoo.com)" <jeyes4us@yahoo.com>, "David McKenzie" <drdavid@mckenzieeyecare.com>, "Jennie Smith Zolman" <jenniesmithod@yahoo.com>, "Johndra McNeely" <uptownnw@yahoo.com>, "Mike Campbell (mcamp16035@aol.com)" <mcamp16035@aol.com>, "Mike Zolman" <focusedeyedoc@yahoo.com>, "Pete Smith" <smithforhouse@gmail.com>, "Ted Newman" <tnewman123@bellsouth.net>, "Wayne Cannon" <wmcannon15@gmail.com>
Cc:

All, below is the e-mail sent out by Dr. Mike Zolman with his thoughts and the info the Consumer Protection in Eye Care Act and another presentation from the AOA.

Passing along so everyone can get reacquainted with the info.

Thanks!!

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From: Michael Zolman
Sent: 3/19/2015 12:15 PM
To: Bob Branch; Wayne Cannon; Jennie Smith; Michael Campbell; David McKenzie; Johndra McNeely; Ted Newman
Cc: Jackie Rivers; Anna Balderson
Subject: Kiosks and Online Eye Exams

It was great seeing everyone last weekend at our Spring Convention!

I thought we had a productive board meeting but as ya'll know, we ran short on time and didn't have time to bring up New Business. I wanted to bring up some new business that I feel is of utmost importance to our profession and one that we need to address quickly and attack aggressively. That is the issue of kiosks and online eye exams.

At the HOD at SECO, AOA President David Cockrell stated that the single biggest threat to our profession he feels is 1800 seeking legislation to be able to 'change' a doctor's CL prescription to a proprietary brand of their choosing . He felt this way because this could set a precedent for other retailers to propose similar type legislation on our profession. While this is certainly a big threat, I feel the issue of kiosks and online eye exams are an even greater threat. Here's why:

As of now, Self-Refracting Kiosks currently exist and are being heavily marketed in Europe and Asia. The patient puts in a few dollars, the kiosk 'interacts' with the pt to determine the refraction and a prescription for glasses (or CL) is generated for the pt to take to the nearest optical or the pt can order the glasses or CL online from the kiosk and then have them sent directly to the patient's house. No exam needed, no doctor needed. In the US though, there has to be a doctor's signature in order to have a valid prescription. But what would happen when you combine a Self-Refracting Kiosk with Telemedicine? It would only take one sellout OD or ophthalmologist to approve of countless prescriptions generated from self-refracting kiosks and forego the exam altogether.

Now play this forward when the self-refracting/telemedicine kiosk becomes popular and known to the public. Who would be interested in this technology? I think it is reasonable for every Walmart, Lenscrafters, Costco, Pearl, Sears, JCPenney, America's Best, Eyeglass World.....(the list goes on and would likely include every commercial retail optical) ..... would have great interest in this technology. Our colleagues in commercial practices would be at great risk of becoming irrelevant in that practice model. Why? In the eyes of a commercial retail corporation, which would be more cost effective?.....paying ~$50,000 to $100,00 for this technology that takes up less than 10 square/feet of space and can generate prescription in only a few minutes; or, guaranteeing an Optometrist an annual salary, paying for 1-3 lanes of equipment, paying for the office space, paying for the staff and maintaining a contract with an optometrist to ensure he is there 6 days a week so that he can generate a prescription at the end of a 20 minute eye exam? Both scenarios generate prescriptions for the optical but the kiosk could do it for much much less and more quickly. Plus, theoretically by way of telemedicine, one OD could oversee prescriptions for countless kiosk locations vs these locations needing to hire multiple ODs to generate prescriptions. The savings would be huge. And as much as we like to think that patients would not do this because there is no health evaluation of the eyes by a doctor, how many patients do we see daily who really come in just wanting a new prescription for glasses and/or contacts? This would allow the patient to 'skip going to the doctor' and allow them to get what they want. This holds true for online eye exams as well.

I know this sounds a bit far fetched right now and Im not typically 'the sky is falling' kind of guy but I think there is some real validity to this possibility and could be a reality in the not so distance future. Plus, with total eye care being a 35 BILLION DOLLAR industry, 23 BILLION coming from glasses and CL sales, the financial incentive is certainly there to eliminate the need to have an OD to generate a prescription in the eyes of a retailer.

I don't need to tell any of you that this is potentially a huge threat to our profession but more importantly to the general public. Think of all the glaucoma, ARMD, Diabetic retinopathy, Cataracts, amblyopia, (the list goes on and on) that would be missed. Fortunately, the AOA is on the ball and recently drafted a bill that can be modified on a state-by-state basis to prevent this but it is up to the individual state to modify it and then introduce it to their state legislation. The bill is called The Consumer Protection in Eye Care Act. We will need to go through our current practice act to make sure the two complement each other but I think this is something we definitely want to do.

I have attached the draft bill from the AOA as well as some information from the AOA that Jackie gathered for us. Please review it.

I would like to open this up for discussion and get everyone's feedback. And provided there is no one on the board outright against this bill, I would like to make a motion that we work together and consult with our lobbyist and attorney to discuss what we need to do to get this bill ready so that we can present this to the SC legislature first thing next January when congress is back in session.

I would like for SC to be one of the first states to make this bill a law instead of one of the last!!! Let's prevent a fire instead of putting out a fire later. Let's be the state that has the legislation that all the other states wish they had!!!

What does everyone think?

Michael W. Zolman, OD

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SGRC Webinar

Online Vision Screening, Self-adjusting Glasses and Kiosks and What ODs Need to Know

American Optometric Association

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Introduction

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State Government Relations

State Government Relations Committee:

- Deanna S. Alexander, OD, Chair
- Lee Ann Barrett, OD
- Michael Bennett, OD
- Matt Burchett, OD
- Chris Colburn, OD
- Michael G. Horstman
- Steve Langsford, OD
- Gary L. Robbins
- James D. Sandefur, OD
- Roger R. Seelye, OD
- John B. Whitlow, OD
- Paul Zerbinopoulos, OD
- Brian Reuwer, Staff
- Kristen Skiles, Staff

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Agenda for Tonight

- Introduction of Speakers and Topic by Deanna Alexander, SGRC Chair
- Background on the Issue – Drs. Alexander, Zerbinopoulos, Seelye and Steele.
- Recommendations for State Affiliates – Dr. Alexander
- Review of the "Consumer Protection in Eye Care Act" – Mr. Reuwer
- Questions – All Panelists

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Panelists

- Deanna Alexander, OD – Legislative Chair, Colorado and SGRC Chair
- Paul Zerbinopoulos, OD – Legislative Chair, Rhode Island and SGRC Member
- Roger Seelye, OD – Legislative Chair, Michigan and SGRC Member
- Zack Steele, OD – President-Elect, Alabama Optometric Association
- Brian Reuwer – Staff AOA

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BACKGROUND

Kiosks

- A lot of concern among the profession because of a proposed law in Utah that could possibly legalize self-refracting kiosks.
- In addition, Rite-Aid and CVS have tested eyeglass selling kiosks (with existing prescription).
- With online retailors setting up brick and mortar stores and more companies looking to get into eyeglass sales, it's a bet that further technological developments will be made to subvert the eye exam to sell more glasses.

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Direct-to-Consumer Eye Care

1 800 CONTACTS®

eyeconic.com

glasses.com by 1 800 CONTACTS

Coastal.com
THE BETTER WAY TO BUY EYEWEAR

WARBY PARKER

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Direct-to-Consumer Eye Care

- Rite Aid Pharmacy seeks to build 800 "Wellness Stores" within it's existing pharmacies by 2014
- Vision Center – a new, easy-to-use, interactive kiosk that allows customers to conveniently order prescription glasses and contact lenses online for home delivery and offers eyeglass frames to try on.
- Technology developed by DB Vision

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Direct-to-Consumer Eye Care

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SoloHealth Kiosk

- Measures blood pressure
- Measures visual acuity
- Recommends exam if acuity is below a "standard."
- 1000 units deployed in WalMart and Sam's Club stores
- FDA Approval for measurement of blood pressure.

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What About a Subjective Refraction?

- Automated Subjective Refractors: Do they really exist?

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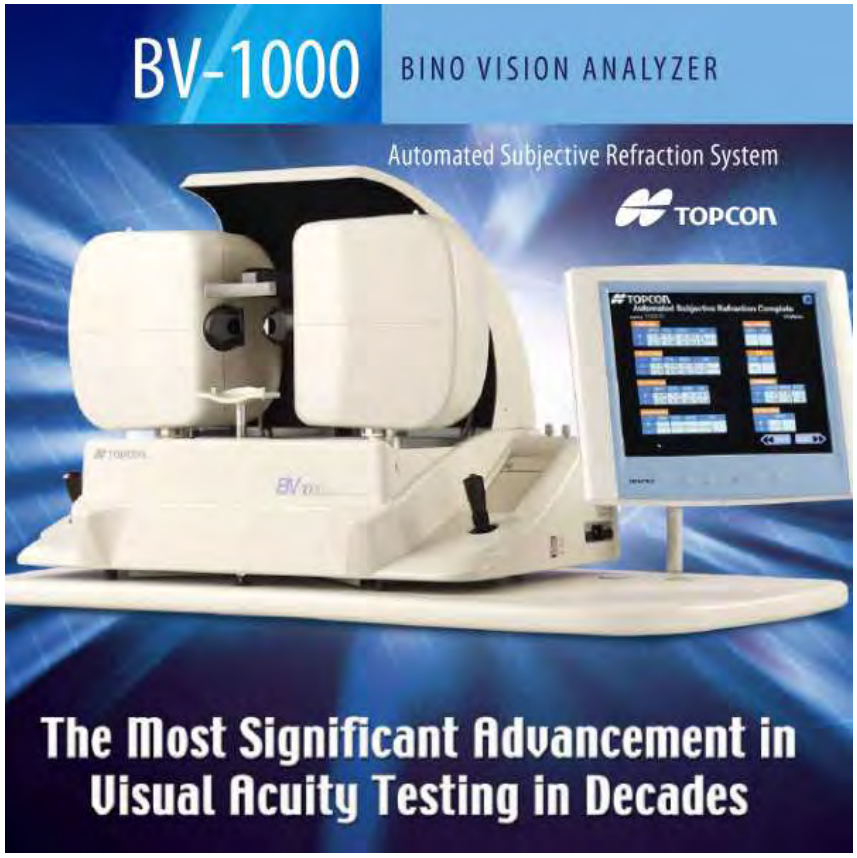
Automated Subjective Refractor



- Topcon BV-1000
- Released in 2002
- Peer reviewed in 2003
- Marketed heavily in Europe and Asia

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SCOPA 000167

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Topcon BV-1000

- Uses patient-guided voice prompts to perform complete binocular subjective refraction
- Unit has two joystick controls (for right or left-handed use) and a button for making responses to various questions
- Measures objective refraction, binocularity, **subjective refraction**, alignment, binocular balance, and near addition
- Peer reviewed study in 2003 in *Optometry and Vision Science*

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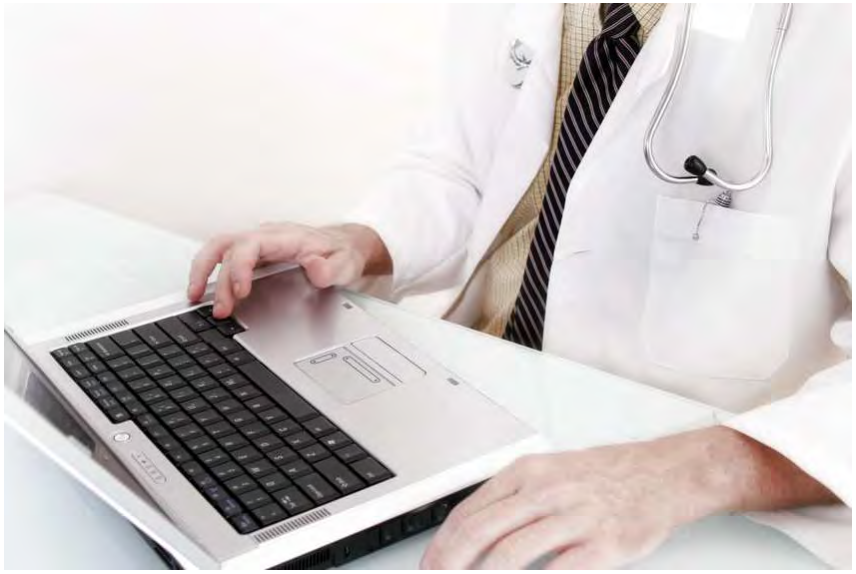
Online Eye Exams

- Kiosks aren't the only changes coming. Several companies are developing virtual eye exams that will allow people to skip "going to the doctor."



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EyeNetra

October 15, 2010

Cell Phones as Eye Doctors

A prototype device provides access to full-service optometry in your pocket.

Netra is an inexpensive and easy-to-attach add-on for self-testing eyesight quickly, easily, and accurately with a mobile phone.
Credit: Andy Ryan, MIT Media Lab

It won't be long before most people are carrying high-end scientific equipment around in their pockets at all times, said Ramesh Raskar, an associate professor at the MIT Media Lab and the leader of the Camera Culture group there. That equipment comes in the form of smart phones, and Raskar believes this development "will change everything."

Speaking at the 25th anniversary celebration for the Media Lab, Raskar outlined how he wants to take advantage of the increasingly sophisticated power of today's mobile devices. He said it dawned on him that the 300 dpi resolution on a smart phone screen made it the rival of expensive, specialized devices.

One of his group's first experiments is the prototype of Netra, a system that can identify problems with a person's eyesight using only a smartphone, software, and inexpensive optical add-ons. The system, Raskar said, could help people who can't afford or get access to full-service optometry.

- EyeNetra is developing a product called Netra that would allow people to do self-eye exams using their cell phone and a "$2 piece of plastic."
- This is intended for the third world where medical access is an issue but it could easily be deployed in the US

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Opternative

- AOA became aware of an effort by Opternative to market an online eye exam.
- After consulting with the Illinois Optometric Association, the AOA sent a letter to Opternative explaining that their proposed eye exam would not meet the requirements for an eye exam under the Illinois optometric practice act.
  - And the AOA issued a statement calling for people to get an in-person eye exam before getting a prescription.
  - That statement is on the AOA website here: http://www.aoa.org/newsroom/american-optometric-association-cautions-consumers-about-claims-of-online-eye-exams

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OPTERNATIVE

Reinventing Refraction

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OPTERNATIVE

Launch Plan

Launching 2014

Direct to consumer solution

Online optical retail solution

$30-40 per exam

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Adjustable Eyeglasses Sold DTC

- Companies are developing products that would allow patients to adjust glasses without a current RX.
- Primarily the technology uses:
  - Alvarez Lens Technology
  - Fluid-Injection, Variable Focus Lens Technology
- Companies maintain that these are simply readers and that they are intended to be a back up pair of glasses
- While many of these products are sold through optometry offices, several of them are sold directly to consumers on the internet.

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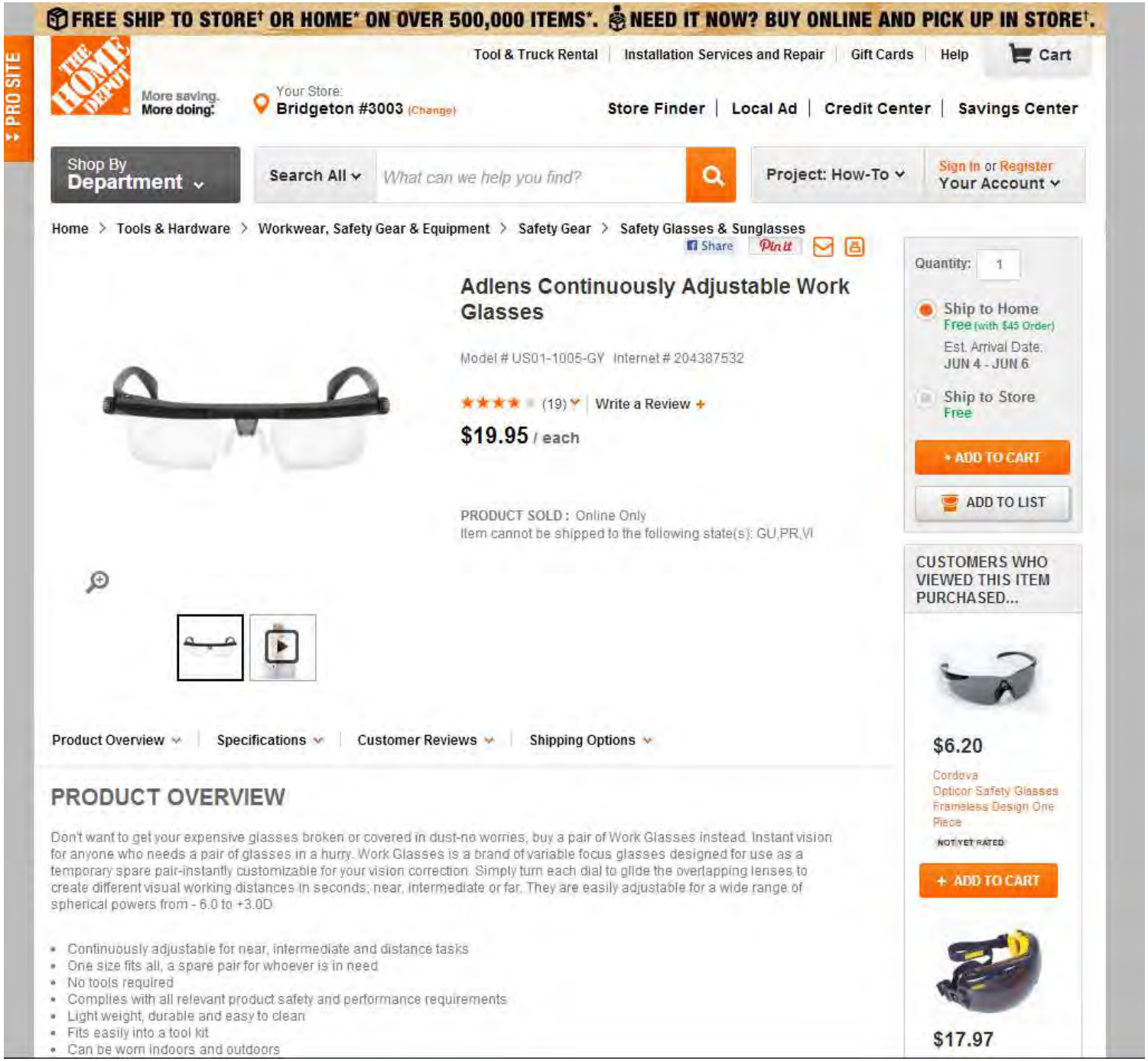

SCOPA 000176

Why are We Discussing Any of This???

- The total vision care market, as defined by The Vision Council's VisionWatch survey, reached $35.47 billion in the 12-month period, and includes dollars spent at retail at all retail types at any retail location and spent on the sale of either spectacle lenses (including Rx Sun), frames, contact lenses, plano sunglasses, OTC readers or revenue earned by refractive surgery or eye examinations.
- The report shows an increase in Rx spectacle lens sales of 6.0 percent to **$10.85 billion** in that 12-month period, while frame sales at retail rose 2.7 percent in dollars to **$8.77 billion** during the year ending June. Contact lens sales, in dollars, climbed 5.9 percent to $4.1 billion in that period.

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Can We Fight This and Protect Our Patients?

YES!!!

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Suggested Actions For State Affiliates

- Pass the "Consumer Protection in Eye Care Act"
- Add autorefractors to the definition of the practice of optometry
  - Only 7 states specifically have this language
- Give the Board of Optometry (and/or Opticianry) authority to investigate non-licensed professionals
  - About half the state boards have this authority
- A requirement for glasses RX is specifically included in the law to dispense
  - Most states have this requirement but some do not
- ODs should be included in the state telemedicine act
  - Most states have a telemedicine act but not all include ODs

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State Responses

- Alabama Experience
- Michigan Experience

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AOA Model Legislation

CONSUMER PROTECTION IN EYE CARE ACT

American Optometric Association

What Does the Model Bill Do?

- The model language will be written to amend a state's Public Health Act:
- In states without a public health code, the affiliates will have to find a way to enforce the law through the practice act or a standalone law.

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Section 1 - Definitions

- "**Contact Lenses**" means any lens placed directly on the surface of the eye, regardless of whether or not it is intended to correct a visual defect. Contact lens includes, but is not limited to all cosmetic, therapeutic, and corrective lenses.

- "**Department**" means the Department of Health or the department that handles licensure.

- "**Dispense**" means the act of furnishing a pair of spectacles or contact lenses to a patient.

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Definitions

- "**Eye Examination or evaluation**" means an assessment of the ocular health and visual status of a patient that does not consist solely of objective refractive data or information generated by an automated testing device, including an autorefractor, in order to establish a medical diagnosis or for the establishment of a refractive error.

- "**Kiosk**" means automated equipment or application designed to be used on a phone, computer or internet based device that can be used either in-person or remotely to conduct an eye examination or evaluation as defined in this Act.

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Definitions

- "**Online Eye Examination**" means an online vision screening of visual performance measuring visual acuity, contrast, and color vision.

- "**Over the counter spectacles**" means eyeglasses or lenses for the correction of vision that may be sold by any person, firm or corporation at retail without a prescription.

- "**Prescription**" means a provider's handwritten or electronic order as defined in this act, based on an eye examination or evaluation that corrects refractive error.

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Definitions

- "**Provider**" means an individual licensed under the medical or Osteopathic Practice an Act or the Optometric Practice Act.

- "**Spectacles**" means an optical instrument or device worn or used by an individual that has one or more lenses designed to correct or enhance vision addressing the visual needs of the individual wearer and are commonly known as glasses, including spectacles that may be adjusted by the wearer to achieve different types or levels of visual correction or enhancement.

- "**Spectacles**" exclude optical instruments or devices not intended to correct or enhance vision or are sold without consideration of the visual status of the individual who will use the optical instrument or device.

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Section 2 – Consumer Protections

Prescription Lenses

- No person in this state may dispense spectacles or contact lenses to a patient without a valid prescription from a provider.
- A prescription for spectacles or contact lens may not be made based on telemedicine services or based solely on the refractive error of the human eye generated by a kiosk.
- An expiration date on spectacles of not less than one year from the date of examination by the licensee or a statement of the reasons why a shorter time is appropriate based on the medical needs of the patient.
- Providers must release a spectacle prescription upon request from a patient and that prescription will include medical findings and any refractive error discovered during the examination.

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Kiosk Language

- The kiosk is approved by the United States Food and Drug Administration for the intended use;
- The kiosk is designed and operated in a manner that provides any accommodation required by the federal Americans with Disabilities Act;
- The kiosk and accompanying technology used for the collection and transmission of information and data, including photographs and scans, gathers and transmits protected health information in compliance with the federal Health Insurance Portability and Accountability Act;
- The procedure for which the kiosk is used has a recognized Current Procedural Terminology (CPT) code;

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Kiosk Language (continued)

- The physical location of the kiosk prominently displays the name and state license number of the individual who will read and interpret the diagnostic information and data, including photographs and scans;

- Diagnostic information and data, including photographs and scans, gathered by the automated equipment is read and interpreted by a provider; and

- The owner or lessee of the automated equipment maintains liability insurance in an amount adequate to cover claims made by individuals diagnosed or treated based on information and data, including photographs and scans, generated by the automated equipment.

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Over the Counter Spectacles

- Over the counter spectacles shall have the following language attached to each pair of spectacles displayed or offered for sale and in at least ten point **bold** type permanently affixed in plain view to the top of any point of sale display or, if there is no display, in the area of sale:

"ATTENTION: READY-TO-WEAR NON-PRESCRIPTION GLASSES ARE NOT INTENDED TO REPLACE PRESCRIBED CORRECTIVE LENSES OR EXAMINATIONS BY AN EYE CARE PROFESSIONAL. CONTINUOUS EYE CHECK-UPS ARE NECESSARY TO DETERMINE YOUR EYE HEALTH STATUS AND VISION NEEDS."

- The lenses in such glasses shall be of uniform focus power in each eye, *shall not be adjustable* and shall not exceed 2.75 diopters.

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Section 3 – Enforcement and Violations

- A person or governmental entity that believes a violation of this part or a rule promulgated under this part has occurred or has been attempted may make an allegation of that fact to the department in writing.

- If, upon reviewing an allegation, the department determines there is a reasonable basis to believe the existence of a violation or attempted violation of this part or a rule promulgated under this part, the department shall investigate.

- The department may hold hearings and administer oaths and order testimony to be taken at a hearing or by deposition conducted pursuant to the administrative procedures act and shall report its findings to the department.

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Enforcement and Violations

- The department may proceed if it is determined that a violation of this law has occurred.

- Nothing in this section shall require the department to wait until human harm has occurred to initiate an investigation.

- The department, upon finding after notice and an opportunity for a hearing that a person has violated or attempted to violate any provision of this part, may impose an administrative fine of not more than $1,000.00 for each violation of this part. If the department finds that a violation or attempted violation occurred and did not result in significant harm to human health, the department may issue a warning instead of imposing an administrative fine.

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Enforcement and Violations

- The department shall advise the attorney general of the failure of a person to pay an administrative fine imposed under this section. The attorney general may bring an action in a court of competent jurisdiction for the failure to pay an administrative fine imposed under this section.

- At the request of the department, the attorney general may file a civil action seeking an injunction or other appropriate relief in the name of the people of the state to enforce this act and the rules promulgated under this act. The court may impose on any person who violates this part or attempts to violate this part a civil fine of not more than $5,000.00 for each violation or attempted violation. In addition, the attorney general may bring an action in circuit court to recover the reasonable costs of the investigation from any person who violated this part or attempted to violate this part.

- The department may promulgate rules under the administrative procedures act that it determines necessary to implement, administer, and enforce this section.

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Questions From the Audience

American Optometric Association

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American Optometric Association

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From: Jackie Rivers
Sent: Monday, June 27, 2016 1:59 PM
To: penfields@penfields.com
Subject: Fwd: SCOPA - Powerpoint presentation for PC
Attachments: Optometry at its finest!v2.pptx

Sent from my iPhone

Begin forwarded message:

> **From:** "Jackie Rivers" <jrivers@sceyedoctors.com>
> **To:** "penfields10@pensfields.com" <penfields10@pensfields.com>
> **Subject: Fwd: SCOPA - Powerpoint presentation for PC**
>
> Sent from my iPhone
>
> Begin forwarded message:
>
> From: "Jackie Rivers" <jrivers@sceyedoctors.com<mailto:jrivers@sceyedoctors.com>>
> To: "Chris Wroten" <cwroten@od.sco.edu<mailto:cwroten@od.sco.edu>>
> Subject: SCOPA - Powerpoint presentation for PC
>
> Hi Dr. Wroten! Our presentation is attached. I will also have a copy with me if needed. There shouldn't be any changes made but…☺
>
> Jackie Rivers
> Executive Director
> SC Optometric Physicians Association
> 2730 Devine Street
> Columbia, SC 29205
> 803-799-6721 toll free 877-799-6721
> fax: 803-799-1064
> www.sceyedoctors.com<http://www.sceyedoctors.com><http://www.sceyedoctors.com/>
>
> [cid:16%253aX%253aRgAAAABLMiP7M5b4TqzD7PJzhgdiBwDa0nOsEjiBTqW3srFcjyEbAAAAAAEKAADa0nOsEjiBTqW3srFcjyEbAACaf8UyAAAJ%253aEACPBitetQixT4mR9GeF0c2B]

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SCOPA
South Carolina Optometric Physicians Association

Optometry at its finest!

It was a GREAT day in South Carolina

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Our Recipe for Success?

- Great Grassroots
- Great team and a great plan
- Great implementation
- Perseverance!

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What worked for us?

- Being Politically Active.
- Being visible in the community: SC Mission events, Special Olympics, WellPartners Dental and Eye Clinic, numerous community health fair events some of which were at the invitation of legislators for their underserved constituents.
- SCOPA board members were engaged.
- Being an election year where the entire House and Senate are up for re-election.
- SCOPA lobbyist, members and Ophthalmology Executive Director/Lawyer quietly met over the summer and fall to agree on language for the legislation.
- Companion bills were introduced: S.1016 and H.4728.
- Having great primary sponsors.
- Numerous co-sponsors for both bills.
- Several group meetings with House and Senate staff, agency legislative liaisons, ophthalmology representatives.
- A great lobbying team that knew the system, members and procedures and was able to push and get ahead of bill issues.

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Some Highpoints:

- S.1016 was introduced by Senator Cleary on January 21st.
- January – April: worked closely with legislative staff, attended and testified at numerous subcommittee and full committee hearings. Working with state house staff proved to be crucial – having them involved helped us tremendously in being able to move quickly through legislative process and calendar.
- March: Opternative hired a lobbying firm and their efforts to kill our bill began.
- On April 26th the bill was passed out of the Senate by a vote of 40 – 1.
- On April 27th the bill was introduced and had it's first read in the House. It was referred to and recalled from committee on the same day! Due in part to having state house staff involved but also because of Representative (Dr.) Deborah Long being a respected member of the SC House.
- On April 28th the bill received its second reading in the house; had a roll call vote of 100-1 and was given unanimous consent for the third reading the following legislative day.
- The bill was ratified on May 11th - vetoed by Gov. Haley on May 16th

SCOPA members went to work!

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The Veto…

Representative Deborah Long and our lobbying team met with the Governor's Chief of Staff. WE knew the arguments and that we would likely see a veto.

In the words of Governor Nikki Haley

"Today, I am vetoing and returning without my approval, R.178, S.1016, a bill that requires prescription from a licensed optometrist or ophthalmologist to receive glasses or contacts based on an in-person comprehensive eye examination. I am vetoing this bill because it uses health practice mandates to stifle competition for the benefit of a single industry, effectively banning eye care kiosks statewide."

She doesn't stop there…

"…optometrists argue that kiosks create an uneven playing filed because licensed providers cannot take advantage of this technology and charge patients for its use in a medical practice…send a bill to my desk that allows for the expanded use of automatic vision evaluation in all medical settings, and I will sign it.

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The Override!

We had our members prepared with a message to contradict the Governor's veto. We asked SCOPA members to again reach out to their legislators explaining why the Governor was wrong and asked them to override.

They listened!

We had a little help from our friends

AMERICAN OPTOMETRIC ASSOCIATION

Johnson & Johnson
VISION CARE, INC.

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The Results…

The Senate
39 Yeas
3 Nays

The House
98 Yeas
3 Nays

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From: Michael Zolman <focusedeyedoc@yahoo.com>
Sent: Tuesday, March 01, 2016 11:32 AM
To: Jackie Rivers; Mike Campbell; Philip Flynn; Pete Smith; Kirby D. Shealy III
Cc: Anna Balderson
Subject: Re: Meeting Monday

[redacted]

Michael W. Zolman, OD

Infinity Eye Care and Low Vision Rehabilitation Center
325 Folly Rd., Suite #109
Charleston, SC 29412

P: 843.795.6464
F: 843.795.6433
www.myinfinityeyecare.com

On Tuesday, March 1, 2016 10:51 AM, Jackie Rivers <jrivers@sceyedoctors.com> wrote:

All – wanted to pass along the feedback from the AOA regarding the proposed amendment from Opternative.

Kirby, I neglected to include you in the forward this morning. In case you need it I've attached a copy of the bill from yesterday.

Thanks!

From: Hendricks, Catherine [mailto:CHendricks@AOA.ORG]
Sent: Tuesday, March 01, 2016 10:50 AM
To: Jackie Rivers <jrivers@sceyedoctors.com>; Carey, Daniel <DCarey@AOA.ORG>
Subject: RE: Meeting Monday

Hi Jackie,

Removing MDs basically makes the bill moot. Continue talking about patient safety, the medical device aspects (contacts deprive the cornea of oxygen and must be monitored for signs of wear), and the cost of emergency room treatment (CDC report) for keratitis.

If you sponsor is willing to run with it as is, do it. Give them the ground support and ammo to move it.

Thank you!

Catherine Hendricks
Manager, State Government Relations

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703-837-1017 office
703-739-9497 FAX
AMERICAN OPTOMETRIC ASSOCIATION

From: Jackie Rivers [mailto:jrivers@sceyedoctors.com]
Sent: Tuesday, March 01, 2016 10:36 AM
To: Carey, Daniel <DCarey@AOA.ORG>; Hendricks, Catherine <CHendricks@AOA.ORG>
Subject: FW: Meeting Monday

Hi Daniel and Catherine! Wanted to share with you the proposed edit from Opternative. I've attached the latest version of our bill.

From: Angelia Smith Owens [mailto:angelia@kmso.net]
Sent: Tuesday, March 01, 2016 10:30 AM
To: Michael Campbell <mcamp16035@aol.com>; Jackie Rivers <jrivers@sceyedoctors.com>
Cc: 'Mark Kelley' <mark@kmso.net>
Subject: FW: Meeting Monday

FYI from Opternative's lobbyist. His reference isn't clear, but I believe he means they want to revise definition of provider, which is (7) in Julie's amendment from last week and (11) in the bill as introduced. (Jackie please forward)

From: Adams, Robert [mailto:RAdams@mwcllc.com]
Sent: Tuesday, March 01, 2016 10:16 AM
To: Julie Price
Cc: Stokes-Murray, Lynn (LStokes-Murray@MCNAIR.NET); Puhlasky, Jason J. (Jason@parkerpoeconsulting.com); JCNicholson@scmedical.org; kkent@hsbcopperdome.com; 'Bruning, Shannon' (SBruning@mcnair.net); ronscott11@aol.com; Damon Jeter (djeter@jetcorpconsulting.com); benhomeyer@1101publicaffairs.com; Mark Kelley; 'Angelia Smith Owens'; Ron Scott; Boan, William D.; Phillips, Katherine A.; 'rebecca.leach@llr.sc.gov'; Boan, William D.
Subject: RE: Meeting Monday

Group –

I apologize for this, but Billy and I have received new instructions from our client, Opternative, which are different than what I communicated to you in yesterday's meeting.

We would like to make a change to section (11), striking every word after Optometry:

The following would be deleted:

"or the South Carolina Board of Medical Examiners."

Again, we apologize for any confusion this may have caused.

Thanks,
Robert

Robert Adams
SVP Government Relations - State
McGuireWoods Consulting LLC
1301 Gervais Street

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From: Jackie Rivers <jrivers@sceyedoctors.com>
Sent: Tuesday, April 01, 2014 11:59 AM
To: Angelia Smith Owens
Subject: FW: AOA Update on Opternative
Attachments: AOA warns public about online eye exams.pdf

Hey – is this what you were talking about?

From: Jackie Rivers
Sent: Monday, March 17, 2014 3:38 PM
To: 'Angelia Smith Owens'; 'Mark Kelly'
Cc: Wayne Cannon; 'jvaught@vaughteye.com'; 'David McKenzie'
Subject: FW: AOA Update on Opternative

Good afternoon Angelia and Mark. Dr. Cannon asked me to forward you this update on Opternative, just so you all are in the loop on what's going on with this online "eye exam" website that is supposed to be live this summer.

I've attached the article as a pdf. Crazy concept, hard to believe it's being put in place!

From: Reuwer, Brian [mailto:BReuwer@AOA.ORG]
Sent: Thursday, March 13, 2014 2:52 PM
To: State Executive Directors
Cc: Hymes, Jon; Brauns, Renee; Frawley, Jennifer A.; Skiles, Kristen
Subject: AOA Update on Opternative

Good afternoon,

I want to send you a quick update on AOA actions on the Opternative issue, which is the online "eye exam" website that is supposed to be live this summer. The AOA has written an article that was published this morning on aoa.org/news that describes a little more detail on our response which you may want to share with your members. In addition, you might find the article in the Chicago Tribune interesting as well, while Opternative did not comment on our letter, I think the story shows insight into how they will likely respond back to us.

From an SGRC perspective, we are investigating what legal justifications they may use once the program goes live plus the wider issue of the introduction of kiosks in your state. Once we have completed this review, we will make recommendations to state affiliates about suggested strategies to stop this from operating in your state.

If you have any questions about the article or anything else associated with Opternative or kiosks please do not hesitate to contact me.

Brian

http://www.aoa.org/news/advocacy/aoa-warns-public-about-online-eye-exams
http://bluesky.chicagotribune.com/originals/chi-opternative-aoa-warning-dangers-bsi-20140312,0,0.story

Brian Reuwer
Associate Director, State Government Relations
American Optometric Association

1505 Prince St. Suite 300
Alexandria, VA 22314
Phone - 703-837-1343
Cell - 517-290-3532
BReuwer@aoa.org

Click here to view a 99-second video on the historic AOA SUPER ADVOCACY CONFERENCE 2013, and for information on attending next year's meeting.

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AOA warns public about online eye exams

The AOA is warning consumers about possible risks associated with online refractive eye exams.

Such online sites tout convenience. But any alleged advantages come with risks, the AOA cautions. In a statement, AOA President Mitchell T. Munson, O.D., says the association has received an increasing number of questions about the safety and validity of this type of online test.

The AOA contends that such tests are no substitute for an in-person comprehensive eye exam by an optometrist or ophthalmologist.

"We believe that claiming to have performed an eye exam without physically examining a patient is offering misleading information and may contribute to a patient believing—incorrectly—that his or her eye health needs have been met," Dr. Munson says.

The value of in-person exams

One such website says its online refraction test is only available to those between the ages of 18 and 40 who are in good health—meaning people with no history of conditions such as hypertension, cataracts, glaucoma or diabetes.

An online exam has the potential to miss critical, underlying health problems.

But what if patients don't know they have these diseases?

Diabetes, for example, affects more than 8 percent of the U.S. population, but roughly 7 million people are unaware that they have this condition, according to estimates from the Centers for Disease Control and Prevention.

Like diabetes, most systemic conditions are asymptomatic in their earliest and most treatable stages.

These are precisely the types of chronic conditions an OD can diagnose and manage during a comprehensive eye exam, the AOA maintains. A recent study by UnitedHealthcare supports the role ODs play in identifying chronic health issues.

An online exam has the potential to miss critical, underlying health problems, says Beth Kneib, O.D., director of the AOA Clinical Resources Group.

"If you look at refraction only, you're not personally looking in the patient's eye, you're not examining their eye health, you're not looking at their history or observing medical conditions firsthand," she says.

Perhaps a patient is having a shift in vision because of cataracts and isn't aware of it. "And they could be getting better treatment by having the cataract addressed. Maybe they have diabetes and

they have fluctuating vision, and they don't know their glucose is causing their decreased vision if they're just getting lens prescriptions over the Internet," Dr. Kneib says.

Dr. Munson cautions that any delay in intervention in such cases could result in progressive vision damage and more costly and intensive treatments down the road.

"Consumers with chronic conditions such as diabetes or hypertension may be at significant risk regarding proper diagnosis and treatment of potentially sight-threatening diseases if they are not properly evaluated by an eye doctor," Dr. Munson says.

The AOA is calling for a thorough evaluation of online eye-testing sites, and how they might affect patient health. The AOA also plans to monitor these sites and play an active role in fact-checking their claims.

March 13, 2014

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From: angelia@kmso.net
Sent: Tuesday, January 19, 2016 5:18 PM
To: Angelia Smith Owens
Subject: Fwd: SCOPA's Bill - How to Reference

Angelia Smith Owens
Kelley, McCain & Smith Owens, LLC
803.608.4800 cell
803.254.1110 office
Angelia@kmso.net

Begin forwarded message:

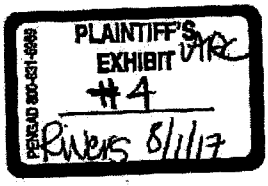
From: Jackie Rivers <jrivers@sceyedoctors.com>
Date: January 19, 2016 at 1:26:43 PM EST
To: "repmkelley@aol.com" <repmkelley@aol.com>, Angelia Smith Owens <angelia@kmso.net>, Philip Flynn <pdflynn@hotmail.com>, Wayne Cannon <wmcannon15@gmail.com>
Cc: Mike Campbell <mcamp16035@aol.com>, Jennie Smith Zolman <jenniesmithod@yahoo.com>
Subject: FW: SCOPA's Bill - How to Reference

Hi all!! Please see message below from Dr. Campbell. Dr. Jennie Zolman asked me to be sure that I sent you this message as well. Wanna try and keep us all on the same page. Thanks!!

From: Jackie Rivers
Sent: Tuesday, January 19, 2016 11:40 AM
To: Anna Balderson <abalderson@sceyedoctors.com>; Bob Branch <jeyes4us@yahoo.com>; David McKenzie <drdavid@mckenzieeyecare.com>; Jennie Smith Zolman <jenniesmithod@yahoo.com>; Johndra McNeely <uptownnw@yahoo.com>; Justine O'Dell <justinejodell@gmail.com>; Mike Campbell <mcamp16035@aol.com>; Mike Zolman <focusedeyedoc@yahoo.com>; Pete Smith <smithforhouse@gmail.com>; Ted Newman <tnewman123@bellsouth.net>
Subject: SCOPA's Bill - How to Reference

All, Dr. Campbell asked me to let everyone know that it will be very important, once our bill gets dropped and we start talking with legislators and encouraging members to do the same that we refer to the bill as the Eye Care Consumer Protection Law. It will be important that we not refer to this bill as the "kiosk" bill. We want this bill to be about ensuring the safety and wellbeing of the public and not telemedicine. This is also a recommendation from the AOA as well.

Thanks!



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From: Michael Zolman <focusedeyedoc@yahoo.com>
Sent: Tuesday, May 17, 2016 11:16 PM
To: Mike Campbell; Jackie Rivers; Anna Balderson; Jennie Smith; Ted Newman; David McKenzie; Johndra McNeely; Pete Smith; Bob Branch; Justine O'Dell; Mark Kelley; Angelia Smith Owens
Subject: Fw: Governor Haley's Decision on The Consumer Eye Care Protection Bill

Excellent information....especially coming from someone close to Sen. Leatherman

Michael W. Zolman, OD

Infinity Eye Care and Low Vision Rehabilitation Center
325 Folly Rd., Suite #109
Charleston, SC 29412

P: 843.795.6464
F: 843.795.6433
www.myinfinityeyecare.com

On Tuesday, May 17, 2016 8:31 PM, christy wallace <bcbcwallace@yahoo.com> wrote:

Dr. Zolman, I spoke with a representative today from Jay Jordan's office and he also met with Senator Hugh Leatherman's campaign manager. He says he will keep me posted as things move forward but that it looks really good right now that this veto will be over-ridden by the senate and the house. I will update you if I hear more from him. Thanks for your hard work! Dr. Christy Wallace Florence

On Tuesday, May 17, 2016 7:44 AM, Michael Zolman <scoa@ciclt.net> wrote:

May 17, 2016
Dear Colleagues,

It comes with great concern and disappointment to inform you that Governor Haley has **VETOED** our bill, S.1016 - The Consumer Eye Care Protection Bill. Despite all of our support for her in the past.....Despite all of our phone calls, emails and faxes asking her to support our bill....Despite our bill UNANIMOUSLY passing both the House and Senate, she has decided to stand alone in the SC government and veto our bill. Governor Haley apparently is more concerned with not preventing technology, regardless if it has been proven or not and regardless of the potential harm it could cause, than protecting the safety of her citizens. She is singling out OPTOMETRY as being self

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serving and being 'just a small group of eye care professionals'. (**Please click here to review her official explanation of her veto**).

But this fight is not over and **WE WILL NOT GO DOWN WITHOUT A FIGHT**! We have a plan and a very good chance to still make our bill a law. We will VETO her veto but we need your help to do so!

Here's how this works:

The Senate and House will have a chance to vote to override her veto. It takes 2/3 of those voting to override her veto in the Senate and if so it will go to the House for the same 2/3 vote. It only needs one vote in the Senate and House to bring up the chance to override the governor's veto and to get the process started, which we are confident we will get. Once the Senate votes, if the Senate does not get 2/3 then the bill is dead and will not go to the House. If the governor's veto is overridden in the Senate the bill comes to the House and if it fails to get the 2/3 vote in the House then the bill also dies. But, if it is overridden in the Senate and the House, then the bill becomes law.

Remember, our bill originally passed UNANIMOUSLY in both the House and Senate so we feel we have a good chance to be successful with overriding the governors veto. Make no mistake though, the governor has her 'people' in both the House and Senate that will do whatever she asks them to do (although we believe this number to be relatively small). So what was once a 'yea' vote could become a 'nay' vote if your Senator does not get your feedback.

What YOU need to do:

Call your Senator TODAY! Since our bill was first introduced in the Senate, it must get 2/3 majority first before moving to the House. **Click here to access a spreadsheet that will tell you who your senator is**. (Scroll through to find your society and name and senator's contact information). Tell your senator you are asking for their support to override the governors veto of S.1016. Tell them this bill is crucial for maintaining the standard of healthcare in our state and that it is to prevent UNTESTED, NON-FDA APPROVED technology that puts the vision, eye health and general health care of their constituents at risk. Tell them this bill is EXTREMELY IMPORTANT to the SC Optometric Physicians Association and SC Medical Association, (the only groups of eye care professionals), and most importantly the citizens of SC.

We do NOT want to make this an anti-Opternative arguement as Legislators frown upon legislation that singles out and restricts a specific business. We must maintain the argument that this bill protects the consumer from false and misleading claims to what an eye exam is as well as that it protects our citizens from unproven technology and that anything less jeopardizes consumers health care.

Once we get 2/3rds vote in the Senate, we will let you know and then we will proceed to do the same for the House but first we must focus our attention on the Senate.

Also, remember this is an election year. A lot of legislators are up for re-election and want your vote. Your voice will be heard a lot more clearly than the governors but will not be heard at all if you do not call.

Do not let apathy kill this bill.
Do not let Governor Haley trivialize and demean our profession to Congress.
Do not let Governor Haley have the final say as to what is acceptable for your patients.

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EXHIBIT 6

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STATE OF SOUTH CAROLINA
DEPARTMENT OF LABOR, LICENSING AND REGULATION
BEFORE THE MEDICAL BOARD OF EXAMINERS

IN THE MATTER OF	)	
	)	
BOARD BUSINESS/DISCUSSIONS	)	
	)	TRANSCRIPT
	)	
	)	
	)	
	)	
	)	

Given before Tina F. Behles, Nationally Certified Court Reporter and Notary Public in and for the State of South Carolina, on Monday, May 2, 2016 through Tuesday, May 3, 2016 at the offices of The South Carolina Department of Labor, Licensing and Regulation, 110 Centerview Drive, Columbia, South Carolina.

Reported by:
Tina F. Behles, CVR-M

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But I'm very hopeful that we will get statutory telemedical legislation here. It'll make our job a lot easier and we can, more or less, as a board put that one to rest as a discussion topic.

The problem is gonna be auditing and enforcing the role of advanced practitioners who are involved in the telemedical field. And I can speak to that later to some of my board members. Thank you. Go ahead, please.

MS. BEESON: There was also a House version of that telemedicine bill. It did not advance beyond the 3M Committee. It is word for word the same version as the Senate Bill prior to its most recent amendment. I think it was just simply getting it in the correct format for the, the way legislative counsel would draft it. So just, you know, that's out there.

The Eye Care Consumer Protection Law. That is -- actually that has been ratified on Friday. And that pertains to the dispensing of spectacles or contact lenses. The bill says a person in this state may not dispense spectacles or contact lenses to a patient without a valid prescription from a provider.

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This was pushed largely by the optometrist community and it, it arises out of the use of kiosks. So that just, be on the lookout for that bill.

We did not -- because it crossed over into the ophthalmologist community as well as the optometrists, we encouraged that it not be added to either practice act, so it's in a stand-alone chapter, Chapter 24 or Title 40 now. It's the only thing in there so far as we can tell, so that's what that bill does ---

DR. GARDNER: --- ophthalmology didn't -- I guess they approved it then? More or less.

MS. BEESON: I think they worked very closely with the optometrists. I think there were a number of meetings. We attended them. A number of work sessions. But they, they worked out something they could live with.

DR. GARDNER: Less rancorous than the prescription part we did last year.

MS. BEESON: There were 14 abortion bills so far as I could tell this year. One survived crossover. That was House Bill 3114, the South Carolina Pain Capable Unborn Child Protection Act. At the end of 2015, it was in

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STATE OF SOUTH CAROLINA)
)
COUNTY OF LEXINGTON)

Be it known that I, Tina F. Behles, Nationally Certified Court Reporter and Notary Public in and for the State of South Carolina, took the foregoing discussion on Monday, May 2, 2016 through Tuesday, May 3, 2016 at offices of the South Carolina Department of Labor Licensing and Regulation, 110 Centerview Drive, Columbia, South Carolina;

That the foregoing 266 pages constitute a true and accurate transcription of the motions made at that time to the best of my skill and ability;

I further certify that I am not counsel or kin to any of the parties to this cause of action, nor am I interested in any manner of its outcome.

In witness whereof, I have hereunto set my hand and seal this 3rd day of June 2016.

/s/ Tina F. Behles [digitally signed]

Tina F. Behles, CVR-M
Notary Public for South Carolina
My commission expires January 13, 2020

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EXHIBIT 7

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STATE OF SOUTH CAROLINA)) COUNTY OF RICHLAND)	IN THE COURT OF COMMON PLEAS FOR THE FIFTH JUDICIAL CIRCUIT Civil Action No. 2016-CP-40-06276
Opternative, Inc.,)) Plaintiff,) v.)) South Carolina Board of Medical Examiners,) South Carolina Department of Labor,) Licensing and Regulation,)) Defendants,)) and)) South Carolina Optometric Physicians) Association,)) Defendant-Intervenor.)	**DEFENDANT-INTERVENOR SOUTH CAROLINA OPTOMETRIC PHYSICIANS ASSOCIATION'S ANSWERS TO PLAINTIFF'S FIRST SET OF INTERROGATORIES**

TO: MILES E. COLEMAN, ESQUIRE; WILLIAM C. WOOD, JR., ESQUIRE; ROBERT J. MCNAMARA, ESQUIRE; AND JOSHUA A. WINDHAM, ESQUIRE, ATTORNEYS FOR PLAINTIFF OPTERNATIVE, INC.:

Pursuant to Rules 26 and 33 of the *South Carolina Rules of Civil Procedure*, Defendant-Intervenor South Carolina Optometric Physicians Association ("Defendant" or "SCOPA"), by and through its undersigned attorneys, hereby answers Plaintiff Opternative, Inc.'s ("Plaintiff" or "Opternative") First Set of Interrogatories to South Carolina Optometric Physicians Association, dated March 3, 2017.

In setting forth answers thereto, Defendant does not waive the attorney-client, work product, or any other privilege or immunity from disclosure which may attach to information called for herein or responsive to the Interrogatories. Defendant does not concede the relevance or materiality of the Interrogatories, and the subject matters to which the Interrogatories refer. These answers are

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submitted by the Defendant subject to, and without in any way waiving or intending to waive, but on the contrary intending to reserve and reserving:

A. All questions as to competency, relevancy, materiality, privilege and admissibility as evidence for any purpose of any of the documents referred to or answers given, or the subject matter thereof in any subsequent proceeding in, or the trial of, this action or any other action or proceeding;

B. The right to object to other discovery procedures involving or relating to the subject matter of the Interrogatories; and

C. The right at any time to revise, correct, add to or clarify any of the answers set forth herein or documents referred to herein.

ANSWERS

Defendant-Intervenor South Carolina Optometric Physicians Association hereby answers Plaintiff Opternative, Inc.'s First Set of Interrogatories, dated March 3, 2017, as follows:

1. Identify the public health or safety purpose you contend is advanced by the ECCPL, and explain specifically how you contend the ECCPL is tailored to achieve that purpose.

ANSWER: The ECCPL protects patients of ophthalmologists and optometrists from unwittingly putting their eye health at risk by obtaining a prescription for corrective lenses without a comprehensive eye examination. Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination.

2. Identify any factual evidence – including, but not limited to, legislative evidence, scientific studies, investigations, interviews, or testimony – that you believe supports the assertion that the ECCPL actually advanced the public health or safety purpose identified in Interrogatory No. 1. For each piece of evidence identified, please provide a brief summary. If you can identify no such evidence, please state that.

ANSWER: See answer to interrogatory number one (1). Defendant-Intervenor anticipates offering expert testimony from one or more of the following witnesses to testify regarding diseases of the eye or other health conditions that can go undiagnosed without a comprehensive eye examination:

Michele Donovan, OD

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Visionary Eye Center, Inc.
2015 Sam Rittenberg Blvd
Charleston, SC 29407
(843) 763-2247

Jennifer Smith Zolman, OD
Draisin Vision Group
President, SCOPA Board
1470 Tobias Gadson Blvd., Suite 115
Charleston, SC 29407

Melvin D. Shipp, OD, MPH, DrPH
2104 North 167th LN
Goodyear, AZ 85395

Mark Robinson, M.D.

3. To the extent your response to any Request in the Requests for Admission served simultaneously with these Interrogatories is anything other than an unqualified "Admit," state the entire basis for your denial of any aspect of that Request and cite any relevant documents on which you base your denial.

ANSWER: See "Denied as Stated" Responses to Plaintiff's Requests for Admission.

With respect to Request for Admission Number 6, Defendant-Intervenor is informed and believes that customary professional standards for both optometrists and ophthalmologists require that a comprehensive eye examination be performed prior to writing a prescription for corrective lenses.

With respect to Request for Admission Number 12, Defendant-Intervenor is informed and believes the ECCPL protects patients of ophthalmologists and optometrists from unwittingly putting their eye health at risk by obtaining a prescription for corrective lenses without a comprehensive eye examination. This belief derives from the collective training and clinical experience of Defendant-Intervenor's members. Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination.

With respect to Request for Admission Number 13, Defendant-Intervenor's response is based upon the collective experience of its members, many of whom do not sell any lenses or frames at all.

With respect to Request for Admission Number 16, Defendant-Intervenor would show that it lobbied for the passage of the ECCPL, rather than the AOA.

With respect to Request for Admission Number 18, Defendant-Intervenor would show that it decided to lobby for the passage of the ECCPL without any particular encouragement or prompting by the AOA.

4. Identify each and every person Defendant-Intervenor intends to have offer testimony in this case, and describe the substance of the anticipated testimony. For each person identified, please provide their full name, current address, and a brief description of their credentials to testify on the matter indicated.

ANSWER: See answer to Interrogatory Number 2.

5. Identify each and every person consulted in the preparation of answers to these Interrogatories, indicating for which Interrogatory they were consulted. For each person identified, please provide their full name, current address, phone number, and job position or title.

ANSWER: Defendant-Intervenor consulted with the individuals identified in Interrogatory Number 2, along with members of Defendant-Intervenor's board of directors.

6. Identify each and every document referred to or examined in the preparation of your answers to these Interrogatories, indicating for which Interrogatory each document was referred to or examined.

ANSWER: None.

Kirby D. Shealy III
Justine M. Tate
ADAMS AND REESE LLP
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Attorneys for Defendant-Intervenor South Carolina Optometric Physicians Association

May 1, 2017.

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EXHIBIT 8

STATE OF SOUTH CAROLINA
COURT OF COMMON PLEAS
COUNTY OF RICHLAND
OPTERNATIVE, INC.,
Plaintiff,
vs. CASE NO. 2016-CP-40-06276
SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS, SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION,

Defendants,

SOUTH CAROLINA OPTOMETRIC PHYSICIANS ASSOCIATION,
Defendant-Intervenor.

DEPOSITION OF: MARK E. ROBINSON, M.D., M.P.H.
DATE: September 6, 2023
TIME: 9:32 a.m.
LOCATION: Prisma Health Ophthalmology
4 Medical Park Road
Columbia, SC 29203
TAKEN BY: Counsel for the Plaintiff
REPORTED BY: TRISHA M. THOMAS, RPR
(Appearing by videoconference)

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Yeah. So I think -- I think he did a good job of asking me what -- what my points were but didn't -- didn't tell me what -- what to say.

Q. Okay. That's what I'm getting at. So Mr. Shealy didn't tell you what to say during this deposition one way or the other?

A. No.

Q. Okay. And we'll circle back to some of the stuff you just mentioned. As you noted, it's going to come up throughout the deposition today. I do want to ask about one thing you just mentioned, though, which is --

A. Sure.

Q. -- you used the word trouble, did you have any trouble with the eye exam. What do you mean by that? I'm sorry. Trouble with the technology. What did you mean by that?

A. Oh, about whether their -- their refractive services were accurate or not.

Q. Okay. And so by saying you didn't have trouble with the technology -- just help me understand you. You're saying you didn't have a concern that it was inaccurate?

A. Right. Yeah, yeah. That the -- the issue with -- with the -- with the case, with my

position, is not that I'm questioning whether they can give accurate refractions or not.

Q. Okay. That's helpful to know. Thanks.

A. Sure.

Q. All right. And you mentioned that you have been deposed before. Can you just, you know, tell me how many times, if you recall?

A. Twice.

Q. Okay. And I don't think we need to get too far into those, but what were those two depositions about?

A. So one was about a patient had been injured in a store, and she was -- I don't remember the exact details. She was, I think, suing the owner of the store, versus the person who -- who injured her, was claiming that she had significant eye injuries afterward, and so I was deposed to report on -- on whether I thought her eye was injured or not after that injury.

The other case was a patient who came to me, and she had cataracts and refractive error, and she felt the other doctor had given her a glasses prescription when she should have been referred for cataract surgery, and so I was giving my opinion on the level of cataract and whether

glasses were a reasonable treatment at that point for her eye.

Q. Okay. And do you recall what your recommendation was one way or the other on that?

A. So on that -- on that last case or on -- on both cases?

Q. On the latter, the second case.

A. Yeah. So on the last case, she had very mild cataracts. It was reasonable to have treated her with glasses beforehand. I think she was concerned that the other eye doctor had been trying to sell her glasses unnecessarily. And she had mild cataracts. It was -- it was reasonable to treat with glasses at that point.

Q. And we'll probably get into some of these concepts today, but if you could just maybe explain for me now why you thought it was reasonable for her to get the glasses at that point in the treatment process.

A. Just 'cause her cataracts were very mild. So a cataract is a cloudy lens, that starts to get a little cloudy, which the process -- well, it probably starts from the time we're very young, but you start having a bit of a cloudy lens in your 40s, usually. And cataracts don't do any damage to

the eyes, so when the vision can still be corrected well, to 20/20, 20/25, we don't recommend cataract surgery at that point. You just get a pair of glasses and -- and fix the refractive error. You don't -- you don't need to have a cataract surgery until it's stopping your best corrected vision to being 20/40 or worse.

Q. Okay. So there are at least some situations, then, when in your medical opinion it's okay to prescribe lenses for patients, you know, even though they may have other kind of systemic or hidden eye diseases, for lack of a better term?

A. Yeah. Absolutely.

Q. Okay. How do you figure out when it's appropriate to do that?

A. Well -- so there's maybe a couple issues there. One is if it's something that's actually making their vision blurry, the underlying disease, one would be, well, if it's something that just makes the vision blurry, or is it something that is damaging the eye. So in the case of a cataract, it does not damage the eye except in rare cases where the cataract has gotten so advanced it could narrow the angle and -- or sometimes it leaks lens material and causes inflammation, but those --

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pages of this document -- well, let's put it this way. Paragraph 3, it looks like isn't about you. The first two are about you. Is that fair to say? Paragraphs 1 and 2?

A. Let's see. Yes. The first two are about me. Number 3 becomes -- right. So number 3 is more of a general statement about ophthalmologists. Yeah. So it's -- it's possible some of those things that were more just sort of facts -- that maybe that came from somewhere else.

Q. Okay. By somewhere else, do you mean Mr. Shealy or an attorney?

A. Yes. Or -- yeah. Or some other fact sheet, maybe. Again, it's -- I don't remember.

Q. Okay. But that category of allegations -- or sorry. That category of paragraphs in this affidavit looks like it would be 3 through -- I'm just scrolling through the shared screen here -- 3 through -- well, you tell me where it ends because you're distinguishing between facts of the case and then your opinions. So where would you kind of cut it off, where the facts of the case end and your opinions begin?

A. Right. Okay.

Q. And let me know if you need me to

scroll on my screen. I think you have a physical copy, right?

A. Yeah. I'll look at my physical copy just 'cause it's easier to read. Let's see.

Q. Sure.

A. Okay. So -- so it looks as though -- again, as I'm skimming, again, I think these other facts are correct on the earlier ones, at least as they relate to the -- to the medical issues, but number 13 is where I give a more specific opinion about corneal irritation and contact lens overwear.

Q. Okay. Any others that you would describe as a specific opinion of yours, as opposed to a fact of the case?

A. Let's see. So number 14 talks about systemic or body-wide disease processes. Number 15, they may go undiagnosed. Number 16. So number 17 is a fact about who the American Academy of Ophthalmology is.

Q. Okay.

A. Number 18 says how frequent the visits should be. Again, it's been so long since I -- I wrote this it's hard for me to remember, again, if, some of this, I could have had help with the editing of it, even on these later statements,

possibly, or maybe just -- just by the way, like, some of it was -- was phrased, but, again, I would still agree with -- like number 14, for example: Ophthalmologists are under an affirmative obligation to look after the health and safety of their patients.

I agree with that. I don't think I would have just written that off the top of my head to have phrased it that way, if that makes that sense.

Q. Okay. Let me see if I can -- I can summarize this. And tell me if this is a fair statement. I'm not trying to put words in your mouth, but I think we can probably pass this topic if we can agree on this.

A. Okay. Good.

Q. It sounds to me like you drafted this document with perhaps some help from Mr. Shealy on some of the items, at least in the process of editing the language, but that you ultimately agree with all of the statements in this affidavit today?

A. Right. I think that sounds reasonable.

Q. Okay. And, you know, having reviewed this document before today, is there anything in here that was true in 2017 when you wrote it but

that you no longer feel is true today?

A. I essentially agree with everything. The only -- again, this is probably a small point, but I said I had never given anyone a refraction without an eye exam in number 20, and that's certainly true professionally. There was a relative I gave a refraction to probably a couple years ago, but I emphasized the importance of them -- of getting a complete eye exam, which they did within a year after I -- I did that.

Q. Okay.

A. So with that one exception, I think, yes, I stand by everything that's in the affidavit.

Q. Okay. My understanding of Paragraph 20 -- and you can correct me if I'm reading this wrong. Let me just read it, and let's see if we can understand it together: It is my opinion to a reasonable degree of medical certainty that almost all practicing eye care providers are very rarely providing a refraction without an eye exam, unless they had previously given the patient an eye examination within the prior year. I cannot ever remember doing so myself, end quote.

So when you say that you are now saying you can recall at least one example of doing that,

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what work is within the prior year doing there?
A. I'm sorry. What is --
Q. Well, let me ask that a different way. When you say within the prior year, what do you mean there?
A. Oh, well, so normally our -- our refractions, they expire after one year. So if I had examined a patient in May and given them a refraction and they lost the refraction for some reason and they call within that year and request another one, then we would print that off and send it to them because it had not expired yet.
Q. Okay. So in that situation you can think of examples of you having done that. Is that fair to say?
A. Oh, yeah. Yeah. Absolutely. If it's within a year and the prescription hasn't expired, we would give them -- we would give them a copy of that prescription, yes.
Q. Okay. And so when you're --
A. And so, again -- and I should say I'm not giving them another refraction. We're just printing off the prescription that was already, you know, given three months prior or six months prior.
Q. You're just essentially renewing the

prescription. Is that a fair way to say?
A. Well, just giving them a copy of the -- of the -- right. Yeah.
Q. Would the new -- would the prescription that you're giving them there be for -- for a year, or would it be for the duration of the year that you had given it to them for?
A. Right. Yeah. It should still expire whenever the original one expired, yeah.
Q. Okay. So in Paragraph 20 here, when you say that you can't remember having doing so -- having done so yourself, you're referring to providing a refraction to a patient without an eye exam outside that one-year period?
A. Right.
Q. Okay. Got it. And then can you tell me what the situation was with the relative, kind of how that played out?
A. Oh. Just that for some reason she wanted to get a pair of glasses quickly, and, again, it was just for glasses, not contact lenses, and so I said, okay, you know, we can give you the prescription and -- but just make sure that you -- you know, you still get a complete eye exam when you're due, so...

Q. Okay. How old was this relative?
A. I don't remember. Now she's -- she was probably around 43.
Q. Okay. Did she come into your practice?
A. No.
Q. How did that -- well, tell me how -- you tell me how it worked 'cause I don't want to keep guessing.
A. Well, right. So -- so this person just asked for me to renew the -- she had an expired prescription and said that she saw fine with it and that she understood -- and so one issue with that is, well, if you renew it and it's not right, you know, it -- there may be something a little bit off, and she understood that, and so 'cause she was my relative, I was willing -- I was willing to do that for her, although normally, again, for my patients I don't do that because if they just come in with an old prescription, it could be off and now they're trying to get a new glasses prescription after they just bought one, so, again, it's not something that you would normally do with somebody, you know, in that sort of person that you don't know or in that professional relationship but that I was willing to do for a relative.

Q. Presumably, though, for your relative you have the same medical standard of care and duty to that person as you would for a patient, right?
A. Oh, absolutely. But -- but, again, I think what this is -- the issue, medically, is that a refraction -- whether you do a refraction or not or whether you want to do it or not, the key is that they still get a dilated, complete eye exam when they're supposed to get one.
Q. Understood. So for that patient who is -- you said 43, approximately?
A. Uh-huh.
Q. It looks to me like on Paragraph 19, this American Academy of Ophthalmology standard, she would be between 40 and 54.
A. Uh-huh.
Q. The academy would recommend her getting that comprehensive eye exam every two to four years; is that right?
A. That's right.
Q. And is that standard, as articulated in Paragraph 19 of your affidavit, consistent with your professional standards?
A. Yes.
Q. Okay. And is it fair to say that's an

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accurate reflection of the ophthalmological standard of care, generally speaking?

A. Yes.

Q. Okay. So for that patient who was your relative who was 43 years old who did receive the prescription for glasses without having a comprehensive eye exam, what was your recommendation in terms of how soon she needed to get her comprehensive eye exam?

A. Yeah. I said -- again, it's been a couple years. I think I said within the next year or so.

Q. Okay.

A. And she got back to us and said that she did do that, so...

Q. Good. Okay. Were you aware one way or the other if she had had a comprehensive eye health exam before coming to you?

A. She said she had, yeah. It's been a while now, so, again, I don't remember exactly -- exactly when that was.

Q. Okay. Did you feel that with this particular patient who happened to be your relative that you were doing anything unsafe?

A. No. Because I trusted her to -- to get

the eye exam.

Q. Okay.

A. And we -- and we have enough follow-up, too, that I would see her -- I would see her again to be able to -- to ask her if she did it.

Q. Okay. That's helpful. Let me take this off the screen for now. We're probably going to come back to your affidavit, but I want to zoom out just a little bit.

I know we kind of jumped the gun on some of these topics, but if you could just step back with me for a second and -- I don't know a ton about your professional background. Would you mind just running me through your career? And I realize this may be a tall order for, perhaps, any of us on this call, but if you could give me kind of a -- the highlight reel of how you got from Mark Robinson, not the doctor, to Mark Robinson the doctor.

A. Sure. Yeah. So for undergraduate I went to the University of North Carolina at Chapel Hill and then did my medical school there, got a one-year degree, my master's of public health. I did my residency. I did an intern year in -- in Virginia, which for ophthalmology your intern year

can be -- can be separate from the ophthalmology residency. I did my ophthalmology residency at Georgetown in Washington Hospital Center in Washington, D.C.

I then went into private practice in Roanoke, Virginia, for three years and then in Danville, Virginia, for three years. And then I did a one-year fellowship in neuro-ophthalmology at Dean McGee Eye Institute in Oklahoma. Then I came here, the University of South Carolina and Prisma Health, in 2015 and have been practicing neuro-ophthalmology and general ophthalmology and being part of a program to train ophthalmology residents since that time.

Q. Okay. About how much clinical experience in terms of years do you have?

A. Well, so I started my residency when I was about 27, and I'm 46, so about 19 years. Well, I guess almost 20 years now.

Q. Okay. And are you -- today, are you practicing in a clinical setting, or are you mostly in a teaching capacity?

A. So it's mostly clinical setting. The way we teach in -- in medicine, for the most part, is we're in a clinical setting, and the residents

come and -- and work with us. So I'll give maybe, you know, a few hours of lecture a month, but most of our teaching is in the setting of seeing patients.

Q. Got it. Okay. What about during the COVID-19 pandemic? How did your practice work during that time?

A. Yeah. So things slowed down a little bit. There may have been a week or two at -- where sort of, with the -- the peak concern of infection, that we stopped seeing patients except for an emergency, but otherwise -- so it was a little -- I don't know if quiet is quite the right word. It was less busy for some number of months in clinic 'cause fewer patients came.

Q. Okay. But y'all were ultimately still practicing for the vast majority of the pandemic?

A. Yes.

Q. Okay. And let me just pull the affidavit that you wrote back up. Wanted to ask a question about just a few definitional things, if you don't mind, so we're kind of all using the same terms today. So let's just start with one that you've already used. It shows up in Paragraph 20, and you talked a little bit about it. What is a

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refraction?

A. Yeah. So a refraction is the process by which you give someone a pair of glasses to correct their refractive error, so that's -- refractive error is just how the light comes into the eye. If it's not focused on the retina, then the vision is blurry, and so a refraction is to help focus that light right onto the retina, so if it's normally focused in front of the retina, you're going to push -- you're going to use lenses to push that focus back. If it's behind the retina, you use lenses to bring that focus forward.

Q. Okay. And is a refraction something that you give to a patient who is receiving a new prescription or a changed prescription, or does a refraction only apply to -- well, let me -- scratch that.

Let me ask it this way. Would you perform a refraction for every single eyeglass prescription you would write?

A. Yes. Yes.

Q. Okay. And that includes renewals of a prescription that hasn't changed?

A. Well, yes. 'Cause if they're -- if they're seeing 20/20, we will double-check that the

prescription is -- is what it -- what it should be.

Q. Okay. And can you walk me through -- as if I know knowing about it, can you walk me through the process of a patient walking into your office and then them walking out of the office with a pair of glasses and a prescription? How does that work?

A. Yeah. So when they come in, if they would -- if they're not seeing well, if they aren't seeing 20/20, then a refraction -- you put a -- it's called a phoropter -- it's spelled P-H-O-R-O-P-T-E-R -- up in front of their face. They can look through. You check one eye at a time. You give them different lenses until you find what the right correction is. You may use a machine called and autorefractor to begin with, which is a machine that can see how the light is focused in the eye, so that would give you a starting place. So you would do that.

And then if they were a new patient or if they were due for their complete eye exam, which most of them are when they come in, then we do the complete eye exam as well. And when they leave, if nothing else was found, you know, that -- that we have to do, we -- then we tell them that their eyes

are healthy and we -- and if they would like the glasses prescription, then we give them the glasses prescription.

Q. Okay.

A. There is -- there is a fee they have to pay for the refraction because that's not paid for by insurance, so that would be, I guess, part of the process as well.

Q. Okay. Do you have any assistants or physician extenders who work in your office?

A. I do, yeah. Yeah. So my -- so my refractions are usually done by my technicians.

Q. Okay. And sorry. Just to get our terms straight, what's a -- what's a technician, in your understanding?

A. Yeah. So an ophthalmic technician is someone who we train to do parts of the eye exam. So they'll check the vision. They can do a refraction. They check the pressure. They can check some of the initial parts of the eye exam before the doctor comes and sees the patient.

Q. Okay. And just so that I understand that, how much of a -- how much of the eye exam can a technician perform before you get involved?

A. They -- they do the initial part, so

they'll help document, I guess, eye exam plus -- in terms of the whole visit, they'll help document the history. So they'll fill out the history. They'll check the vision. They can do a refraction. They can check the eye pressure. They'll check how the eyes move, the motility. They'll check visual fields to finger counting where you close one eye and you will have them count fingers in the different parts of their visual field.

Q. Okay. And are these technicians licensed to practice medicine or optometry or anything like that?

A. No. There's no license. They can get certifications at different levels, but there's no -- there's no requirement of a certification or license for an ophthalmic technician to be an ophthalmic technician.

Q. Okay. You mentioned that most are due for a complete eye exam when they come in to see you, but presumably some are not due for that; is that fair?

A. Yes, that's fair.

Q. Okay. And whether they're due for a comprehensive eye health exam, is it -- that depends on whether they're meeting the frequency

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recommendations set forth in Paragraph 19 of your affidavit?

A. Yes. I would say -- and in practice, though, if I have a patient come in after one year and they have not had a dilated exam, I dilate them if it's been a year, in general, not that I would always do that because that's more frequent than what's recommended, but, in general, if it's been a year and they haven't been dilated, then we dilate them so that we've looked at their whole eye.

Q. Okay. I mean, the standard of care set forth in Paragraph 19, there's nothing unsafe about a physician following that, right, when deciding whether a patient gets that comprehensive eye health exam?

A. Right. Nothing -- you know, so some of those recommendations, right, they're -- they're sort of just things that they think the -- that the statistical risk of something bad happening in a year or two years or four years is low enough and, given the resources that we have, those are their recommendations, at least that's my understanding. Somehow, when I've seen a patient, if they're in my office and it's been a year, I like to dilate because something could have happened in that time

even though it's less than the guidelines set up.

Q. Okay. But I mean, if you decided to follow these recommendations to the letter, do you think you would be violating any kind of patient safety rule or putting patients at risk or anything like that?

A. Well, not violating a rule, but, again, I just recognize that those rules aren't absolutes, right. It's -- again, it's statistics. There -- there could be something I could miss if I did not do that. It would be rare, thankfully.

Q. Let's put it this way. You wouldn't be at risk for discipline, would you, from the medical board or anything like that?

A. No. No.

Q. Okay. And if you heard of a different physician than yourself, a different ophthalmologist, you know, following these guidelines to the letter, would you think that they were putting patients at risk?

A. Well, again, the way you're -- that you're phrasing it, I would say they aren't doing anything wrong medically.

Q. Okay. What about an eye chart? What is that?

A. So an eye chart has different-sized letters that are put usually -- you know, the standard would be at some distance from the eye and then you use that to see how small of the letters someone could read, and that usually correlates with if they have either refractive error or some other eye disease making things blurry but -- but, yes, that's what we use as we refract the patient or just to measure their vision in general.

Q. I see. So an eye chart is part of the refraction process?

A. Well, yes. And also just checking the eye health in general, right, that someone -- if someone can see 20/20, that's -- that's a good sign that -- that certain parts of their eye are -- are working well.

Q. Okay. Have you ever been in a situation where one of these technicians that you work with performs the refraction and then -- suppose there's somebody who doesn't need that comprehensive eye health exam that day and then you prescribe the lenses for them but you don't actually see the patient that day. Has that ever happened?

A. Not that I'm remembering. Usually I

like to at least pop in and -- and see them, look at their eye, double-check the refraction. Because if the refraction hasn't expired yet, then we just print it off. And if a patient comes in for refraction, I like to see them myself.

But if what you're getting at -- is that the standard of care -- I think there probably are -- well, but, again, if somebody's -- yeah. I'm trying to think when somebody would need a refraction checked outside of that one year where it had already expired where I wouldn't see the patient. Yeah. I don't think I would. I'm trying to think, though, if you're getting at, well, what's the standard of care with respect -- would someone just get a glasses prescription. Again, it might be some doctor would think, hey, if it's -- if they had their -- their complete exam, say, 18 months ago, so like you're saying, if they're within that two-year window, then someone -- I imagine there -- that there might be practices where a technician might give that -- might give that refraction and -- and the doctor would sign off on it.

Q. Okay. And at least in that case without performing the comprehensive eye health

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exam because they're within that recommended range or frequency, right?

A. Yes. Yes. I could see that -- I could see that happening, yeah.

Q. Okay. And even if -- even if you haven't done that yourself -- you used the phrase earlier -- there's nothing medically wrong with that. Is that fair to say about this example too?

A. Yes. I think so.

Q. Okay. I want to ask about expirations of prescriptions. So you mentioned that in South Carolina eyeglass prescriptions, contact lens prescriptions expire after one year; is that right?

A. Well, I think -- I believe it's up to the prescriber's discretion when to put, you know, expiration date. I put a year on mine, but I don't know that there's a particular rule about -- about that.

Q. Well, I guess setting aside the law, then, 'cause we're not -- we're not sure about that, you said your practice is to put a year. Is that how all ophthalmologists do it, or is that just, you know, your preference? Or explain how that works.

A. Yeah. It's been my preference and just

what I've, yeah, been used to doing, yeah.

Q. Okay. I just want to understand why.

A. Well, so I would say that one reason is if their refractive error changes and it's more than a year out, they will get an inaccurate glasses prescription. That -- that's probably the main reason why I'm -- I'm putting expiration date on there.

Q. I'm not sure I understand your answer, but that's probably just because I'm not --

A. Well, just -- yeah. No. That's okay. So just that over time our glasses prescriptions can shift a little bit, and so if you've got a prescription and it's been 18 months and then someone takes that into an optical shop and those glasses are made and then they're not quite right, it could be because, well, the patient waited 18 months. You know, so now you've gone through that hassle of getting a wrong pair of glasses rather than just having an up-to-date glasses prescription would -- which would reduce the chance of having a pair of glasses that -- that didn't work for the patient.

Q. Are there patients for whom their vision remains relatively stable for a period of

years?

A. Yes.

Q. How common is that?

A. Yeah. I'd say that's the most common, probably.

Q. Okay. Is that particular to a certain age group or demographic?

A. I would say retractive error in general stays relatively stable for everybody. Well -- everybody. I guess kids, when they're becoming more nearsighted, you know, that's where every -- I mean, sometimes their prescription can change six months or a year, but if we're talking the kind of adult -- you know, adult age range, most of the time it stays stable. Maybe younger adults in their late teens, early 20s may still have progressive refractive error if they're becoming more nearsighted, but I would say for a lot of folks, even 50-year-olds, 60-year-olds, their prescription usually stays about the same unless they're developing a cataract that's worsening that makes them more nearsighted. So most people, it stays relatively stable, I would say.

Q. Well, that's actually sort of why I'm -- that's my understanding too, as somebody who

wears glasses, so I'm just sort of trying to understand why your practice is that you would put a one-year expiration on prescriptions as a matter course if, largely speaking, refractive error is not changing.

A. Yeah. Because let's say 5 percent -- and, again, I don't know what it is. Let's say 5 percent of people, that prescription is going to be wrong. That's a -- you know, that's still enough of a -- of a problem, right? People go and they get glasses made. They don't work. They come in to see us and then we have to -- you know, we give them a new prescription. They have to go get the glasses remade. That's significant time and expense to getting -- you know, getting that problem fixed.

Q. So for that 95 percent, approximately, of patients whose refractive error is not changing -- let me give a -- let me give an example and just see what -- what you would say about this. So suppose I'm -- I'll just use myself. I'm 31. You know, suppose my prescription is working great for me, or at least that's how I perceive it. I'm asymptomatic and that I don't have any noticeable signs of eye disease to my knowledge. I feel good.

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comprehensive eye health exam always involve every single one of those tests?

A. Well, I guess it depends on the definition of comprehensive, but if it's comprehensive, then, yes, I think everything I listed would be part of a comprehensive eye exam. Now, if you mean do we always examine all those things for every patient, like, again, if it's their yearly exam, then yes, we -- now, we don't always do a refraction at their yearly eye exam, but we should always do those other parts that I listed.

Q. Okay. What about it's not a yearly exam? What about -- we're going to keep using me an example. I'm making myself the center of attention today. So suppose I saw you six months ago. I got a comprehensive eye health exam. Again, I'm 31, feel healthy, and I come in and I have something like -- suppose I think I have pink eye, and I come in and you've done the full comprehensive eye health exam six months ago. How would you -- how would you treat me that a situation?

A. Yeah. So normally, if you came in with pink eye, we would still give you a comprehensive

eye exam 'cause we just want to make sure that we're not missing something else, but to -- you know, so the eyes are red 'cause what if there's something inside causing inflammation or that.

But let's say -- what if you came in 'cause you had, like, you know, gotten some particles in your eye. Maybe that's maybe more to your point. If you have some irritation on the surface, then, yeah, we'd look at the surface. We would not perform a comprehensive eye exam. We would make sure your cornea wasn't scratched, and we wouldn't need to dilate your eyes -- eyes for that.

Q. Okay. So it's not the case that every time you see a patient for any reason you're performing this -- the full battery of these tests you described in Paragraph 10, right?

A. That's true.

Q. And whether you perform that full battery of tests depends on the last time the patient got the full battery of tests, right?

A. Yes.

Q. Yes?

A. Sorry. I was nodding my head. Yeah.

Q. That's okay. That's okay. I do it all

the time.

A. Yes.

Q. It depends on -- does it depend on anything else?

A. Well, and their presenting symptoms of what they're coming back with, right? So, yeah, like is there -- do they have something that would make me think, hey, let's just dilate your eyes and make sure nothing's going on in the back of the eye. So it just depends on what their other symptoms were, but if there wasn't something that made me think that, then, no, I wouldn't dilate their eyes.

Q. Okay. Basically you're treating patients on an individualized basis based on their symptoms, history, age, and those kinds of considerations, right?

A. Yes.

Q. Okay. There's not a cut-and-paste approach to this?

A. Right. Although, like you said, as you've been pointing out, the general guidelines, yeah, give you some guidance, but yeah.

Q. Okay. So what you're saying is the -- basically the outer bounds of when they would need

that full battery of tests are set forth in Paragraph 19 in those guidelines, but otherwise you exercise your discretion on a case-by-case basis to figure out what a patient needs?

A. Yes. I think that sounds accurate.

Q. Okay. Oh, and you mentioned certain diseases. Let's see here. Oh, Paragraph 16. And so you have a list of diseases there that a comprehensive eye health examination can detect. And it looks like you mention, glaucoma, cataracts, macular degeneration, binocular vision disorders and corneal dystrophy, diabetes, hypertension. I can't even say the next one, if you could say it for me.

A. Yeah. Hypercholesterolemia.

Q. Autoimmune disorders --

A. It just means high -- yeah. It's just high cholesterol.

Q. Right. Autoimmune disorders and other systemic diseases. So setting aside other systemic diseases, which is maybe -- well, actually, let me just ask it this way. What diseases other than the ones that are listed here in 16 are you looking for during a comprehensive eye health exam?

A. Yeah. So things can be seen on the

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retina, on the optic nerve that are from -- so if someone had something like central nervous system pathology, so a condition -- I'm trying -- so as a neuro-ophthalmologist, one that I see is something called -- it's a bit of a mouthful -- idiopathic intracranial hypertension, where people can have raised intracranial pressure, and that will present as swollen optic discs, which can be detected on an eye exam.

Q. And you wrote a -- you wrote a paper on that, didn't you?

A. I did, yes.

Q. Yeah. Any other diseases that come to mind as ones you would look for during that comprehensive eye health exam?

A. Yeah. So you can look for inflammation in the eye, so that kind of goes along with underlying autoimmune disorders, so do they have inflammation in the front of their eye, inflammation in the back of their eye. So one particular autoimmune disease is called sarcoid, S-A-R-C-O-I-D.

What other things can we see sometimes? I mean -- so -- and I guess to be pertinent to this conversation would be systemic things that are

otherwise asymptomatic, I would think, but sarcoid could fit that bill. Idiopathic intracranial hypertension could -- could be asymptomatic to the patient.

Q. Let me ask it this way. Is there any other major category of problem that you would be looking for that isn't covered by Paragraph 16 here?

A. No. I don't think so.

Q. Okay. I'm just trying to make sure I'm not missing something major. That's all.

A. Uh-huh.

Q. With that relative of yours that we talked about a little while ago, is it possible that she would have -- she could have had any of these diseases as a sort of hidden disease at the time you wrote her that prescription?

A. Well, yeah. I mean, it's possible anybody, yeah, could have these things, yes.

Q. Okay. And so that would have been a reason to recommend that she go get a comprehensive eye health exam, you know, in the future, right?

A. Right. Yeah. In a timely -- in a timely manner, yes.

Q. Okay. Let me take -- oh, actually,

while we're here, Paragraph 18 -- 17 and 18 mention the American Academy of Ophthalmology. We've talked about them a couple times, but could you just tell me what they are?

A. Yeah. So what -- what I have here from -- that I wrote down earlier, so under the age of 40, every five to ten years; age 40 to --

Q. I'm sorry. I'm sorry. I'm just asking what the AAO -- what your understanding of that organization is.

A. Oh, I'm sorry. What the under -- oh, just their organization, the American Academy of Ophthalmology?

Q. Yeah.

A. Oh. Okay. Well, sort of -- like it's our professional organization. They help set guidelines for the practice of ophthalmology. They help provide educational material for both ophthalmologists and patients. We have an annual meeting that is run by the American Academy of Ophthalmology that's educational.

Is that sort of getting at what you were asking?

Q. Yes. Continue if you have more. That's what I'm looking for.

A. Yeah. Just to -- yeah. So, again, they give guidelines. They give education. They give education to the public too, if I didn't mention that before. They now help facilitate a website called EyeWiki, which is really helpful, where ophthalmologists can write articles on different eye health issues, and so that's a pretty comprehensive online resource that's run by the American Academy of Ophthalmology.

Q. Okay. Do you have any involvement personally with the American Academy of Ophthalmology?

A. So I'm a member. I have been on a committee that writes questions, review questions, for their question bank, which I did, I think, for about three years. I haven't done it in the last year and a half. I've attended their meetings. I don't think I've gone in the last couple years, but I've been, probably, to four or five of their annual meetings.

Q. Is it fair to assume, based on the fact that you're citing them in this affidavit, that you consider them to be generally trustworthy?

A. Yes. Absolutely.

Q. Okay. Have you relied on their

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are getting a partial eye exam, I think some number of people who would have had a -- you know, a disease caught on this otherwise routine eye exam will end up not following through on the comprehensive eye exam and will have, you know, some type of health -- you know, either vision loss or if it was -- you know, rarely, like ocular melanoma, life-threatening something -- that those things will happen.

So I don't want to -- you know, if one of my colleagues was going it, you're right. In some degree it's sort of -- each physician, when it comes to technology and practicing, they have to sort of make their -- make their own decisions, but I think there -- the issue I have with it, I think there's going to be a certain number of people that aren't going to follow through on their -- on their comprehensive eye exam, and I guess that's -- that's what's wrong with it, I think. Again, whether I would judge another doctor, is it -- are they doing something wrong? Maybe that's -- maybe that's sort of a subtly different question.

Q. Okay. You know, you talk about what might happen at a population level, and let me just ask this a little bit of a different way. If the

patients who are using these kind of online tools to take a vision test, if the tools don't write new prescriptions, right, if they only do renewals of existing prescriptions if the patient is still seeing well and the patient actually has had a comprehensive eye health exam within the recommended guidelines, would your answer change at all?

A. Well, right. So if -- if somebody actually followed the advice, like if they got their comprehensive eye exams as indicated, then -- then, right, then I don't -- then I wouldn't have a problem with it, yeah.

Q. And, ultimately, the responsibility is the physician, right, who is reviewing that information to say whether the patient has had that exam recently enough, right?

A. Yes. On an individual level, yes.

Q. Okay. And are you aware of -- well, let me back up a little bit. The affidavit mentions Opternative, Incorporated. I know you mentioned earlier today Visibly, right?

A. Right. That's what the company, I think, has changed its name to.

Q. Right. Yeah. Exactly. I just wanted

to make sure you understood the -- the change. In the -- you know, since you wrote this affidavit, which was around 2017 -- what's that difference between now and today? It's six years, right? Do I have that math right?

A. Yes, that's right.

Q. Are you aware of any examples at all of any kind of population effect of patients using Visibly or any similar technologies according to what you're saying in Paragraph 20?

A. I am not, no.

Q. Were you aware of any when you wrote the affidavit?

A. No.

Q. Okay. So you're -- you're not basing this on any statistical evidence or study or anything like that, are you?

A. No. I would say I'm basing it on the -- that there are incidences of asymptomatic eye diseases that can cause vision loss or, rarely, be -- be life-threatening that are picked up on routine eye exams. So I get referred, you know, some of those. So they do exist, but I don't -- and I've seen some of them, but I don't have any statistical data or study.

Q. Okay. Have you ever personally used the -- well, actually, let me ask it this way. I'll scroll up a little bit. So you mention -- let's see here. Well, you say in the first -- the first paragraph, actually, before 1 but in the paragraph, starts with personally. Do you see that? You say that it's -- this affidavit is based on your personal knowledge. Is that right?

A. Okay. Let me see here. Okay. Yes. Personal knowledge of matters set forth herein, yes.

Q. Okay. Do you have any personal knowledge of Visibly's technology?

A. You mean have I done it myself, so to speak? Would that be --

Q. Yeah.

A. So, no, I have not gone online and done their -- yeah, their refractive test.

Q. Okay. So you don't know how the technology works, do you?

A. Not exactly, no. I realize -- I think I have a general idea, but, no, I don't know exactly what they do.

Q. Okay. Are you aware of -- of whether Visibly is cleared by the FDA or not?

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A. I did read on their website that it was FDA-approved, but I haven't read, again, the details of exactly what the FDA said.

Q. Okay. Would you have any -- if the FDA has cleared this software for marketing to the public and use by the public, do you have any reason to question that determination by the FDA?

A. Well, again, I think it gets at what -- you know, what factors was the FDA, you know, considering. I'm not questioning whether it can give an accurate glasses prescription. Again, my concern is that that's just a partial eye exam and, like we said before, that we're not getting a comprehensive eye exam at that time which could result -- which I think would result, if you did it across populations, some number of people not getting their comprehensive eye exam. So it isn't -- I don't have a problem with the technology itself. It's more just that people aren't going to get the comprehensive eye exam that they -- that they need.

Q. Okay. So just to be clear, I think you said this at the very start of the deposition, but I want to make sure we have it -- have it clear. You don't have any concerns about the actual

efficacy of the technology itself?

A. I don't, yeah.

Q. Okay. And this concern you have about patients not getting comprehensive eye health exams if they use a technology like Visibly, isn't it a concern that would apply to any kind of limited care that a patient gets from an ophthalmologist?

A. Generally speaking, yes. It would be -- we could look at the details of that, but, yes, any limited care, you could always miss -- miss something.

Q. Yeah. Well, I'll just give an example you gave earlier. You mentioned the patient who comes in and they've got -- you know, they've had a comprehensive eye health exam in the past from you but they have, like, a corneal scratch or something like that. So in that examination you're focusing on the cornea and the scratch there. Do I have that right?

A. That's right.

Q. Okay. And so it's possible, right, that that patient leaves your office that day with the corneal scratch problem addressed but then they never come back for a comprehensive eye health exam, right?

A. Yes. If it's a corneal scratch, though, if it's our first time seeing them, we -- we will dilate them and look, but if they're a follow-up, then we wouldn't, yeah.

Q. That's what I'm getting at. I'm getting at a patient who is just coming in for a limited set of care on a discrete issue like the corneal scratch.

A. Yes. If we've done a comprehensive eye exam before and they come in six months later and have a scratch, we -- we will just address that -- that problem for that day, yes.

Q. Yeah. And what I'm getting at is just that the problem of a patient not coming back for a comprehensive eye health exam seems like it's a problem that's just sort of true of all ophthalmological practice, right?

A. Yes. I mean, it's -- it's always -- yeah. I mean, we have lots of patients, even when we have an in-person relationship, they know they have glaucoma, we've told them you can go blind, and they don't follow up for their appointments. So, yes, it is -- it is a universal problem.

Q. And that sounds like it might even apply -- tell me if you're getting out of your

depth with this question, and it's okay if you are, but it sounds like that might even apply to other kinds of medical specialists. So, for example, you know, patients who are supposed to get cancer screenings with a certain degree of frequency from a dermatologist, it's possible that you go see a dermatologist, right, for a skin rash and that you just never go back and get that screening, right?

A. Yes. Yeah. I think that -- I think that makes sense. It makes sense it would occur in all areas of medicine, yeah.

Q. Okay. Basically what I'm getting at is the problem of patients not following up and getting comprehensive exams of any form seems like a problem that's just endemic to the practice of medicine.

A. Yes. I agree.

Q. Okay. I think I want to take about a five-minute break, if that's fine with you?

A. Sure.

Q. Okay.

A. Five-minute break sounds good.

MR. WINDHAM: Great.

(A recess transpired.)

BY MR. WINDHAM:

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Q. We are back on the record then. Dr. Robinson, do you understand that you're still under oath?
A. Yes.
Q. Great. Okay. Well, we left off -- before the break we were talking about screenings for health problems that might come up in other medical specialties like dermatology, for example. Do you recall that?
A. I do, yes.
Q. Is your concern that patients need to get comprehensive eye health exams any different than a dermatologist's concern that a patient come in for a comprehensive screening of their skin?
A. I wouldn't think so.
Q. Okay. Certainly not any more dire or important than any other medical specialist's concern that a patient come in for a comprehensive screening, right?
A. I mean, you could add up, like, what are the potentially life-threatening things they're finding versus ophthalmology, but in general, right. I think -- I think the idea or the -- the idea or the principle is the same, yes.
Q. Okay. And I think what I'm just

getting is that, you know, hidden diseases or long-term chronic diseases could be a problem in really any medical specialty, right?
A. Yes. I think they could.
Q. Okay. And so it's important that patients really in any area of medicine get that comprehensive exam within the recommended frequency by that specialty, right?
A. Yes.
Q. And I know that you have a concern about online vision testing software based on Paragraph 20 of your affidavit. Is that fair?
A. Yes. Yeah.
Q. Okay. Is the concern about patients getting prescriptions for corrective lenses through online tools any different than a concern -- well, let me ask it this way. Would you have the same concern if a patient was getting eye drops through telemedicine?
A. Yes. I would -- I would think I would. Anything where you're not getting a comprehensive eye exam, I would be concerned about, yes.
Q. Okay. So really any ophthalmological service that you could provide via telemedicine where you're not in the room with the patient, you

would have this same concern about patients getting comprehensive eye health exams, right?
A. Yes. I mean, there might be -- like let's say it was glaucoma drops, for example, and you were renewing them. Well, now you're weighing, you know, if they don't -- if they don't get their glaucoma drops renewed, they're going to lose vision, so you have something -- a compelling reason to continue to prescribe those glaucoma drops, but in general, yes, I would be concerned about going too long without a comprehensive eye exam, yes.
Q. Okay. Is there anything about prescription lenses that suggests it's a greater concern, or is the concern just sort of ever present when a patient is getting a service through telemedicine?
A. Yeah. I think it's ever present. I think the concern would just be that needing glasses is an incentive for a patient to go get a comprehensive eye exam, so I'd say, you know, that's the kind of concern, is if they don't have that incentive anymore, life's busy, life's expensive, and then they get their glasses and they just don't go. So that would be my concern for

glasses. And there may be some similarities to that in other areas, but that's why -- it isn't just that they're getting a treatment. It's that that treatment is actually an incentive that helps people to go see the eye doctor.
Q. You said there may be some similarities in other areas. Can you think of any examples?
A. Not off the top of my head, but I certainly believe that there -- you know, that there are. Maybe -- have you thought of some?
Q. No. I just -- you know, you mentioned it, so I thought I'd ask you what you meant.
A. Yeah. No. I -- yeah. There could be, but...
Q. I guess what I'm getting at with my question is it sounds to me like glasses is one example of a -- of a type of care a patient can get through telemedicine where, if they get it, they might not have a comprehensive eye health exam, but the same could be true of eye drops or any other kind of ophthalmological care, right?
A. Yes. Again, it's just that eyeglasses are a big incentive, I think, for people to go to -- you know, to -- to get an eye exam but...
Q. Okay. Let's see here. I wanted to ask

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about -- let's just start general with this. So telemedicine, just the concept of telemedicine, can you explain to me as a layperson what that is?

A. Well, it's -- so you have a doctor visit over some sort of virtual platform, I'm assuming like -- like what we're doing here. I have not participated in that myself as a provider, but -- so that's the idea, is you could -- you can get history, you can -- you can see the patient, but to some degree physical exam -- either to some or to a large degree the physical exam is -- is limited.

Q. Okay. You've never used or participated in telemedicine before?

A. Not as a provider, no.

Q. Oh, okay. What about as a patient?

A. Not as a patient myself, no.

Q. Oh, okay. I don't know. I sense that there that's something you're not --

A. Well, I just --

Q. -- that you mean.

A. I have a family member. I have a family member that has -- a child that has done some telemedicine visits.

Q. Okay. What was that for? You don't

have to tell me their identity, of course. I'm just curious at a general level what that was about.

A. Yeah. So I have a child who has some sort of chronic illness, chronic fatigue. We think it's tickborne, but anyway, long story short, that there's not -- we haven't found a local provider who has been as helpful as a provider that was out of town, so...

Q. Okay.

A. So the telemedicine helped us overcome that -- that distance.

Q. Okay. The child with the -- you know, your child, right?

A. Yes.

Q. What specialty is the -- is your kid seeing in this context?

A. So it was a doctor who was -- they specialize in tickborne illnesses, so...

Q. Okay. Presumably that -- your child is not getting, you know, a full, in-person examination by that physician, right?

A. Well, yes. Well, because we've been to see the physician in person too, but -- but yes, but not every visit but...

Q. Not every visit. Okay. And that's okay with you?

A. Yeah. I mean, they've -- she's also had a pediatrician full visit and -- yeah. So she has had a complete exam otherwise but...

Q. Okay. Basically the more limited consultations you have with this physician in between, you know, the comprehensive visits is what gives you confidence that the care is adequate?

A. Yes.

Q. Okay. Is there any reason to think that that principle would be different in the ophthalmological context?

A. No. No. Again, I think if people are really getting their dilated fundus exams, their complete eye exams, then I don't have a problem.

Q. Okay.

A. I think the issue is just, again, some number of people won't actually, you know, do the complete eye exam.

Q. Got it. I was going to ask you some things about telemedicine, but since you haven't used it, I'll probably skip those things.

A. Sure.

Q. May be fruitless.

Let me ask about contact lenses for a second. You know, we were talking earlier about a patient getting a prescription for glasses and the process for that. Is the process of prescribing contact lenses any different?

A. Yeah. So it's a little bit different because the contact lens actually sits on the surface of their eye, so -- and, again, I -- actually I don't prescribe contact lenses anymore. It's been a long time. But most of the time you're going to look at the -- well, not most of the time. All the time you're going to look at the fit of the contact lens after you've prescribed it. So that's for a new prescription. Now, I think for your technology it's for a renewal, so presumably the fit is already correct but -- but yeah.

So you would look at the -- look at the fit on the eye. Sometimes you have to adjust the prescription a little bit from what their glasses prescription is, but -- but yes. So it's a similar process. You still need a refraction but then there's some other parts just to check the fit on the eye, I guess.

I think you're -- you might have muted yourself, maybe.

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Q. Thank you.
A. You're welcome.
Q. I was going to ask why you say, for a technology like Visibly, presumably the fit is already correct?
A. Well, I think you said you were just doing renewals, right? So if it's renewal --
Q. Sorry. Not me but just for clarity on the record, Visibly.
A. Oh. Yeah. So for Visibly I believe the Visibly's website was saying they do renewal prescriptions, so -- so I was just kind of thinking out loud. So the fit there wouldn't -- wouldn't -- it shouldn't be an issue 'cause the fit was already, you know, determined by an in-person visit.
Q. I see. And is that because the fit of a person's contact lenses typically doesn't change? Is that what you're getting at?
A. Right. I think it typically doesn't. Now, I'm a little outside my area of expertise here just because I haven't prescribed contact lenses now in about ten years, so I don't -- sorry. Light going off again -- so I don't -- I don't have personal experience on how often the fit would

change or -- or not change, but my impression is it -- I don't think that would be a big issue.
Q. Your impression based on your training?
A. Well, yeah. My training and then I did prescribe contact lenses for six years in private practice before becoming --
Q. Okay. So also based on your personal experience, then?
A. Yeah. So for at least six or seven years, I didn't see contact lens fits change very much.
Q. Okay. Let me just look over my notes for a second. We may be at the end here.
I think that's all I have for you today, Dr. Robinson, unless anything is raised on -- on any other questions that my friends on the other side want to ask, so I'll pass the witness.
A. Sounds good. Thanks.
MR. MATTHEWS: Mr. Allen, do you have any questions?
MR. ALLEN: Go ahead. If you have some, I'll defer to you if you want to go first but...

EXAMINATION
BY MR. MATTHEWS:
Q. Let's see. I've just got a couple of questions. Dr. Robinson, how you doing?
A. I'm doing well. How are you?
Q. Hey, my name is Gene Matthews. I'm the -- kind of the third wheel here. I'm representing the Department of Labor, Licensing and Regulation and the Board of Medical Examiners, and the reason we're here is because we're required to defend the constitutionality of a statute that our administrative agency enforces.
One basic question I have is this. As I understand it, the rational basis for the ECCPL, the statute that's being challenged, is that the state has an interest in supporting good eye health and that undiagnosed diseases of the eye are a legitimate public health concern and the legislation at issue isn't designed to encourage in-person comprehensive eye examinations to increase the chances of detecting diseases of the eye. Just presume for a moment that's what the legislature had in mind. Do these themes seem to be reasonable to you?
MR. WINDHAM: Objection.

BY MR. MATTHEWS:
Q. Please answer.
A. Yes.
Q. Okay. Tell me why.
A. Well, just -- I mean, I think there is -- there is a concern that there are these undiagnosed diseases that can be either vision-threatening or life-threatening that are sometimes picked up on a routine eye exam.
Q. Okay. And with that in mind, one of the issues that has come up here is that the law does not appear to require an eye care professional to conduct the -- the eye examination if it -- if you come to the -- say I come to my ophthalmologist. As you can see, I wear glasses. I go to my ophthalmologist and I say I just want prescriptions. I don't want an eye exam. The law does not appear to require that physician to say, well, tough, you're going to get one or I'm not going to serve you. Doesn't appear that that's required. To your mind, does that impair in any way the idea behind the law which is that in-person -- requiring in-person eye exams versus remote eye exams will encourage that patient to get the examination that you prefer?

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CERTIFICATE OF REPORTER

I, Trisha M. Thomas, Court Reporter and Notary Public for the State of South Carolina at Large, do hereby certify that the foregoing transcript is a true, accurate, and complete record.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.

Witness my hand, I have hereunto affixed my official seal this 18th day of September, 2023, at Hardeeville, Jasper County, South Carolina.

Trisha M. Thomas, RPR
My Commission expires
December 2027

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Mark E. Robinson, M.D., MPH

September 19, 2023

RE: Opternative v. South Carolina Board Of MedicalExaminers
9/6/2023, Mark E. Robinson , M.D., MPH (#6074916)

The above-referenced transcript is available for review.

Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at cs-midatlantic@veritext.com.

Return completed errata within 30 days from receipt of testimony.

If the witness fails to do so within the time allotted, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions

Opternative Inc. v. South Carolina Board Of Medical

Mark E. Robinson , M.D., MPH (#6074916)

E R R A T A S H E E T

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REASON_____

No corrections.

Mark E. Robinson 9/26/23

Mark E. Robinson , M.D., MPH Date

ELECTRONICALLY FILED - 2024 May 29 3:14 PM - RICHLAND - COMMON PLEAS - CASE#2016CP4006276

Opternative Inc. v. South Carolina Board Of Medical Examiners

Mark E. Robinson , M.D., MPH (#6074916)

ACKNOWLEDGEMENT OF DEPONENT

I, Mark E. Robinson , M.D., MPH, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

Mark E. Robinson 9/26/23

Mark E. Robinson , M.D., MPH Date

*If notary is required

SUBSCRIBED AND SWORN TO BEFORE ME THIS

_____ DAY OF _____, 20___.

_____

NOTARY PUBLIC

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ELECTRONICALLY FILED - 2024 May 29 3:14 PM - RICHLAND - COMMON PLEAS - CASE#2016CP4006276

STATE OF SOUTH CAROLINA	)	IN THE COURT OF COMMON PLEAS
	)	FOR THE FIFTH JUDICIAL CIRCUIT
COUNTY OF RICHLAND	)	
	)	Civil Action No. 2016-CP-40-06276
Opternative, Inc.,	)	
Plaintiff,	)	
v.	)	**AFFIDAVIT OF MARK E. ROBINSON, M.D., M.P.H.**
	)	
South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation,	)	
Defendants,	)	
and	)	
South Carolina Optometric Physicians Association,	)	
Defendant-Intervenor.	)	

PERSONALLY appeared before me Mark E. Robinson, M.D., M.P.H., who deposes and states that the following is based upon his own personal knowledge, except those matters stated upon information and belief, and as to those matters he believes them to be true:

1. My name is Mark E. Robinson, M.D., M.P.H. I am over the age of 21 years, of sound mind, and have personal knowledge of matters set forth herein. I am authorized to make this Affidavit and have reviewed the allegations of the Plaintiff's Complaint in the above-captioned action and the provisions of the South Carolina Eye Care Consumer Protection Law ("ECCPL").

2. Presently, I am a Neuro-ophthalmologist practicing at Palmetto Health/University of South Carolina. I have held this position since 2015. Prior to this position, I was a practicing

Ophthalmologist in the State of Virginia for six (6) years. I received my Bachelor of Science, Doctor of Medicine and Masters in Public Health from the University of North Carolina, Chapel Hill.

3. Ophthalmologists are medical doctors specializing in eye and vision care, who by study and training are qualified to diagnose and treat ocular diseases, perform eye exams and surgeries and prescribe lenses to correct vision problems.

4. Ophthalmologists who practice in South Carolina are licensed and regulated by the BME.

5. Opternative is a healthcare technology company that has produced certain technology which allows ophthalmologists and optometrists to collect refractive data and other information from patients using a computer ("Technology"). The Technology is designed to be used by a patient without having an ophthalmologist or optometrist in the room.

6. Opternative's Technology can be accessed by individuals through Opternative's website.

7. Opternative's Technology relies on an individual's subjective self-reporting to collect refractive data using a computer.

8. The use of Opternative's Technology does not constitute a comprehensive eye examination.

9. Opternative's Technology generates a set of data about a user and the user's ocular refractive error. This set of data is sent to a licensed ophthalmologist, who determines if a corrective-lens prescription is appropriate.

10. Ophthalmologists conduct comprehensive eye examinations as part of their practice. Comprehensive eye examinations consist of, but are not limited to, the following: a

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review of the patient's health history; measuring visual acuity, both aided and unaided; performing a slit lamp examination of the anterior segments of the eyes and eyelids; performing an internal ophthalmoscopic examination through a dilated pupil, including evaluation of the optic nerve head, macular and peripheral retina; performing a refraction; performing tonometry; evaluating pupils; performing confrontation visual field or similar screening field; performing other tests and procedures as indicated by the patient's chief complaint, case history or objective signs and symptoms discovered during the course of the eye examination; making a diagnosis and formulating a treatment plan.

11. Opternative's Technology collects information by soliciting a user's responses to questions and visual stimuli; it does not measure objective data about the user's eyes.

12. A contact lens is considered a medical device that can be used to correct vision, or for cosmetic or therapeutic reasons. A contact lens evaluation is a set of diagnostic tests and procedures performed in addition to a comprehensive eye examination. These tests and procedures include a measurement of the corneal curvature (keratometry or corneal topography) and an evaluation of the anterior segment and tear layer of the eye in relation to the contact lens fit.

13. Corneal irritation and contact lens over-wear increase the risk of a corneal infection. Corneal infections from contact lens wear are not rare and they can cause scarring and loss of vision. Corneal irritation and signs of contact lens over-wear can be detected on corneal examination. Also, a face-to-face visit with an eye care provider allows the provider to emphasize the importance of not over-wearing contact lenses and the importance of contact lens hygiene. A patient's symptoms may be minimal prior to an infection occurring. Opternative's Technology does not perform a corneal evaluation.

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14. Ophthalmologists are under an affirmative obligation to look after the health and safety of their patients, which requires them to use their medical judgment to determine whether their patients' complaints or symptoms pertaining to their eyesight or eye health are indicators of systemic or body-wide disease processes or pathologies. They are likewise obliged to make such determinations even when the disease processes or pathologies are asymptomatic.

15. Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination.

16. An ophthalmologist that conducts a comprehensive eye examination can detect and diagnose certain diseases of the eye, such as glaucoma, cataracts, macular degeneration, binocular vision disorders and corneal dystrophy. They can also detect diabetes, hypertension, hypercholesterolemia, auto-immune disorders and other systemic diseases.

17. The American Academy of Ophthalmology is a national organization of ophthalmologists that, among other things, helps set the standard of care for ophthalmologists nationwide.

18. The official American Academy of Ophthalmology policy regarding comprehensive eye health exams is that "The frequency of ocular examinations should be based on the presence of visual abnormalities and the probability of visual abnormalities developing." American Academy of Ophthalmology Policy Statement, available at https://www.aao.org/Assets/ff742943-87aa-421d-9461-c04f1dd29956/635609992584670000/frequency-of-ocular-exams-2015-pdf (last visited August 23, 2017).

19. The American Academy of Ophthalmology recommends that adults with no signs or risk factors for eye disease should receive a comprehensive medical eye evaluation at age 40 if they have not previously received one. For asymptomatic individuals or individuals without risk factors aged 40 to 54 years old, the Academy's recommended interval for evaluations is 2 to 4 years. For individuals aged 55 to 64 years old, the Academy's recommended interval for evaluations is 1 to 3 years.

20. It is my opinion to a reasonable degree of medical certainty that almost all practicing eye care providers are very rarely providing a refraction without an eye exam, unless they had previously given the patient an eye examination within the prior year. I cannot remember ever doing so myself. Although giving a refraction online in and of itself would be low risk, if it results in patients not obtaining an eye examination, at a population level, there will be a certain amount of disease that is missed. Also, as previously stated, contact lens wearers are at risk for corneal infections and eye examinations are helpful in reducing that risk.

FURTHER AFFIANT SAYETH NAUGHT.

Mark E. Robinson

Mark E. Robinson, M.D., M.P.H.

SWORN TO BEFORE ME THIS
2nd of ~~September~~ October 2017.

_____ (Seal)
Notary Public for North Carolina
My Commission Expires: 12/3/17

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Affidavit of Daniel Bodde (and Exhibits)

Originally attached to Plaintiff's (First) Motion for Summary Judgment and can be found in the Record on Appeal at pages 170-176

Affidavit of Edward Chaum (and Exhibits)

Originally attached to Plaintiff's (First) Motion for Summary Judgment and can be found in the Record on Appeal at pages 177-179

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Opternative, Inc. v. S.C. Board of Medical Examiners, et al.
(Civil Action No. 2016-CP-40-06276)

SECOND AFFIDAVIT OF CHRISTOPHER O'BRIEN, M.D., M.B.A., M.P.H. (APP 374-APP 377)

ELECTRONICALLY FILED - 2024 May 29 3:14 PM - RICHLAND - COMMON PLEAS - CASE#2016CP4006276

IN THE COURT OF COMMON PLEAS FOR THE FIFTH JUDICIAL CIRCUIT

STATE OF SOUTH CAROLINA COUNTY OF RICHLAND Opternative, Inc., Plaintiff, v. South Carolina Board of Medical Examiners, South Carolina Department of Labor, Licensing and Regulation, Defendants, South Carolina Optometric Physicians Association, Defendant-Intervenor.	Civil Action No. 2016-CP-40-06276 **SECOND AFFIDAVIT OF CHRISTOPHER O'BRIEN, M.D., M.B.A., M.P.H.**

I, Christopher O'Brien, M.D., M.B.A., M.P.H., submit the following testimony under oath:

1. I am a citizen of the United States over eighteen years of age. I am of sound mind and fully competent to make this affidavit, which I make knowingly and based on my personal knowledge.

2. I submit this affidavit to supplement the first affidavit I submitted in this matter on May 12, 2023.

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3. As detailed in my first affidavit, Plaintiff Visibly has produced an FDA-cleared online vision test that allows patients to send medical information to an eye doctor for online, asynchronous review—in other words, a store-and-forward telemedical tool—which eye doctors can then use to determine whether it is appropriate to renew the patient's corrective lens prescription.

4. Based on my review of publicly available websites, South Carolina doctors are currently using store-and-forward telemedical tools to collect medical information from patients remotely for the purpose of determining whether it is appropriate to prescribe eye treatments other than lenses. SkinSolutions.MD, for example, allows patients to submit photos of their eyes and responses to medical screening questions to a South Carolina doctor for online, asynchronous review, and based on that information, the doctor can then decide whether to prescribe the drug Upneeq (an eye drop that treats droopy eyelids) or Latisse (a serum that can thicken eye lashes). *See generally* https://www.skinsolutions.md/.

5. Based on my years of experience personally using Visibly (described in my first affidavit), there is no reason why an eye doctor using Visibly's store-and-forward technology to collect medical information from patients remotely would be any less capable of following "the same standard of care as a licensee

employing more traditional in-person medical care" (S.C. Code Ann. § 40-47-37(A)) when deciding whether to renew a patient's corrective lens prescription, than eye doctors who use SkinSolutions.MD, or any similar store-and-forward telemedical tool, to prescribe any other eye treatment.

6. This testimony is true and correct to the best of my knowledge.

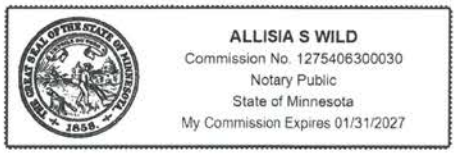
FURTHER AFFIANT SAYETH NOT.

Christopher O'Brien

Christopher O'Brien, M.D., M.B.A., M.P.H.

SWORN to and subscribed before me:

Allisia S Wild



This the 28th day of May, 2024

Notary public for the State of Minnesota

My commission expires 01/31/2027

Notarized remotely online using communication technology via Proof.

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ELECTRONICALLY FILED - 2024 May 31 4:27 PM - RICHLAND - COMMON PLEAS - CASE#2016CP4006276

STATE OF SOUTH CAROLINA)) COUNTY OF RICHLAND)) Visibly, Inc.,) Plaintiff,) v.)) South Carolina Board of Medical Examiners,) South Carolina Department of Labor,) Licensing and Regulation,)) Defendants,) and)) South Carolina Optometric Physicians) Association,)) Defendant-Intervenor.)	IN THE COURT OF COMMON PLEAS FOR THE FIFTH JUDICIAL CIRCUIT Civil Action No. 2016-CP-40-06276 **DEFENDANT-INTERVENOR'S NOTICE OF SUPPLEMENTATION OF THE RECORD**

Defendant-Intervenor South Carolina Optometric Physicians Association ("SCOPA"), by and through its undersigned counsel, hereby supplements the record in support of its Motion for Summary Judgment, filed August 4, 2023, with the entire transcript of Dr. Mark E. Robinson's deposition, taken on September 6, 2023 (**Exhibit 1**), and final version of the 30(b)(6) Deposition of Opternative, Inc. taken on August 1, 2023 (**Exhibit 2)**.

Respectfully submitted,

s/ Kirby D. Shealy III _____
Kirby D. Shealy III (S.C. Bar No. 11556)
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Attorney for Defendant-Intervenor SCOPA

May 31, 2024.

STATE OF SOUTH CAROLINA
COURT OF COMMON PLEAS
COUNTY OF RICHLAND
OPTERNATIVE, INC.,
Plaintiff,
vs. CASE NO. 2016-CP-40-06276
SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS, SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION,

Defendants,

SOUTH CAROLINA OPTOMETRIC PHYSICIANS ASSOCIATION,
Defendant-Intervenor.

DEPOSITION OF: MARK E. ROBINSON, M.D., M.P.H.
DATE: September 6, 2023
TIME: 9:32 a.m.
LOCATION: Prisma Health Ophthalmology
4 Medical Park Road
Columbia, SC 29203
TAKEN BY: Counsel for the Plaintiff
REPORTED BY: TRISHA M. THOMAS, RPR
(Appearing by videoconference)

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ELECTRONICALLY FILED - 2024 May 31 4:27 PM - RICHLAND - COMMON PLEAS - CASE#2016CP4006276

APPEARANCES OF COUNSEL:

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(INDEX AT REAR OF TRANSCRIPT)

MARK E. ROBINSON, M.D., M.P.H.
being first duly sworn, testified as follows:
EXAMINATION
BY MR. WINDHAM:

Q. All right. Well, good morning, Dr. Robinson. My name is Josh Windham, and I represent Visibly, Incorporated, which was formerly called Opternative, Incorporated, the Plaintiff in this case.

How are you doing today?

A. I'm doing well. Thank you. How are you?

Q. Good, good.

A. Good.

Q. I'm thankful that you're here today and that we finally get to meet you.

Do you understand that you're here today to testify in a lawsuit challenging what's called the Eye Care Consumer Protection Law in South Carolina?

A. I do.

Q. Okay. And do you understand that you're here to testify regarding, at least in part, an affidavit that you authored in this case?

A. I do.

Q. Okay. And is there anything, you know, that would prevent you from testifying truthfully today?

A. No.

Q. You're not on any drugs or medications that would impact your ability to testify?

A. No, no. Thankfully not.

Q. All right. And have you ever been deposed before?

A. I have.

Q. Okay. I may ask you about that in a moment, but is it fair to assume you kind of understand how depositions work?

A. I think so. It's been a little while, so if there's any pertinent points you want to refresh me on, that would be fine too.

Q. I'd be happy to. So the basics here are that I'll ask a question, you'll provide an answer, and the court reporter, Ms. Thomas, will try to get everything down. What that means for us today is that our goal is going to be to speak clearly for the court reporter so that she can understand what we're saying. Does that make sense?

A. Uh-huh. It does.

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Q. So no nonverbal answers, right? Sometimes we make sounds, as opposed to using words, and I think, you know, it's most helpful for her if we can articulate what we're thinking in words. Does that make sense?

A. That makes sense.

Q. Okay. And then, you know, I'm going to try to let you finish your answer when I ask a question. Sometimes I get excited and I'm bad at that, so I'm going to do my best today. And then on the other -- on the other end of that, please let me finish my question before you provide an answer. Does that make sense?

A. Sure.

Q. Okay. And, you know, an attorney may object today to a question that I -- that I pose. You know, please still provide an answer unless you're instructed not to -- not to do that.

A. Okay.

Q. And let me know -- ultimately, you're going to be the master of when we take breaks here. You know, if you get tired, feel free to say you need a break, and just -- you know, finish your answer and let me finish my question and then we can kind of go off the record and take a little

break if we need to use the restroom or get lunch or whatever. Hopefully it doesn't go that long.

A. That's right.

Q. All right. Does that make sense?

A. That makes sense.

Q. Okay. Very good. All right. Well, with all that said, did you do anything to prepare for today's deposition?

A. I did. So I looked over the Visibly website. I looked over the statement that I made back in, I think, 2017, was it, that I -- I'm not seeing the date now. I looked -- I tried to find if the American Academy of Ophthalmology had a statement about this, and it looks like the last thing they put out was 2014 and then a news release in 2015. I looked over a systematic review of "Improving Access to Eye Care" as well, which that may not be as relevant but...

And I spoke with Kirby Shealy, the lawyer on the other side. I spoke with him last night, just going over deposition and -- and those sorts of things, sort of our case.

Q. Okay. In terms of that list of documents that you reviewed, we may ask you to produce -- I don't know if you saw -- and I'll

introduce it as an exhibit in a moment. In fact, it might just be easiest to do that right now. Let me pull it up. By the way, do you have access to the Veritext exhibit sharing portal?

A. I do, yeah. I logged on to that -- when I logged on a few days ago, there weren't exhibits in there, at least not that I found, anyway, but...

Q. Okay. And there aren't going to be until I introduce them.

A. Oh, okay. Fair.

Q. Let me try that now, and let's see if it's working for everybody. Just give me one moment.

A. So should I try to log into that too, I guess?

Q. Oh, yes. Let me give you a moment to do that. Just log into that, and the way this will work, I think, is that if I introduce an exhibit in the portal it should show up on your screen as a marked exhibit.

A. Let's see. I see. Access Veritext.

Q. And while you do that, I'm going to introduce what's been marked as -- or, you know, what's going to be marked as Plaintiff's Exhibit 1.

(PLF. EXHIBIT 1, Subpoena in a Civil Case, was marked for identification.)

BY MR. WINDHAM:

Q. Okay. It should be introduced. Let me know if you see it when you're in the portal.

A. Good. Yeah. I've just forgotten my user name. Let's see.

Q. Okay.

A. I remembered the password but not the -- sorry about that. I should have made --

Q. Yeah. Take a moment.

A. Let's see. I think they told me my user name on one of my e-mails, so...

Q. And if you end up having trouble, I can always just share my screen.

A. Okay. Thanks. Let me get one more. All right. Let's see. Where were -- okay. Let me just try one more. Maybe it was just my name was the user names.

Yeah. Maybe, if you don't mind just sharing your screen, that would be great.

Q. Sure. Yeah.

A. Sorry.

Q. I'd be happy to do that. No. No worries.

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A. I was so proud I logged into this this morning I didn't double-check that I could still get into the Veritext.
Q. Not a problem.
Okay. Do you see what I've got there on the screen?
A. I do. State of South Carolina. Yes, I see it.
Q. Okay. And I'm going to scroll through this. It's just a few pages. And I just want to ask if you've seen this document before.
A. I have, yes. That was just requesting that we come to this meeting, I believe.
Q. Okay. So you've seen it. This is the deposition notice in this case -- or the subpoena asking you to attend this deposition. And if we scroll down to the last page there, Exhibit A, have you seen that before?
A. You know, I didn't pay attention to that last thing. It says please provide documents I relied on when writing my deposition -- or my statement.
Q. That's right. And then the second line there has to do with evidence that, you know, you contend supports the assertions in your affidavit,

which we can get to in a moment, the affidavit itself.
A. I see. Okay. Yes. I can -- yeah. I did not notice that at the bottom, so I apologize for that.
Q. Okay. And I may circle back to this in a moment, but what I just want to ask about right now is you mentioned reviewing a few documents before attending this deposition.
A. Uh-huh.
Q. If we asked you to produce those documents to us, would you be able to do that?
A. I would, yes.
Q. Okay.
A. Yeah.
Q. All right. And you mentioned speaking with -- I'm going to take this exhibit off the screen for now. You mentioned speaking with Mr. Shealy before today. Can you describe the nature of your conversation?
A. Yeah. Just about this case and talking about a deposition, what -- the things that I would -- well -- sure if they asked me what I would probably be asked. We talked about, I guess, what the -- that it was an issue of constitutionality

and, I guess, in challenging that, that Visibly would be looking for, I guess, is this arbitrary or not or is there some medical grounds why this law is -- is protecting people, that that would maybe be the main focus; that I am not to receive coaching during the deposition. Those were the main things.
I think I asked if I was supposed to have reviewed any documents ahead of time, and he said no. I think that was mostly -- there was probably a few other details but...
Q. Okay. So -- and this was last night?
A. Uh-huh, yes.
Q. Okay. So last night Mr. Shealy told you not to review any documents before the deposition?
A. No. Let me clarify. I asked him -- I had told him I had gone onto the Veritext and that that deposition file was empty, and I was wondering if that was appropriate. He said that you would probably introduce documents here and there wasn't anything I had to review on -- on Veritext. He did say I should prepare and look at documents I thought were relevant, but --
Q. Okay.

A. -- that there were not -- that there weren't documents already displayed in the Veritext that I was supposed to review. I was concerned because I received that e-mail earlier and logged on and the folders were empty.
Q. Got it. And those will be introduced throughout this deposition, just to clarify that for you.
How long did you talk with Mr. Shealy for last night?
A. Maybe 30 minutes.
Q. And besides the points that you just mentioned, did he tell you what to say in any particular way?
A. He did not. He sort of asked me what -- we kind of went over the main points, and I told -- he asked me what I thought. I told him -- again, so just -- which maybe is getting into things we would say later -- that the issue is it's a partial eye exam.
He asked me if I had any trouble with the technology itself. I said no, not that -- not that I knew of and -- and he -- and he said yeah, that that wasn't their case, that there was a problem with the technology itself.

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Yeah. So I think -- I think he did a good job of asking me what -- what my points were but didn't -- didn't tell me what -- what to say.

Q. Okay. That's what I'm getting at. So Mr. Shealy didn't tell you what to say during this deposition one way or the other?

A. No.

Q. Okay. And we'll circle back to some of the stuff you just mentioned. As you noted, it's going to come up throughout the deposition today. I do want to ask about one thing you just mentioned, though, which is --

A. Sure.

Q. -- you used the word trouble, did you have any trouble with the eye exam. What do you mean by that? I'm sorry. Trouble with the technology. What did you mean by that?

A. Oh, about whether their -- their refractive services were accurate or not.

Q. Okay. And so by saying you didn't have trouble with the technology -- just help me understand you. You're saying you didn't have a concern that it was inaccurate?

A. Right. Yeah, yeah. That the -- the issue with -- with the -- with the case, with my

position, is not that I'm questioning whether they can give accurate refractions or not.

Q. Okay. That's helpful to know. Thanks.

A. Sure.

Q. All right. And you mentioned that you have been deposed before. Can you just, you know, tell me how many times, if you recall?

A. Twice.

Q. Okay. And I don't think we need to get too far into those, but what were those two depositions about?

A. So one was about a patient had been injured in a store, and she was -- I don't remember the exact details. She was, I think, suing the owner of the store, versus the person who -- who injured her, was claiming that she had significant eye injuries afterward, and so I was deposed to report on -- on whether I thought her eye was injured or not after that injury.

The other case was a patient who came to me, and she had cataracts and refractive error, and she felt the other doctor had given her a glasses prescription when she should have been referred for cataract surgery, and so I was giving my opinion on the level of cataract and whether

glasses were a reasonable treatment at that point for her eye.

Q. Okay. And do you recall what your recommendation was one way or the other on that?

A. So on that -- on that last case or on -- on both cases?

Q. On the latter, the second case.

A. Yeah. So on the last case, she had very mild cataracts. It was reasonable to have treated her with glasses beforehand. I think she was concerned that the other eye doctor had been trying to sell her glasses unnecessarily. And she had mild cataracts. It was -- it was reasonable to treat with glasses at that point.

Q. And we'll probably get into some of these concepts today, but if you could just maybe explain for me now why you thought it was reasonable for her to get the glasses at that point in the treatment process.

A. Just 'cause her cataracts were very mild. So a cataract is a cloudy lens, that starts to get a little cloudy, which the process -- well, it probably starts from the time we're very young, but you start having a bit of a cloudy lens in your 40s, usually. And cataracts don't do any damage to

the eyes, so when the vision can still be corrected well, to 20/20, 20/25, we don't recommend cataract surgery at that point. You just get a pair of glasses and -- and fix the refractive error. You don't -- you don't need to have a cataract surgery until it's stopping your best corrected vision to being 20/40 or worse.

Q. Okay. So there are at least some situations, then, when in your medical opinion it's okay to prescribe lenses for patients, you know, even though they may have other kind of systemic or hidden eye diseases, for lack of a better term?

A. Yeah. Absolutely.

Q. Okay. How do you figure out when it's appropriate to do that?

A. Well -- so there's maybe a couple issues there. One is if it's something that's actually making their vision blurry, the underlying disease, one would be, well, if it's something that just makes the vision blurry, or is it something that is damaging the eye. So in the case of a cataract, it does not damage the eye except in rare cases where the cataract has gotten so advanced it could narrow the angle and -- or sometimes it leaks lens material and causes inflammation, but those --

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those are unusual.
So if it's just making the vision blurry and you can correct their vision with glasses to better than 20/40 and as long as it's not causing glare issues at night or something where even if they're not -- even if they can get to better than 20/40 you might still recommend cataract surgery. But if you can get their vision corrected well enough, then they don't need cataract surgery. So that would be one example.
Now, it's different if they have diabetic macular edema causing blurred vision. In that case glasses -- so that's a problem on the retina, and that can -- it both blurs the vision and damages the retina. So in that case you wouldn't want to just prescribe glasses. You would want to fix the underlying problem. So it depends on what the -- what the underlying problem is, if that makes sense.
Q. Okay. Yeah. That makes sense to me.
All right. And we -- we talked a little bit a second ago about the fact that you wrote an affidavit in that -- in this case. I'm just going to put that on the screen so that we all have it and make sure that you know what we're

talking about when I mention it. One second here.
(PLF. EXHIBIT 2, Affidavit of Mark E. Robinson, M.D., M.P.H., was marked for identification.)
BY MR. WINDHAM:
Q. Okay. I'm introducing what's been marked as Plaintiff's Exhibit 2. And I'll share my screen because I think that's what we're going to have to do here.
All right. Do you see this?
A. I do. And I have a copy of it myself but...
Q. I'm sorry?
A. Yeah. And I have a copy myself, which I have ready as well. But, yeah, I can see it.
Q. Okay. All right. And do you recognize this document?
A. I do.
Q. All right. And I'll just scroll through from front to back just so that we've got full thing on the screen. And what is this document that I'm showing you?
A. Yeah. This is the affidavit. This is the -- my summary of -- of my testimony on the issue.

Q. Okay. Great. And you wrote this document, looks like in -- let me back up. Who wrote this document?
A. Yeah. I wrote it.
Q. Did you write the first draft?
A. I did. And I think I edited it, and I may -- you know, so it's -- yeah. It's been a while. I don't remember if anyone else gave me any editing tips, but, yes, I wrote it, edited it, and approved it.
Q. Okay. Did you receive any documentation from Mr. Shealy before drafting this document?
A. Not that I remember.
Q. Okay. Did Mr. Shealy offer any sort of compensation for putting this document together?
A. He did. He asked me what my hourly rate was.
Q. Okay. And what did you say?
A. I think I -- I gave him a rate. I don't -- I don't remember what it was, but in the end I felt like I was just giving my opinion for what was best for the state, so I -- I did not charge anything.
Q. Okay. So at the end of the day, you

didn't charge anything?
A. I did not.
Q. Got it. So Mr. Shealy did not provide you documentation before you put this together. That's right?
A. Not that I'm remembering. I don't know if he gave me -- you know, it's possible I was given some sort of pertinent -- you know, what the case was or what the issues were, but not that I remember.
Q. Okay. And did --
A. Oh, go ahead.
Q. I'm sorry. Go ahead.
A. Well, yeah. Just that, from what I remember, this is -- you know, I thought about -- I mean, I say that. You know, some of the -- the stuff at the beginning, like -- like Opternative is a health care technology company that has produced certain technology which allows -- those sort of description may have been something I was given, just some of the -- of the facts of the case, but the -- the opinions about what I wrote as far as the medical issues were my own.
Q. Okay. So let me see if I can clarify this a little bit. It looks like the first couple

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pages of this document -- well, let's put it this way. Paragraph 3, it looks like isn't about you. The first two are about you. Is that fair to say? Paragraphs 1 and 2?

A. Let's see. Yes. The first two are about me. Number 3 becomes -- right. So number 3 is more of a general statement about ophthalmologists. Yeah. So it's -- it's possible some of those things that were more just sort of facts -- that maybe that came from somewhere else.

Q. Okay. By somewhere else, do you mean Mr. Shealy or an attorney?

A. Yes. Or -- yeah. Or some other fact sheet, maybe. Again, it's -- I don't remember.

Q. Okay. But that category of allegations -- or sorry. That category of paragraphs in this affidavit looks like it would be 3 through -- I'm just scrolling through the shared screen here -- 3 through -- well, you tell me where it ends because you're distinguishing between facts of the case and then your opinions. So where would you kind of cut it off, where the facts of the case end and your opinions begin?

A. Right. Okay.

Q. And let me know if you need me to

scroll on my screen. I think you have a physical copy, right?

A. Yeah. I'll look at my physical copy just 'cause it's easier to read. Let's see.

Q. Sure.

A. Okay. So -- so it looks as though -- again, as I'm skimming, again, I think these other facts are correct on the earlier ones, at least as they relate to the -- to the medical issues, but number 13 is where I give a more specific opinion about corneal irritation and contact lens overwear.

Q. Okay. Any others that you would describe as a specific opinion of yours, as opposed to a fact of the case?

A. Let's see. So number 14 talks about systemic or body-wide disease processes. Number 15, they may go undiagnosed. Number 16. So number 17 is a fact about who the American Academy of Ophthalmology is.

Q. Okay.

A. Number 18 says how frequent the visits should be. Again, it's been so long since I -- I wrote this it's hard for me to remember, again, if, some of this, I could have had help with the editing of it, even on these later statements,

possibly, or maybe just -- just by the way, like, some of it was -- was phrased, but, again, I would still agree with -- like number 14, for example: Ophthalmologists are under an affirmative obligation to look after the health and safety of their patients.

I agree with that. I don't think I would have just written that off the top of my head to have phrased it that way, if that makes that sense.

Q. Okay. Let me see if I can -- I can summarize this. And tell me if this is a fair statement. I'm not trying to put words in your mouth, but I think we can probably pass this topic if we can agree on this.

A. Okay. Good.

Q. It sounds to me like you drafted this document with perhaps some help from Mr. Shealy on some of the items, at least in the process of editing the language, but that you ultimately agree with all of the statements in this affidavit today?

A. Right. I think that sounds reasonable.

Q. Okay. And, you know, having reviewed this document before today, is there anything in here that was true in 2017 when you wrote it but

that you no longer feel is true today?

A. I essentially agree with everything. The only -- again, this is probably a small point, but I said I had never given anyone a refraction without an eye exam in number 20, and that's certainly true professionally. There was a relative I gave a refraction to probably a couple years ago, but I emphasized the importance of them -- of getting a complete eye exam, which they did within a year after I -- I did that.

Q. Okay.

A. So with that one exception, I think, yes, I stand by everything that's in the affidavit.

Q. Okay. My understanding of Paragraph 20 -- and you can correct me if I'm reading this wrong. Let me just read it, and let's see if we can understand it together: It is my opinion to a reasonable degree of medical certainty that almost all practicing eye care providers are very rarely providing a refraction without an eye exam, unless they had previously given the patient an eye examination within the prior year. I cannot ever remember doing so myself, end quote.

So when you say that you are now saying you can recall at least one example of doing that,

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what work is within the prior year doing there?
A. I'm sorry. What is --
Q. Well, let me ask that a different way. When you say within the prior year, what do you mean there?
A. Oh, well, so normally our -- our refractions, they expire after one year. So if I had examined a patient in May and given them a refraction and they lost the refraction for some reason and they call within that year and request another one, then we would print that off and send it to them because it had not expired yet.
Q. Okay. So in that situation you can think of examples of you having done that. Is that fair to say?
A. Oh, yeah. Yeah. Absolutely. If it's within a year and the prescription hasn't expired, we would give them -- we would give them a copy of that prescription, yes.
Q. Okay. And so when you're --
A. And so, again -- and I should say I'm not giving them another refraction. We're just printing off the prescription that was already, you know, given three months prior or six months prior.
Q. You're just essentially renewing the

prescription. Is that a fair way to say?
A. Well, just giving them a copy of the -- of the -- right. Yeah.
Q. Would the new -- would the prescription that you're giving them there be for -- for a year, or would it be for the duration of the year that you had given it to them for?
A. Right. Yeah. It should still expire whenever the original one expired, yeah.
Q. Okay. So in Paragraph 20 here, when you say that you can't remember having doing so -- having done so yourself, you're referring to providing a refraction to a patient without an eye exam outside that one-year period?
A. Right.
Q. Okay. Got it. And then can you tell me what the situation was with the relative, kind of how that played out?
A. Oh. Just that for some reason she wanted to get a pair of glasses quickly, and, again, it was just for glasses, not contact lenses, and so I said, okay, you know, we can give you the prescription and -- but just make sure that you -- you know, you still get a complete eye exam when you're due, so...

Q. Okay. How old was this relative?
A. I don't remember. Now she's -- she was probably around 43.
Q. Okay. Did she come into your practice?
A. No.
Q. How did that -- well, tell me how -- you tell me how it worked 'cause I don't want to keep guessing.
A. Well, right. So -- so this person just asked for me to renew the -- she had an expired prescription and said that she saw fine with it and that she understood -- and so one issue with that is, well, if you renew it and it's not right, you know, it -- there may be something a little bit off, and she understood that, and so 'cause she was my relative, I was willing -- I was willing to do that for her, although normally, again, for my patients I don't do that because if they just come in with an old prescription, it could be off and now they're trying to get a new glasses prescription after they just bought one, so, again, it's not something that you would normally do with somebody, you know, in that sort of person that you don't know or in that professional relationship but that I was willing to do for a relative.

Q. Presumably, though, for your relative you have the same medical standard of care and duty to that person as you would for a patient, right?
A. Oh, absolutely. But -- but, again, I think what this is -- the issue, medically, is that a refraction -- whether you do a refraction or not or whether you want to do it or not, the key is that they still get a dilated, complete eye exam when they're supposed to get one.
Q. Understood. So for that patient who is -- you said 43, approximately?
A. Uh-huh.
Q. It looks to me like on Paragraph 19, this American Academy of Ophthalmology standard, she would be between 40 and 54.
A. Uh-huh.
Q. The academy would recommend her getting that comprehensive eye exam every two to four years; is that right?
A. That's right.
Q. And is that standard, as articulated in Paragraph 19 of your affidavit, consistent with your professional standards?
A. Yes.
Q. Okay. And is it fair to say that's an

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accurate reflection of the ophthalmological standard of care, generally speaking?

A. Yes.

Q. Okay. So for that patient who was your relative who was 43 years old who did receive the prescription for glasses without having a comprehensive eye exam, what was your recommendation in terms of how soon she needed to get her comprehensive eye exam?

A. Yeah. I said -- again, it's been a couple years. I think I said within the next year or so.

Q. Okay.

A. And she got back to us and said that she did do that, so...

Q. Good. Okay. Were you aware one way or the other if she had had a comprehensive eye health exam before coming to you?

A. She said she had, yeah. It's been a while now, so, again, I don't remember exactly -- exactly when that was.

Q. Okay. Did you feel that with this particular patient who happened to be your relative that you were doing anything unsafe?

A. No. Because I trusted her to -- to get

the eye exam.

Q. Okay.

A. And we -- and we have enough follow-up, too, that I would see her -- I would see her again to be able to -- to ask her if she did it.

Q. Okay. That's helpful. Let me take this off the screen for now. We're probably going to come back to your affidavit, but I want to zoom out just a little bit.

I know we kind of jumped the gun on some of these topics, but if you could just step back with me for a second and -- I don't know a ton about your professional background. Would you mind just running me through your career? And I realize this may be a tall order for, perhaps, any of us on this call, but if you could give me kind of a -- the highlight reel of how you got from Mark Robinson, not the doctor, to Mark Robinson the doctor.

A. Sure. Yeah. So for undergraduate I went to the University of North Carolina at Chapel Hill and then did my medical school there, got a one-year degree, my master's of public health. I did my residency. I did an intern year in -- in Virginia, which for ophthalmology your intern year

can be -- can be separate from the ophthalmology residency. I did my ophthalmology residency at Georgetown in Washington Hospital Center in Washington, D.C.

I then went into private practice in Roanoke, Virginia, for three years and then in Danville, Virginia, for three years. And then I did a one-year fellowship in neuro-ophthalmology at Dean McGee Eye Institute in Oklahoma. Then I came here, the University of South Carolina and Prisma Health, in 2015 and have been practicing neuro-ophthalmology and general ophthalmology and being part of a program to train ophthalmology residents since that time.

Q. Okay. About how much clinical experience in terms of years do you have?

A. Well, so I started my residency when I was about 27, and I'm 46, so about 19 years. Well, I guess almost 20 years now.

Q. Okay. And are you -- today, are you practicing in a clinical setting, or are you mostly in a teaching capacity?

A. So it's mostly clinical setting. The way we teach in -- in medicine, for the most part, is we're in a clinical setting, and the residents

come and -- and work with us. So I'll give maybe, you know, a few hours of lecture a month, but most of our teaching is in the setting of seeing patients.

Q. Got it. Okay. What about during the COVID-19 pandemic? How did your practice work during that time?

A. Yeah. So things slowed down a little bit. There may have been a week or two at -- where sort of, with the -- the peak concern of infection, that we stopped seeing patients except for an emergency, but otherwise -- so it was a little -- I don't know if quiet is quite the right word. It was less busy for some number of months in clinic 'cause fewer patients came.

Q. Okay. But y'all were ultimately still practicing for the vast majority of the pandemic?

A. Yes.

Q. Okay. And let me just pull the affidavit that you wrote back up. Wanted to ask a question about just a few definitional things, if you don't mind, so we're kind of all using the same terms today. So let's just start with one that you've already used. It shows up in Paragraph 20, and you talked a little bit about it. What is a

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refraction?

A. Yeah. So a refraction is the process by which you give someone a pair of glasses to correct their refractive error, so that's -- refractive error is just how the light comes into the eye. If it's not focused on the retina, then the vision is blurry, and so a refraction is to help focus that light right onto the retina, so if it's normally focused in front of the retina, you're going to push -- you're going to use lenses to push that focus back. If it's behind the retina, you use lenses to bring that focus forward.

Q. Okay. And is a refraction something that you give to a patient who is receiving a new prescription or a changed prescription, or does a refraction only apply to -- well, let me -- scratch that.

Let me ask it this way. Would you perform a refraction for every single eyeglass prescription you would write?

A. Yes. Yes.

Q. Okay. And that includes renewals of a prescription that hasn't changed?

A. Well, yes. 'Cause if they're -- if they're seeing 20/20, we will double-check that the

prescription is -- is what it -- what it should be.

Q. Okay. And can you walk me through -- as if I know knowing about it, can you walk me through the process of a patient walking into your office and then them walking out of the office with a pair of glasses and a prescription? How does that work?

A. Yeah. So when they come in, if they would -- if they're not seeing well, if they aren't seeing 20/20, then a refraction -- you put a -- it's called a phoropter -- it's spelled P-H-O-R-O-P-T-E-R -- up in front of their face. They can look through. You check one eye at a time. You give them different lenses until you find what the right correction is. You may use a machine called and autorefractor to begin with, which is a machine that can see how the light is focused in the eye, so that would give you a starting place. So you would do that.

And then if they were a new patient or if they were due for their complete eye exam, which most of them are when they come in, then we do the complete eye exam as well. And when they leave, if nothing else was found, you know, that -- that we have to do, we -- then we tell them that their eyes

are healthy and we -- and if they would like the glasses prescription, then we give them the glasses prescription.

Q. Okay.

A. There is -- there is a fee they have to pay for the refraction because that's not paid for by insurance, so that would be, I guess, part of the process as well.

Q. Okay. Do you have any assistants or physician extenders who work in your office?

A. I do, yeah. Yeah. So my -- so my refractions are usually done by my technicians.

Q. Okay. And sorry. Just to get our terms straight, what's a -- what's a technician, in your understanding?

A. Yeah. So an ophthalmic technician is someone who we train to do parts of the eye exam. So they'll check the vision. They can do a refraction. They check the pressure. They can check some of the initial parts of the eye exam before the doctor comes and sees the patient.

Q. Okay. And just so that I understand that, how much of a -- how much of the eye exam can a technician perform before you get involved?

A. They -- they do the initial part, so

they'll help document, I guess, eye exam plus -- in terms of the whole visit, they'll help document the history. So they'll fill out the history. They'll check the vision. They can do a refraction. They can check the eye pressure. They'll check how the eyes move, the motility. They'll check visual fields to finger counting where you close one eye and you will have them count fingers in the different parts of their visual field.

Q. Okay. And are these technicians licensed to practice medicine or optometry or anything like that?

A. No. There's no license. They can get certifications at different levels, but there's no -- there's no requirement of a certification or license for an ophthalmic technician to be an ophthalmic technician.

Q. Okay. You mentioned that most are due for a complete eye exam when they come in to see you, but presumably some are not due for that; is that fair?

A. Yes, that's fair.

Q. Okay. And whether they're due for a comprehensive eye health exam, is it -- that depends on whether they're meeting the frequency

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recommendations set forth in Paragraph 19 of your affidavit?

A. Yes. I would say -- and in practice, though, if I have a patient come in after one year and they have not had a dilated exam, I dilate them if it's been a year, in general, not that I would always do that because that's more frequent than what's recommended, but, in general, if it's been a year and they haven't been dilated, then we dilate them so that we've looked at their whole eye.

Q. Okay. I mean, the standard of care set forth in Paragraph 19, there's nothing unsafe about a physician following that, right, when deciding whether a patient gets that comprehensive eye health exam?

A. Right. Nothing -- you know, so some of those recommendations, right, they're -- they're sort of just things that they think the -- that the statistical risk of something bad happening in a year or two years or four years is low enough and, given the resources that we have, those are their recommendations, at least that's my understanding. Somehow, when I've seen a patient, if they're in my office and it's been a year, I like to dilate because something could have happened in that time

even though it's less than the guidelines set up.

Q. Okay. But I mean, if you decided to follow these recommendations to the letter, do you think you would be violating any kind of patient safety rule or putting patients at risk or anything like that?

A. Well, not violating a rule, but, again, I just recognize that those rules aren't absolutes, right. It's -- again, it's statistics. There -- there could be something I could miss if I did not do that. It would be rare, thankfully.

Q. Let's put it this way. You wouldn't be at risk for discipline, would you, from the medical board or anything like that?

A. No. No.

Q. Okay. And if you heard of a different physician than yourself, a different ophthalmologist, you know, following these guidelines to the letter, would you think that they were putting patients at risk?

A. Well, again, the way you're -- that you're phrasing it, I would say they aren't doing anything wrong medically.

Q. Okay. What about an eye chart? What is that?

A. So an eye chart has different-sized letters that are put usually -- you know, the standard would be at some distance from the eye and then you use that to see how small of the letters someone could read, and that usually correlates with if they have either refractive error or some other eye disease making things blurry but -- but, yes, that's what we use as we refract the patient or just to measure their vision in general.

Q. I see. So an eye chart is part of the refraction process?

A. Well, yes. And also just checking the eye health in general, right, that someone -- if someone can see 20/20, that's -- that's a good sign that -- that certain parts of their eye are -- are working well.

Q. Okay. Have you ever been in a situation where one of these technicians that you work with performs the refraction and then -- suppose there's somebody who doesn't need that comprehensive eye health exam that day and then you prescribe the lenses for them but you don't actually see the patient that day. Has that ever happened?

A. Not that I'm remembering. Usually I

like to at least pop in and -- and see them, look at their eye, double-check the refraction. Because if the refraction hasn't expired yet, then we just print it off. And if a patient comes in for refraction, I like to see them myself.

But if what you're getting at -- is that the standard of care -- I think there probably are -- well, but, again, if somebody's -- yeah. I'm trying to think when somebody would need a refraction checked outside of that one year where it had already expired where I wouldn't see the patient. Yeah. I don't think I would. I'm trying to think, though, if you're getting at, well, what's the standard of care with respect -- would someone just get a glasses prescription. Again, it might be some doctor would think, hey, if it's -- if they had their -- their complete exam, say, 18 months ago, so like you're saying, if they're within that two-year window, then someone -- I imagine there -- that there might be practices where a technician might give that -- might give that refraction and -- and the doctor would sign off on it.

Q. Okay. And at least in that case without performing the comprehensive eye health

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exam because they're within that recommended range or frequency, right?

A. Yes. Yes. I could see that -- I could see that happening, yeah.

Q. Okay. And even if -- even if you haven't done that yourself -- you used the phrase earlier -- there's nothing medically wrong with that. Is that fair to say about this example too?

A. Yes. I think so.

Q. Okay. I want to ask about expirations of prescriptions. So you mentioned that in South Carolina eyeglass prescriptions, contact lens prescriptions expire after one year; is that right?

A. Well, I think -- I believe it's up to the prescriber's discretion when to put, you know, expiration date. I put a year on mine, but I don't know that there's a particular rule about -- about that.

Q. Well, I guess setting aside the law, then, 'cause we're not -- we're not sure about that, you said your practice is to put a year. Is that how all ophthalmologists do it, or is that just, you know, your preference? Or explain how that works.

A. Yeah. It's been my preference and just

what I've, yeah, been used to doing, yeah.

Q. Okay. I just want to understand why.

A. Well, so I would say that one reason is if their refractive error changes and it's more than a year out, they will get an inaccurate glasses prescription. That -- that's probably the main reason why I'm -- I'm putting expiration date on there.

Q. I'm not sure I understand your answer, but that's probably just because I'm not --

A. Well, just -- yeah. No. That's okay. So just that over time our glasses prescriptions can shift a little bit, and so if you've got a prescription and it's been 18 months and then someone takes that into an optical shop and those glasses are made and then they're not quite right, it could be because, well, the patient waited 18 months. You know, so now you've gone through that hassle of getting a wrong pair of glasses rather than just having an up-to-date glasses prescription would -- which would reduce the chance of having a pair of glasses that -- that didn't work for the patient.

Q. Are there patients for whom their vision remains relatively stable for a period of

years?

A. Yes.

Q. How common is that?

A. Yeah. I'd say that's the most common, probably.

Q. Okay. Is that particular to a certain age group or demographic?

A. I would say retractive error in general stays relatively stable for everybody. Well -- everybody. I guess kids, when they're becoming more nearsighted, you know, that's where every -- I mean, sometimes their prescription can change six months or a year, but if we're talking the kind of adult -- you know, adult age range, most of the time it stays stable. Maybe younger adults in their late teens, early 20s may still have progressive refractive error if they're becoming more nearsighted, but I would say for a lot of folks, even 50-year-olds, 60-year-olds, their prescription usually stays about the same unless they're developing a cataract that's worsening that makes them more nearsighted. So most people, it stays relatively stable, I would say.

Q. Well, that's actually sort of why I'm -- that's my understanding too, as somebody who

wears glasses, so I'm just sort of trying to understand why your practice is that you would put a one-year expiration on prescriptions as a matter course if, largely speaking, refractive error is not changing.

A. Yeah. Because let's say 5 percent -- and, again, I don't know what it is. Let's say 5 percent of people, that prescription is going to be wrong. That's a -- you know, that's still enough of a -- of a problem, right? People go and they get glasses made. They don't work. They come in to see us and then we have to -- you know, we give them a new prescription. They have to go get the glasses remade. That's significant time and expense to getting -- you know, getting that problem fixed.

Q. So for that 95 percent, approximately, of patients whose refractive error is not changing -- let me give a -- let me give an example and just see what -- what you would say about this. So suppose I'm -- I'll just use myself. I'm 31. You know, suppose my prescription is working great for me, or at least that's how I perceive it. I'm asymptomatic and that I don't have any noticeable signs of eye disease to my knowledge. I feel good.

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And I come to you and say, hi, Dr. Robinson. My prescription has expired. I'd like to get it renewed because I'd like to go get a different pair of glasses somewhere. How would you treat me in that situation?

A. Yeah. So -- and when was your last complete eye exam when you're coming to see me?

Q. So I'm 31 years old. Let's say it was two years ago.

A. Yeah. So I would recommend that you have a complete eye exam and -- and give you a refraction and give you a prescription.

Q. Okay. And would I -- what if I wanted to opt out of that complete eye exam? What would you say?

A. Yeah. I mean, that's a good question. I think, yeah, if somebody came to me and said, hey, I just want the refraction, I don't want the complete eye exam, and they hadn't had one -- and it's been, what, two years?

Q. Let's even just say 18 months for purposes of the example.

A. I mean, if -- probably what I would do is explain, hey, there are rare risks that there could be something worse, you know, going on in

your eye. But if they were there in my chair and had made the appointment, then I -- then I probably would give them that refraction but with that warning that, hey, you know, there are things that could be potentially vision or even life-threatening that we did not check on today.

Q. Okay. So you would -- you basically would provide them a disclaimer that, hey, you're not getting a comprehensive eye health exam today, but those are important and you should get one in the future?

A. Yes. But I wouldn't necessarily be happy with that situation. That's just the -- that's sort of the practical reality of what I would do. I would -- I would prefer that -- and, like, if someone just called my office saying, hey, that's what I want to do, I don't think we would make them an appointment, but once they were in my chair, the reality of the situation is -- is, yes, that's -- that's what I would do, I think.

Q. Okay. I'm a little confused on that, but maybe you can help me understand. So I'm looking at Paragraph 19, and I'm just -- I'll read the first sentence: The American Academy of Ophthalmology recommends that adults with no signs

or risk factors for eye disease should receive a comprehensive medical eye evaluation at age 40 if they have not previously received one, end quote.

So in this example, I'm 31. I have previously received one. Just kind of help me understand the relationship between what you're saying and this recommendation.

A. Well, right. I would say those recommendations are a minimum standard. It's hard -- like if I'm taking care of a patient, I like to have examined them and looked at their -- at their eye health, so that's why that makes me uncomfortable, that they want to come in and say, hey, actually I just want the glasses prescription; don't examine my eyes.

That -- even though, yes, I say, hey -- you know, if they ask me about what the minimum standards are, I'd say you are within the minimum standards, but you're here in my exam lane, like you're this -- you know, you're just this far away from a complete eye exam and there are rare risks. Why not just go ahead and get it. And that way, if it's my patient and now I've established that doctor-patient relationship, I like to have obviously examined the patient and looked at their

eyes, so...

Q. I understand. Okay. So it's -- this is a preference of yours, but ultimately, if a patient comes in and they're in your room and they say, look, I don't have time for this today, I just need a new pair of glasses, that's -- you would do that?

A. I think I would, but I wouldn't be entirely happy with it, but, yes --

Q. Okay.

A. -- I would give the warnings and do it.

Q. Let me ask -- let me ask this with a wrinkle. If you're the one who did the initial comprehensive eye health exam -- suppose you did the exam yourself 18 months ago. Would that change your answer at all?

A. Yes. I would -- I would feel much more comfortable in that situation. I'd still say, hey, you know, you're here. I'd recommend a complete eye exam 'cause rare things can be missed, but they're rare and if -- if you want that refraction and that's all you want today, then -- then I would do that, yes.

Q. Okay. And I think I still want a little clarity on the term refraction and how that

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relates to somebody who has a prescription they like. So when -- if I come in and I've got what I perceive to be perfect vision with my glasses but they've expired, how would that vision testing or vision examination process work for you?

A. Right. So we would check their vision with their glasses on with each eye, see what they saw. So let's say, like in your -- in your case, let's say their prescription hasn't changed and they see 20/20 in each eye, then they would take their glasses off, and we would put that little machine called the phoropter in front of their face, again, check one eye at a time. We would put in different lenses and see if we could improve their prescription from what they had before, and if it ends up measuring the same, then we would end up giving them the same prescription as their old glasses.

Q. Okay. Just out of curiosity, could I -- well, let me back up. With the phoropter, you're using the eye chart, right?

A. You are, yes.

Q. Okay. Is there a way to -- suppose I walk into your office and I've got the glasses that I love and I think I'm seeing great and, instead of

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looking through a phoropter, I just look at the eye chart. Is there a way you can figure out if I'm still seeing okay with my glasses without the phoropter?

A. Yeah. Sure. If you see 20/20 with your current glasses, that's a good sign that they are either right or they're awfully close to being right.

Q. Okay. And so the phoropter would be a way of trying to figure out if we can improve the prescription from where it's at if I'm not seeing perfectly?

A. Yes.

Q. Okay. Scrolling up to Paragraph 10, mentions comprehensive eye examinations. I know we've talked about that a few times already, and I know you've written about it here, but let me just ask if you could say it, you know, today in your own words and then we might go through some of this language. Just could you tell me a comprehensive eye health examination is?

A. A comprehensive eye exam?

Q. Yes.

A. Okay. Yeah. So -- so we check the vision. We, again, check ocular motility. We

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check how the eyes can -- can move in all the different directions. We'll check the visual fields, at least a finger counting with each eye. We'll look at the front of the eye. We like to dilate the eye and then look at the back and look at the optic nerves and the retina. And then also we also take their history as part of that exam.

Q. Okay. Is the technician able to do all of those things, or can they only do some of those things?

A. So they do some. They will record all of the histories for us, past medical history, allergies, medications. We are supposed to -- and I do. I like to double-check that -- what we call the history of present illness, so we'll say, hey, I saw you reported this, is that right, and ask any clarifying questions, so we'll clarify that. But otherwise -- or if there's some pertinent thing where if they're coming in for a problem, I might ask about, oh, are you still on this medication or something like that. But if -- let's say that -- that they're healthy. Then I don't double-check with the -- with the patient the other parts of the histories.

And then I don't -- so, again, the

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technician can check vision. They check the refraction. I'll double-check the refraction sometimes if something has changed in way that I think I -- I want to double-check but not always.

The technician checks the pressure. Most of the time, that's fine, but in my glaucoma patients or if there are other things, I'll double-check the pressure myself. The technician will check the peripheral vision to finger counting and the ocular motility unless I see something.

And then from there, I look. I use -- it's called a slit lamp, which that's our microscope that's mounted horizontally so we can look at the eye. So I'll do the slit lamp to look at -- at the front of the eye, which, again, the eyelids, the conjunctiva, which is the lining on the front of the eye, the cornea, the anterior chamber, the iris, the lens, and then, once the eye is dilated, I can use other lenses to look back at the optic nerve and retina. So the actual looking at the eye with the microscope, sometimes checking the pressure, are parts that the -- that the doctor does.

Q. Okay. I mean, that's a lot of different tests. What I'm wondering is does a

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comprehensive eye health exam always involve every single one of those tests?

A. Well, I guess it depends on the definition of comprehensive, but if it's comprehensive, then, yes, I think everything I listed would be part of a comprehensive eye exam. Now, if you mean do we always examine all those things for every patient, like, again, if it's their yearly exam, then yes, we -- now, we don't always do a refraction at their yearly eye exam, but we should always do those other parts that I listed.

Q. Okay. What about it's not a yearly exam? What about -- we're going to keep using me an example. I'm making myself the center of attention today. So suppose I saw you six months ago. I got a comprehensive eye health exam. Again, I'm 31, feel healthy, and I come in and I have something like -- suppose I think I have pink eye, and I come in and you've done the full comprehensive eye health exam six months ago. How would you -- how would you treat me that a situation?

A. Yeah. So normally, if you came in with pink eye, we would still give you a comprehensive

eye exam 'cause we just want to make sure that we're not missing something else, but to -- you know, so the eyes are red 'cause what if there's something inside causing inflammation or that.

But let's say -- what if you came in 'cause you had, like, you know, gotten some particles in your eye. Maybe that's maybe more to your point. If you have some irritation on the surface, then, yeah, we'd look at the surface. We would not perform a comprehensive eye exam. We would make sure your cornea wasn't scratched, and we wouldn't need to dilate your eyes -- eyes for that.

Q. Okay. So it's not the case that every time you see a patient for any reason you're performing this -- the full battery of these tests you described in Paragraph 10, right?

A. That's true.

Q. And whether you perform that full battery of tests depends on the last time the patient got the full battery of tests, right?

A. Yes.

Q. Yes?

A. Sorry. I was nodding my head. Yeah.

Q. That's okay. That's okay. I do it all

the time.

A. Yes.

Q. It depends on -- does it depend on anything else?

A. Well, and their presenting symptoms of what they're coming back with, right? So, yeah, like is there -- do they have something that would make me think, hey, let's just dilate your eyes and make sure nothing's going on in the back of the eye. So it just depends on what their other symptoms were, but if there wasn't something that made me think that, then, no, I wouldn't dilate their eyes.

Q. Okay. Basically you're treating patients on an individualized basis based on their symptoms, history, age, and those kinds of considerations, right?

A. Yes.

Q. Okay. There's not a cut-and-paste approach to this?

A. Right. Although, like you said, as you've been pointing out, the general guidelines, yeah, give you some guidance, but yeah.

Q. Okay. So what you're saying is the -- basically the outer bounds of when they would need

that full battery of tests are set forth in Paragraph 19 in those guidelines, but otherwise you exercise your discretion on a case-by-case basis to figure out what a patient needs?

A. Yes. I think that sounds accurate.

Q. Okay. Oh, and you mentioned certain diseases. Let's see here. Oh, Paragraph 16. And so you have a list of diseases there that a comprehensive eye health examination can detect. And it looks like you mention, glaucoma, cataracts, macular degeneration, binocular vision disorders and corneal dystrophy, diabetes, hypertension. I can't even say the next one, if you could say it for me.

A. Yeah. Hypercholesterolemia.

Q. Autoimmune disorders --

A. It just means high -- yeah. It's just high cholesterol.

Q. Right. Autoimmune disorders and other systemic diseases. So setting aside other systemic diseases, which is maybe -- well, actually, let me just ask it this way. What diseases other than the ones that are listed here in 16 are you looking for during a comprehensive eye health exam?

A. Yeah. So things can be seen on the

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retina, on the optic nerve that are from -- so if someone had something like central nervous system pathology, so a condition -- I'm trying -- so as a neuro-ophthalmologist, one that I see is something called -- it's a bit of a mouthful -- idiopathic intracranial hypertension, where people can have raised intracranial pressure, and that will present as swollen optic discs, which can be detected on an eye exam.

Q. And you wrote a -- you wrote a paper on that, didn't you?

A. I did, yes.

Q. Yeah. Any other diseases that come to mind as ones you would look for during that comprehensive eye health exam?

A. Yeah. So you can look for inflammation in the eye, so that kind of goes along with underlying autoimmune disorders, so do they have inflammation in the front of their eye, inflammation in the back of their eye. So one particular autoimmune disease is called sarcoid, S-A-R-C-O-I-D.

What other things can we see sometimes? I mean -- so -- and I guess to be pertinent to this conversation would be systemic things that are

otherwise asymptomatic, I would think, but sarcoid could fit that bill. Idiopathic intracranial hypertension could -- could be asymptomatic to the patient.

Q. Let me ask it this way. Is there any other major category of problem that you would be looking for that isn't covered by Paragraph 16 here?

A. No. I don't think so.

Q. Okay. I'm just trying to make sure I'm not missing something major. That's all.

A. Uh-huh.

Q. With that relative of yours that we talked about a little while ago, is it possible that she would have -- she could have had any of these diseases as a sort of hidden disease at the time you wrote her that prescription?

A. Well, yeah. I mean, it's possible anybody, yeah, could have these things, yes.

Q. Okay. And so that would have been a reason to recommend that she go get a comprehensive eye health exam, you know, in the future, right?

A. Right. Yeah. In a timely -- in a timely manner, yes.

Q. Okay. Let me take -- oh, actually,

while we're here, Paragraph 18 -- 17 and 18 mention the American Academy of Ophthalmology. We've talked about them a couple times, but could you just tell me what they are?

A. Yeah. So what -- what I have here from -- that I wrote down earlier, so under the age of 40, every five to ten years; age 40 to --

Q. I'm sorry. I'm sorry. I'm just asking what the AAO -- what your understanding of that organization is.

A. Oh, I'm sorry. What the under -- oh, just their organization, the American Academy of Ophthalmology?

Q. Yeah.

A. Oh. Okay. Well, sort of -- like it's our professional organization. They help set guidelines for the practice of ophthalmology. They help provide educational material for both ophthalmologists and patients. We have an annual meeting that is run by the American Academy of Ophthalmology that's educational.

Is that sort of getting at what you were asking?

Q. Yes. Continue if you have more. That's what I'm looking for.

A. Yeah. Just to -- yeah. So, again, they give guidelines. They give education. They give education to the public too, if I didn't mention that before. They now help facilitate a website called EyeWiki, which is really helpful, where ophthalmologists can write articles on different eye health issues, and so that's a pretty comprehensive online resource that's run by the American Academy of Ophthalmology.

Q. Okay. Do you have any involvement personally with the American Academy of Ophthalmology?

A. So I'm a member. I have been on a committee that writes questions, review questions, for their question bank, which I did, I think, for about three years. I haven't done it in the last year and a half. I've attended their meetings. I don't think I've gone in the last couple years, but I've been, probably, to four or five of their annual meetings.

Q. Is it fair to assume, based on the fact that you're citing them in this affidavit, that you consider them to be generally trustworthy?

A. Yes. Absolutely.

Q. Okay. Have you relied on their

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guidelines outside of what you cite in this affidavit?

A. Yes. I think so.

Q. Just generally, in your practice you tend to follow what they recommend?

A. Yes. I try to.

Q. Okay. Let me pull this down. And we'll pull up -- just because you mentioned it in your affidavit, let me pull up another exhibit here.

(PLF. EXHIBIT 3, American Academy of Ophthalmology Policy Statement on Frequency of Ocular Examinations, was marked for identification.)

BY MR. WINDHAM:

Q. Okay. I'm introducing what's been marked as Exhibit 3. And I'm going to share my screen.

All right. Let me know when you see this document.

A. I can see it.

Q. Okay. What is this document?

A. So it says it's a policy statement from the American Academy of Ophthalmology and then the next subheading is Frequency of Ocular

Examinations.

Q. Okay. I'm asking, really, do you recognize this document. Have you seen it before?

A. I probably looked at it before. I'm not -- again, I did not look at that particular document in preparation for -- for this deposition, so I'm -- I'm not remembering, but, yes, I've probably looked at it in the past.

Q. Okay. Let me just scroll down a little bit to the second page of this. I guess the bottom of the first page and the beginning of the second page. It talks about evaluation and mentions -- well, actually, let me give you a second, if you haven't looked at this before, just to read through the paragraph that starts with Evaluation in bold, and let me know when you've finished.

A. Yeah. Let me see if I can just...

The light's going off. Sorry. That's why I'm waving.

Q. That's okay.

A. Okay. So I just read the evaluation section.

Q. Okay. Is that the information that's cited in your affidavit, to the best of your knowledge?

A. Yes. So I probably did review their -- again, it's been a while, right, so -- and, again -- 'cause I didn't comment on anything prior to the age of age 40 in my affidavit. Let's see. So, yes, I was probably referencing -- yeah. I would have. I would have referenced the -- these guidelines.

Q. Got it. Okay. Is this paragraph an accurate reflection of what you believe today?

A. Well, the only thing -- I think it's interesting. So they say, if you look in -- which is probably why you've pulled this up, but it says: Before the onset of presbyopia (at approximately age 40), the majority of American adults experience no changing refractive error or significant ocular disease and routine eye examinations are not indicated.

So that's interesting 'cause I have this news release from the AAO, and, again, I don't -- you know, which may not be as official as -- as this document, but it says under the age of 40 they're recommending an eye exam every five to ten years.

But I think it's interesting that even in -- even in this sentence here it says, you know,

the majority of American adults experience no significant refractive or ocular disease. I don't know that I would -- personally, I wouldn't go from that statement to then the -- you know, sort of the conclusion of that is and routine eye examinations are not indicated. So I might not agree with that, with that sentence.

Q. And this sentence about before age 40?

A. Right. In the sentence about before age 40, yeah.

Q. Okay. I guess your preference would be something like the other statement that the AAO put out about five to ten years?

A. Yes. I think -- and, again, I have to -- you know, I mean, that's a pretty broad range too, every five to ten years. I think some of what's going into these underlying statements is taking into account resources that a society has to -- you know, to perform these -- these eye exams.

Q. Sure. Okay. So maybe let's put it this way. And tell me if this makes sense. Would it be fair to say it's ideal that if we have infinite resources every single day of your life you would get a comprehensive eye health exam?

A. Well, no. Because there's still the

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resource of time, right, that that -- you know, for the patients, that isn't a good use of their time even if you had -- you know, you're right. It's -- it's a judgment call. At some point you have to come up with some interval that seems reasonable, so...

Q. Okay. Got it. And I guess what I'm trying to understand is whether you believe that this is an interval that seems reasonable or whether you have a different opinion.

A. Yeah. I might say, under age 40, maybe every five years. I don't know that I like the -- as much the five to ten, but, yeah, I might say every -- every five years sounds reasonable.

Q. Okay. So this paragraph sounds reasonable except the under age 40, at which point you would recommend every five years?

A. Yes.

Q. Okay. With regard to -- I think you mentioned a second ago that your -- you were talking about your affidavit, and you said that you weren't commenting on anything under age 40. Did I have that right, or did I mishear you?

A. Oh, I was saying it looks like in my affidavit, because I was quoting those -- let's

see. Yeah. In Section 19 we did not talk about under the age of 40, probably because I was referencing their policy statement which didn't mention anything under the age of 40.

Q. Okay. Does your affidavit -- generally speaking, do the things you say in it apply to folks under age 40 as well?

A. Well, again, for under the age of 40, I think I would say an eye exam -- again, I would -- I would rather go on the -- the shorter end of that five-to-ten-year interval of, say, every five years under the age of 40.

Q. Okay. I'm just asking about the affidavit, broadly speaking. So, for example, you have some commentary in Paragraph 20 of the affidavit. That commentary, does it apply to all age groups or only some age groups, or what are you getting at there?

A. Yeah. I would say all age groups, that I would want a -- yeah. In terms of Paragraph 20, that I would want a complete eye exam on my patients, yes.

Q. Okay. Give me just a second. Let me try to -- all right. Just a few questions about Paragraph 20 here. So let's just start with -- I

want to go sentence by sentence, if you don't mind. The first sentence, I'll just read it: It's my opinion to a reasonable degree of medical certainty that almost all practicing eye care providers are very rarely performing -- or providing a refraction without an eye exam, unless they had previously given the patient an eye examination within the prior year, end quote.

When you say it's your opinion to a reasonable degree of medical certainty, what are you basing that opinion on?

A. Yeah. So that's a good question. Just that this is what I was taught, I guess, in my training, that as doctors, if it's been -- if it's been a year or longer, we -- we do a complete eye exam when they come back.

Q. Okay. When you say your training, do you just mean the school you went to?

A. Yeah. And my residency, from what -- yeah.

Q. Okay. So you're not relying, in this paragraph at least, on data or a study or something like that, are you?

A. No. No.

Q. Okay. No empirical evidence underlying

this statement, right?

A. No. Just, I guess, my experience and being around other eye doctors, but, no, I can't -- I can't quote anything beyond that.

Q. Okay. And then you say -- I'll skip forward a couple sentences. You say, and I'm quoting again: Although giving a refraction online in and of itself would be low risk -- and I'll just stop there for a second. Why do you say giving a refraction online in and of itself would be low risk?

A. Well, 'cause in and of itself, I don't think it's doing -- it's doing harm.

Q. Okay. Why don't you think that?

A. Well -- well, I'm trying to think how to -- maybe I can phrase it in the other way. I think the risk of -- the risk of a -- of a refraction is that the patient now has gotten their glasses. They think that they've gotten the key points of their eye exam and then they don't go somewhere for a complete eye exam when it's due. I guess that's -- that's my concern, is that it's -- it's a partial -- it's part of an eye exam. I don't think that that itself has much risk other than, you know, maybe the glasses aren't quite

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right or something like that but...
Q. Right. In this paragraph, in Paragraph 20, when you use the word refraction, are you talking -- is it fair to say that's a word you're using to describe just providing a prescription for corrective lenses, any prescription for corrective lenses?
A. Yes. Yes.
Q. Okay. So it would include something like -- do you recall the example we went through earlier where, if I'm the patient, I go into your office. I have 20/20 vision with my existing prescription, and I look at the eye chart and you're renewing that prescription without using a phoropter. Would it include that as well?
A. Well, again, we don't -- if they came into my office, we wouldn't renew the prescription just based on them reading 20/20. We would still put them in the phoropter and check their prescription, even if they read 20/20, but -- but that's not -- but that's not my -- my issue here. I think if -- again, that you can -- if somebody was 20/20 and happy, I think you could probably give them that pair of glasses and that would be accurate for -- you know, for most people.

Q. If they had looked at the eye chart and they were seeing well with it, is what you're saying?
A. Yes. Uh-huh.
Q. Okay.
A. Yeah.
Q. What if that patient had -- let me put it this way. If there were an FDA-cleared software, so the FDA has cleared the software for use by physicians, and a patient takes an online vision test in the way we're describing, they're looking at an eye chart online, and the FD -- again, the FDA has cleared this, and the results are sent to a physician and they're still seeing well with their prescription and they have received the disclaimer that says this is not a comprehensive eye health exam, do you have a problem with renewing the prescription in that context?
A. Yeah. Just I think there's something different about it being online and a paper disclaimer versus the patient being in your office and you're actually able to talk with them and sort of have that face-to-face relationship.
Q. And what is different about it?

A. Yeah. That -- we might be getting into philosophy here but --
Q. Well, just to be clear, I'm not -- I'm actually not asking about anything abstract or philosophical. I'm trying to understand, empirically, what the difference is.
A. Well, again, I think there's a difference between a patient in your office that you are speaking to face to face, giving -- giving that disclaimer in person that, like, hey, you know, in -- like you said, in that case of that person comes into my office and they -- and they really want a refraction and that's all they want, I think there is a difference between me saying, in person, hey, this is not what -- you know, what I think is best and -- but since you made the appointment and you're here in my chair, you know, okay, I'll do this, but I would say I wouldn't -- if that -- if that kept happening, I think we would come up with a policy to be, like, whoa, who are all these patients that think they're just coming in for a -- for a refraction and we would -- you know, we would stop doing that. So I think -- I think we have to be careful of the fact I might do something one time as an exception, maybe -- again,

the fact that it's in person I think makes it different, but if that kept happening, I -- then I don't think I would keep making that exception, if that makes sense.
Q. Well, you know, earlier you were talking about the fact that if other ophthalmologists were following these AAO guidelines with regard to frequency of exams, they wouldn't be doing anything medically wrong, and so I'm just trying to understand -- let's just suppose one of your colleagues, somebody else who is not you, was using an FDA-cleared software that operated as a digital eye chart, it provided a disclaimer to a patient that they were not receiving a comprehensive eye health exam, it required them to have had one within these guidelines, within the range required in the guidelines. Is there anything wrong with that physician using this tool for that patient?
A. Yeah. I -- what I think is hard is that -- my light's going off again. What I would be concerned about -- and it's hard, like -- so, you know, again, this word wrong or what have you, what I'd be concerned about is I think what will -- what will happen on a population level, if people

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are getting a partial eye exam, I think some number of people who would have had a -- you know, a disease caught on this otherwise routine eye exam will end up not following through on the comprehensive eye exam and will have, you know, some type of health -- you know, either vision loss or if it was -- you know, rarely, like ocular melanoma, life-threatening something -- that those things will happen.

So I don't want to -- you know, if one of my colleagues was going it, you're right. In some degree it's sort of -- each physician, when it comes to technology and practicing, they have to sort of make their -- make their own decisions, but I think there -- the issue I have with it, I think there's going to be a certain number of people that aren't going to follow through on their -- on their comprehensive eye exam, and I guess that's -- that's what's wrong with it, I think. Again, whether I would judge another doctor, is it -- are they doing something wrong? Maybe that's -- maybe that's sort of a subtly different question.

Q. Okay. You know, you talk about what might happen at a population level, and let me just ask this a little bit of a different way. If the

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patients who are using these kind of online tools to take a vision test, if the tools don't write new prescriptions, right, if they only do renewals of existing prescriptions if the patient is still seeing well and the patient actually has had a comprehensive eye health exam within the recommended guidelines, would your answer change at all?

A. Well, right. So if -- if somebody actually followed the advice, like if they got their comprehensive eye exams as indicated, then -- then, right, then I don't -- then I wouldn't have a problem with it, yeah.

Q. And, ultimately, the responsibility is the physician, right, who is reviewing that information to say whether the patient has had that exam recently enough, right?

A. Yes. On an individual level, yes.

Q. Okay. And are you aware of -- well, let me back up a little bit. The affidavit mentions Opternative, Incorporated. I know you mentioned earlier today Visibly, right?

A. Right. That's what the company, I think, has changed its name to.

Q. Right. Yeah. Exactly. I just wanted

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to make sure you understood the -- the change. In the -- you know, since you wrote this affidavit, which was around 2017 -- what's that difference between now and today? It's six years, right? Do I have that math right?

A. Yes, that's right.

Q. Are you aware of any examples at all of any kind of population effect of patients using Visibly or any similar technologies according to what you're saying in Paragraph 20?

A. I am not, no.

Q. Were you aware of any when you wrote the affidavit?

A. No.

Q. Okay. So you're -- you're not basing this on any statistical evidence or study or anything like that, are you?

A. No. I would say I'm basing it on the -- that there are incidences of asymptomatic eye diseases that can cause vision loss or, rarely, be -- be life-threatening that are picked up on routine eye exams. So I get referred, you know, some of those. So they do exist, but I don't -- and I've seen some of them, but I don't have any statistical data or study.

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Q. Okay. Have you ever personally used the -- well, actually, let me ask it this way. I'll scroll up a little bit. So you mention -- let's see here. Well, you say in the first -- the first paragraph, actually, before 1 but in the paragraph, starts with personally. Do you see that? You say that it's -- this affidavit is based on your personal knowledge. Is that right?

A. Okay. Let me see here. Okay. Yes. Personal knowledge of matters set forth herein, yes.

Q. Okay. Do you have any personal knowledge of Visibly's technology?

A. You mean have I done it myself, so to speak? Would that be --

Q. Yeah.

A. So, no, I have not gone online and done their -- yeah, their refractive test.

Q. Okay. So you don't know how the technology works, do you?

A. Not exactly, no. I realize -- I think I have a general idea, but, no, I don't know exactly what they do.

Q. Okay. Are you aware of -- of whether Visibly is cleared by the FDA or not?

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A. I did read on their website that it was FDA-approved, but I haven't read, again, the details of exactly what the FDA said.

Q. Okay. Would you have any -- if the FDA has cleared this software for marketing to the public and use by the public, do you have any reason to question that determination by the FDA?

A. Well, again, I think it gets at what -- you know, what factors was the FDA, you know, considering. I'm not questioning whether it can give an accurate glasses prescription. Again, my concern is that that's just a partial eye exam and, like we said before, that we're not getting a comprehensive eye exam at that time which could result -- which I think would result, if you did it across populations, some number of people not getting their comprehensive eye exam. So it isn't -- I don't have a problem with the technology itself. It's more just that people aren't going to get the comprehensive eye exam that they -- that they need.

Q. Okay. So just to be clear, I think you said this at the very start of the deposition, but I want to make sure we have it -- have it clear. You don't have any concerns about the actual

efficacy of the technology itself?

A. I don't, yeah.

Q. Okay. And this concern you have about patients not getting comprehensive eye health exams if they use a technology like Visibly, isn't it a concern that would apply to any kind of limited care that a patient gets from an ophthalmologist?

A. Generally speaking, yes. It would be -- we could look at the details of that, but, yes, any limited care, you could always miss -- miss something.

Q. Yeah. Well, I'll just give an example you gave earlier. You mentioned the patient who comes in and they've got -- you know, they've had a comprehensive eye health exam in the past from you but they have, like, a corneal scratch or something like that. So in that examination you're focusing on the cornea and the scratch there. Do I have that right?

A. That's right.

Q. Okay. And so it's possible, right, that that patient leaves your office that day with the corneal scratch problem addressed but then they never come back for a comprehensive eye health exam, right?

A. Yes. If it's a corneal scratch, though, if it's our first time seeing them, we -- we will dilate them and look, but if they're a follow-up, then we wouldn't, yeah.

Q. That's what I'm getting at. I'm getting at a patient who is just coming in for a limited set of care on a discrete issue like the corneal scratch.

A. Yes. If we've done a comprehensive eye exam before and they come in six months later and have a scratch, we -- we will just address that -- that problem for that day, yes.

Q. Yeah. And what I'm getting at is just that the problem of a patient not coming back for a comprehensive eye health exam seems like it's a problem that's just sort of true of all ophthalmological practice, right?

A. Yes. I mean, it's -- it's always -- yeah. I mean, we have lots of patients, even when we have an in-person relationship, they know they have glaucoma, we've told them you can go blind, and they don't follow up for their appointments. So, yes, it is -- it is a universal problem.

Q. And that sounds like it might even apply -- tell me if you're getting out of your

depth with this question, and it's okay if you are, but it sounds like that might even apply to other kinds of medical specialists. So, for example, you know, patients who are supposed to get cancer screenings with a certain degree of frequency from a dermatologist, it's possible that you go see a dermatologist, right, for a skin rash and that you just never go back and get that screening, right?

A. Yes. Yeah. I think that -- I think that makes sense. It makes sense it would occur in all areas of medicine, yeah.

Q. Okay. Basically what I'm getting at is the problem of patients not following up and getting comprehensive exams of any form seems like a problem that's just endemic to the practice of medicine.

A. Yes. I agree.

Q. Okay. I think I want to take about a five-minute break, if that's fine with you?

A. Sure.

Q. Okay.

A. Five-minute break sounds good.

MR. WINDHAM: Great.

(A recess transpired.)

BY MR. WINDHAM:

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Q. We are back on the record then. Dr. Robinson, do you understand that you're still under oath?
A. Yes.
Q. Great. Okay. Well, we left off -- before the break we were talking about screenings for health problems that might come up in other medical specialties like dermatology, for example. Do you recall that?
A. I do, yes.
Q. Is your concern that patients need to get comprehensive eye health exams any different than a dermatologist's concern that a patient come in for a comprehensive screening of their skin?
A. I wouldn't think so.
Q. Okay. Certainly not any more dire or important than any other medical specialist's concern that a patient come in for a comprehensive screening, right?
A. I mean, you could add up, like, what are the potentially life-threatening things they're finding versus ophthalmology, but in general, right. I think -- I think the idea or the -- the idea or the principle is the same, yes.
Q. Okay. And I think what I'm just

getting is that, you know, hidden diseases or long-term chronic diseases could be a problem in really any medical specialty, right?
A. Yes. I think they could.
Q. Okay. And so it's important that patients really in any area of medicine get that comprehensive exam within the recommended frequency by that specialty, right?
A. Yes.
Q. And I know that you have a concern about online vision testing software based on Paragraph 20 of your affidavit. Is that fair?
A. Yes. Yeah.
Q. Okay. Is the concern about patients getting prescriptions for corrective lenses through online tools any different than a concern -- well, let me ask it this way. Would you have the same concern if a patient was getting eye drops through telemedicine?
A. Yes. I would -- I would think I would. Anything where you're not getting a comprehensive eye exam, I would be concerned about, yes.
Q. Okay. So really any ophthalmological service that you could provide via telemedicine where you're not in the room with the patient, you

would have this same concern about patients getting comprehensive eye health exams, right?
A. Yes. I mean, there might be -- like let's say it was glaucoma drops, for example, and you were renewing them. Well, now you're weighing, you know, if they don't -- if they don't get their glaucoma drops renewed, they're going to lose vision, so you have something -- a compelling reason to continue to prescribe those glaucoma drops, but in general, yes, I would be concerned about going too long without a comprehensive eye exam, yes.
Q. Okay. Is there anything about prescription lenses that suggests it's a greater concern, or is the concern just sort of ever present when a patient is getting a service through telemedicine?
A. Yeah. I think it's ever present. I think the concern would just be that needing glasses is an incentive for a patient to go get a comprehensive eye exam, so I'd say, you know, that's the kind of concern, is if they don't have that incentive anymore, life's busy, life's expensive, and then they get their glasses and they just don't go. So that would be my concern for

glasses. And there may be some similarities to that in other areas, but that's why -- it isn't just that they're getting a treatment. It's that that treatment is actually an incentive that helps people to go see the eye doctor.
Q. You said there may be some similarities in other areas. Can you think of any examples?
A. Not off the top of my head, but I certainly believe that there -- you know, that there are. Maybe -- have you thought of some?
Q. No. I just -- you know, you mentioned it, so I thought I'd ask you what you meant.
A. Yeah. No. I -- yeah. There could be, but...
Q. I guess what I'm getting at with my question is it sounds to me like glasses is one example of a -- of a type of care a patient can get through telemedicine where, if they get it, they might not have a comprehensive eye health exam, but the same could be true of eye drops or any other kind of ophthalmological care, right?
A. Yes. Again, it's just that eyeglasses are a big incentive, I think, for people to go to -- you know, to -- to get an eye exam but...
Q. Okay. Let's see here. I wanted to ask

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about -- let's just start general with this. So telemedicine, just the concept of telemedicine, can you explain to me as a layperson what that is?

A. Well, it's -- so you have a doctor visit over some sort of virtual platform, I'm assuming like -- like what we're doing here. I have not participated in that myself as a provider, but -- so that's the idea, is you could -- you can get history, you can -- you can see the patient, but to some degree physical exam -- either to some or to a large degree the physical exam is -- is limited.

Q. Okay. You've never used or participated in telemedicine before?

A. Not as a provider, no.

Q. Oh, okay. What about as a patient?

A. Not as a patient myself, no.

Q. Oh, okay. I don't know. I sense that there that's something you're not --

A. Well, I just --

Q. -- that you mean.

A. I have a family member. I have a family member that has -- a child that has done some telemedicine visits.

Q. Okay. What was that for? You don't

have to tell me their identity, of course. I'm just curious at a general level what that was about.

A. Yeah. So I have a child who has some sort of chronic illness, chronic fatigue. We think it's tickborne, but anyway, long story short, that there's not -- we haven't found a local provider who has been as helpful as a provider that was out of town, so...

Q. Okay.

A. So the telemedicine helped us overcome that -- that distance.

Q. Okay. The child with the -- you know, your child, right?

A. Yes.

Q. What specialty is the -- is your kid seeing in this context?

A. So it was a doctor who was -- they specialize in tickborne illnesses, so...

Q. Okay. Presumably that -- your child is not getting, you know, a full, in-person examination by that physician, right?

A. Well, yes. Well, because we've been to see the physician in person too, but -- but yes, but not every visit but...

Q. Not every visit. Okay. And that's okay with you?

A. Yeah. I mean, they've -- she's also had a pediatrician full visit and -- yeah. So she has had a complete exam otherwise but...

Q. Okay. Basically the more limited consultations you have with this physician in between, you know, the comprehensive visits is what gives you confidence that the care is adequate?

A. Yes.

Q. Okay. Is there any reason to think that that principle would be different in the ophthalmological context?

A. No. No. Again, I think if people are really getting their dilated fundus exams, their complete eye exams, then I don't have a problem.

Q. Okay.

A. I think the issue is just, again, some number of people won't actually, you know, do the complete eye exam.

Q. Got it. I was going to ask you some things about telemedicine, but since you haven't used it, I'll probably skip those things.

A. Sure.

Q. May be fruitless.

Let me ask about contact lenses for a second. You know, we were talking earlier about a patient getting a prescription for glasses and the process for that. Is the process of prescribing contact lenses any different?

A. Yeah. So it's a little bit different because the contact lens actually sits on the surface of their eye, so -- and, again, I -- actually I don't prescribe contact lenses anymore. It's been a long time. But most of the time you're going to look at the -- well, not most of the time. All the time you're going to look at the fit of the contact lens after you've prescribed it. So that's for a new prescription. Now, I think for your technology it's for a renewal, so presumably the fit is already correct but -- but yeah.

So you would look at the -- look at the fit on the eye. Sometimes you have to adjust the prescription a little bit from what their glasses prescription is, but -- but yes. So it's a similar process. You still need a refraction but then there's some other parts just to check the fit on the eye, I guess.

I think you're -- you might have muted yourself, maybe.

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Q. Thank you.
A. You're welcome.
Q. I was going to ask why you say, for a technology like Visibly, presumably the fit is already correct?
A. Well, I think you said you were just doing renewals, right? So if it's renewal --
Q. Sorry. Not me but just for clarity on the record, Visibly.
A. Oh. Yeah. So for Visibly I believe the Visibly's website was saying they do renewal prescriptions, so -- so I was just kind of thinking out loud. So the fit there wouldn't -- wouldn't -- it shouldn't be an issue 'cause the fit was already, you know, determined by an in-person visit.
Q. I see. And is that because the fit of a person's contact lenses typically doesn't change? Is that what you're getting at?
A. Right. I think it typically doesn't. Now, I'm a little outside my area of expertise here just because I haven't prescribed contact lenses now in about ten years, so I don't -- sorry. Light going off again -- so I don't -- I don't have personal experience on how often the fit would

change or -- or not change, but my impression is it -- I don't think that would be a big issue.
Q. Your impression based on your training?
A. Well, yeah. My training and then I did prescribe contact lenses for six years in private practice before becoming --
Q. Okay. So also based on your personal experience, then?
A. Yeah. So for at least six or seven years, I didn't see contact lens fits change very much.
Q. Okay. Let me just look over my notes for a second. We may be at the end here.
I think that's all I have for you today, Dr. Robinson, unless anything is raised on -- on any other questions that my friends on the other side want to ask, so I'll pass the witness.
A. Sounds good. Thanks.
MR. MATTHEWS: Mr. Allen, do you have any questions?
MR. ALLEN: Go ahead. If you have some, I'll defer to you if you want to go first but...

EXAMINATION
BY MR. MATTHEWS:
Q. Let's see. I've just got a couple of questions. Dr. Robinson, how you doing?
A. I'm doing well. How are you?
Q. Hey, my name is Gene Matthews. I'm the -- kind of the third wheel here. I'm representing the Department of Labor, Licensing and Regulation and the Board of Medical Examiners, and the reason we're here is because we're required to defend the constitutionality of a statute that our administrative agency enforces.
One basic question I have is this. As I understand it, the rational basis for the ECCPL, the statute that's being challenged, is that the state has an interest in supporting good eye health and that undiagnosed diseases of the eye are a legitimate public health concern and the legislation at issue isn't designed to encourage in-person comprehensive eye examinations to increase the chances of detecting diseases of the eye. Just presume for a moment that's what the legislature had in mind. Do these themes seem to be reasonable to you?
MR. WINDHAM: Objection.

BY MR. MATTHEWS:
Q. Please answer.
A. Yes.
Q. Okay. Tell me why.
A. Well, just -- I mean, I think there is -- there is a concern that there are these undiagnosed diseases that can be either vision-threatening or life-threatening that are sometimes picked up on a routine eye exam.
Q. Okay. And with that in mind, one of the issues that has come up here is that the law does not appear to require an eye care professional to conduct the -- the eye examination if it -- if you come to the -- say I come to my ophthalmologist. As you can see, I wear glasses. I go to my ophthalmologist and I say I just want prescriptions. I don't want an eye exam. The law does not appear to require that physician to say, well, tough, you're going to get one or I'm not going to serve you. Doesn't appear that that's required. To your mind, does that impair in any way the idea behind the law which is that in-person -- requiring in-person eye exams versus remote eye exams will encourage that patient to get the examination that you prefer?

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A. Right. I don't -- I don't think so, no.
Q. Okay. The issue has come up also that, you know, there's a -- well, how best to put this -- that the sole purpose for the law is to essentially corner the market for optometrists and ophthalmologists at the expense of those who offer eye care remotely. Do you have any information about that one way or another?
A. I don't. I've heard that that was what maybe was the -- that that was the -- a reason against the law -- I could say it that way but -- but, no, I don't have any other information about that.
Q. Okay. Do any set of physicians other than ophthalmologists or specialists such as optometrists conduct eye exams? Like would a general practitioner conduct an eye exam?
A. Well, there are times where a general practitioner might look -- you know, try to peek inside at the retina. They use a different device called a direct ophthalmoscope. So they might try to screen and look in at the optic disc, look at the blood vessels, look for hypertension, look for diabetes, but those exams are pretty limited, and I

tend to think most of them don't do it because it's just too hard, so...
Q. Well, I guess my question is: Ordinarily I would not go to a GP for a comprehensive eye exam?
A. No, no, no.
Q. All right. Because ordinarily they couldn't provide one?
A. Right.
Q. All right. So maybe just -- we can end this pretty quickly then. As I understand your testimony, you do believe that there is a rational basis -- that's a bit of a legal term, so let me change it. You believe that there's a good reason for a law that encourages in-person eye exams and -- and that's -- the reason for that is to assist in detection of eye diseases?
A. Yes.
Q. Do you have any information that these diseases could be detected by a remote exam?
A. Well, yeah. I mean, if we had cameras that can -- you know, that could take a photograph of the fundus, you know, that would be one technology that could be done remotely. And checking pressure, I think would be harder in the

eye, to screen for glaucoma, but I'm sure, you know, a device could be made that the patient could use somehow, so it may be in the future there are ways to do -- you know, to sort of get the information you need, but at the moment there's no sort of -- that I know of -- no sort of up-and-running system that's --
Q. Right.
A. -- doing the things of a comprehensive eye exam.
Q. And, again, this may -- question to you may seem hardly -- or horridly elementary, but when you talk about eye pressure, is that, when I'm in an eye exam and that thing, like, comes at your eye and kind of sticks in it and it's so comfortable that I want to run screaming from the room? That's what that is?
A. Right. Yeah. They can do it either noncontact, with an air puff -- so if you ever have the air puff checking your pressure, that would be the air puff -- or there are other devices that gently tap on the eye or touch the eye to get the pressure.
Q. Okay. Got it. Got it. Those are all the questions I have. Thank you so much.

A. You're welcome. Thank you.

EXAMINATION

BY MR. ALLEN:
Q. Hi, Dr. Robinson.
A. Hi.
Q. My name is Luke Allen. I represent the South Carolina Optometric Physicians Association, otherwise known as SCOPA. I just have a couple quick questions.
You testified earlier with the situation with your relative when you gave them the refractive eye reading without the eye exam. Do you know what date that occurred?
A. I don't. It was two or three years ago, maybe. I don't remember exactly.
Q. Was it after you prepared that affidavit in this case?
A. Oh, yes. Yeah.
Q. So apart from that one caveat, is there anything that you would change in your affidavit as far as its accuracy or anything else?
A. No. I don't -- I don't think so.
Q. Have there been any instances in your practice personally where a patient came in for an eye exam and you were able to discover a potential

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problem with diabetes or high blood pressure or other systemic problem that the patient wasn't already aware of?

A. Yeah. So I've certainly diagnosed a good number of patients with glaucoma who didn't know it. That would be one of the more common things. Diabetes, where they have some -- yeah. So diabetic retinopathy, that would be one. And I've seen other patients that have been -- it's been -- because now I'm a neuro-ophthalmologist, so things are referred to me. I've seen people with idiopathic intracranial hypertension where their -- sorry. My light's going off again -- where their optic discs are swollen, and that's been diagnosed on -- on a routine examine and then referred to me. And I've seen some folks with that who didn't present until they had lost a lot of vision, but whether they would have -- you know, those folks didn't go for a routine eye exam, but I don't remember, if they had glasses, whether they, you know, would have or not, but there certainly are some things I've seen that -- that were caught on a routine eye exam.

Q. What types of medicines are you able to prescribe as an ophthalmologist?

A. Yeah. Well, so as an ophthalmologist, we're medical doctors, so we're not limited. We can prescribe anything, I believe. I mean, we're supposed to -- but prescribe within our scope, so most of what we prescribe are eye drops, but we can prescribe prednisone if there's an autoimmune condition. I prescribe something called acetazolamide, which reduces the intracranial pressure in patients with idiopathic intracranial hypertension. So that's a pill by mouth. We also use that for glaucoma. If the pressure is really high, general ophthalmologists will prescribe that as well. So yeah. So mostly, as eye doctors, we prescribe eye drops, but we're allowed prescribe more if needed.

Q. Are you able to prescribe any of that to a patient that you have never personally examined just based on a set of questions?

A. So I haven't done any telemedicine, so I don't know the rules about that.

Q. Well, would you personally do that?

A. You know, as an eye doctor, I don't think that I would. I mean -- so no. As far as a neuro-ophthalmologist who -- you know, my practice is very much -- I need to see the eye to -- and

inside the eye, so I guess no. No, I wouldn't.

Q. Okay. Now, I don't believe I have any further questions. Thank you.

A. Thank you.

EXAMINATION

BY MR. WINDHAM:

Q. I think I just have one and then maybe you'll be out of here.

A. All right.

Q. All right. So Mr. Allen asked a question about whether you ever had caught -- I think the -- the way you put it was -- or he put it was caught or diagnosed certain hidden diseases or undiagnosed diseases in your office. Do you remember that?

A. Yes.

Q. Okay. Do you recall if any of those patients who you've uncovered hidden diseases for were seeing 20/20?

A. Well, so I -- I don't remember their particular visual acuity. What I will say about glaucoma though, because it takes out peripheral vision first, they see 20/20 until the very end, so -- which is -- I mean, it's still good to catch it then, before it goes all the -- you know, before

they lose all their vision but -- so I imagine many of those folks were -- you know, were 20/20, but I can't tell you for sure.

Q. Okay. I think that's all the questions I have for you today. Thanks so much for being here.

A. Yeah. Thank you. Thanks for all the good questions.

MR. WINDHAM: Thank you, Doctor. Enjoyed it.

(The witness, after having been advised of his right to read and sign this transcript, does not waive that right.)

(The deposition was concluded at 11:39 a.m.)

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CERTIFICATE OF REPORTER

I, Trisha M. Thomas, Court Reporter and Notary Public for the State of South Carolina at Large, do hereby certify that the foregoing transcript is a true, accurate, and complete record.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.

Witness my hand, I have hereunto affixed my official seal this 18th day of September, 2023, at Hardeeville, Jasper County, South Carolina.

Trisha M. Thomas, RPR
My Commission expires
December 2027

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Mark E. Robinson, M.D., MPH

September 19, 2023

RE: Opternative v. South Carolina Board Of MedicalExaminers
9/6/2023, Mark E. Robinson , M.D., MPH (#6074916)

The above-referenced transcript is available for review.

Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at cs-midatlantic@veritext.com.

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Mark E. Robinson , M.D., MPH (#6074916)

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Opternative Inc. v. South Carolina Board Of Medical Examiners
Mark E. Robinson , M.D., MPH (#6074916)

ACKNOWLEDGEMENT OF DEPONENT

I, Mark E. Robinson , M.D., MPH, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

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South Carolina Rules of Civil Procedure

Part V. Depositions and Discovery

Court Rule 30

(e) Submission to Witness; Changes; Signing. When the testimony is fully transcribed the deposition shall be submitted to the witness for examination and shall be read to or by him unless such examination and reading are waived by the witness and by the parties. Any changes in form or substance which the witness desires to make shall be entered upon the deposition by the officer with a statement of the reasons given by the witness for making them. The deposition shall then be signed by the witness, unless the parties by stipulation waive the signing or the witness is ill or cannot be found or refuses to sign. If the deposition is not signed by the witness within 30 days of its submission to him, the officer shall sign it and state on the record the fact of the waiver or of the illness or absence of the witness or the fact of the refusal to sign together with the reason, if any, given therefor; and the deposition may then be used as fully as though signed unless on a motion to suppress under Rule 32(d)(4) the court holds

that the reasons given for the refusal to sign require rejection of the deposition in whole or in part.

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VERITEXT LEGAL SOLUTIONS

COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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STATE OF SOUTH CAROLINA
COUNTY OF RICHLAND

COURT OF COMMON PLEAS

- - -

OPTERNATIVE, INC.,
Plaintiff,
vs.
SOUTH CAROLINA BOARD OF MEDICAL EXAMINERS, SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION,
Defendants,
AND
SOUTH CAROLINA OPTOMETRIC PHYSICIANS ASSOCIATION,
Defendant-Intervenor.

CIVIL ACTION NO.:
2016-CP-40-06276

VIDEOCONFERENCED 30(B)(6) DEPOSITION OF OPTERNATIVE, INC. GIVEN BY JOEL STONEDALE

DATE TAKEN: Tuesday, August 1, 2023
TIME BEGAN: 10:00 a.m.
TIME ENDED: 12:45 p.m.
LOCATION: Remote Deposition
REPORTED BY: Deidre Osborne, RPR

A P P E A R A N C E S
(via videoconference)

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E X H I B I T S

DEFENDANTS'	DESCRIPTION	MARKED
1	Notice of Deposition	6
2	FDA 510(K) Summary Letter	53
3	Letter Dated 8/12/2022	104
4	Letter Dated 9/30/2022	106

(It is hereby stipulated and agreed by and between counsel for the respective parties that this deposition is being taken in accordance with the South Carolina Rules of Civil Procedure and that the deponent does not waive reading and signing of this deposition transcript.)

- - -

JOEL STONEDALE, after having been first duly sworn, was examined and testified as follows:

- - -

EXAMINATION

- - -

BY MR. SHEALY:

Q. Okay. Mr. Stonedale, can you hear me okay?

A. Yes, sir.

Q. Okay. My name is Kirby Shealy. I'm a lawyer in Columbia, South Carolina, and I represent the South Carolina Optometric Physicians Association which is an intervenor in this lawsuit that has given rise to this deposition. And you, I understand, have been designated to testify on behalf of Visibly. Is that your understanding?

A. Yes, sir.

Q. All right. We issued a deposition notice that contains certain topics. Do you recall seeing a

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list of topics?
A. Yes, sir.
Q. Okay. I'm going to show my screen to you, and I think this is the right one. All right. Can you see -- can you see that now?
A. Yes, I can.
Q. And the document I'm showing you is captioned South Carolina Optometric Physicians Association's Notice of Taking 30(B)(6) Deposition of Opternative, Incorporated.
And, first, let me make sure that the record is clear. Is -- the company now known as Visibly, was it formally known as Opternative, Inc.?
A. Yes.
Q. Okay. And the -- this deposition notice contains a set of topics, and let me ask you: Have you seen the deposition notice before?
A. Yes.
Q. You have. Okay.
And have you seen the list of topics that numbers 15?
A. Yes, sir.
Q. Okay. And do you believe that you are the person most knowledgeable to testify on Visibly formerly known as Opternative's behalf as to these 15

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topics?
A. Yes, sir.
MR. SHEALY: Okay. All right. Madam Court Reporter, I'm going to ask you to mark this deposition notice as Exhibit 1 to today's deposition.
THE STENOGRAPHER: Yes, sir.
- - -
(Notice of Deposition marked Defendants' Exhibit Number 1 for identification.)
- - -
BY MR. SHEALY:
Q. Okay. And I'll stop sharing.
All right. Mr. Stonedale, have you given a deposition before?
A. No.
Q. All right. So I'm sure Visibly's lawyers have -- have gone over some of this with you, but I'm required by the Rules of Civil Procedure in South Carolina to mention certain things to you. So bear with me for a moment.
So a deposition is just an opportunity for the lawyers in a case that's pending in court to put a witness under oath and ask them questions to sort of develop their testimony before trial. It is a

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way -- it's part of what we lawyers call the discovery process, and that process is aptly named a process of trying to figure out, to discover, what documents, witnesses, evidence, each side has in the case so that we're prepared, so that we're not surprised when we go to trial. So I'm going to ask you a few questions, first, to get to know you and -- and a little bit about your history with Visibly, and then we'll dive into questions related to these topics on Exhibit 1.
If at any point today I ask you a question that you find to be vague or confusing or if I use words that you don't know or use words you do know in a way that you do not understand, please tell me. Please let me know that. It's not my intention today to try to confuse you in any way. And I will tell you that I will ask you a poor question from time to time. But if you answer a question that I pose to you, I will assume that you understood the question. Is that fair?
A. Yes, sir.
Q. Okay. And as you just did, if you'll provide your answers both verbally, in other words, yes, no, yellow, 1946, whatever the answer happens to be, and at sufficient volume for our court reporter

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to take down your answer, that will make for a clean record.
Our court reporter, Ms. Osborne, is typing everything that we say while we're on the record, and she will produce a little booklet, and it'll have every question that I pose to you and every answer that you -- that you give, and we want that record to be as clear as possible.
And we all communicate in -- in non-verbal ways more than we realize. We nod our head, as you're doing from time to time. We say uh-huh or huh-uh. We respond with other gestures, and we communicate in ways that we don't even realize non-verbally with our facial expressions and whatnot. If you give a non-verbal response, I may prompt you to convert whatever your response is into a verbal response. Everybody does that. It's not that you have failed in some way if you give a non-verbal response. It's just that -- the prompting is just so that we make sure that that record is clear.
And if you will do me the courtesy of waiting until I have finished forming my question before you begin providing your response, I'll do you the return courtesy of waiting until you have finished answering before I pose another question to

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you.

When we talk over each other, it makes it difficult on our court reporter, and this format of using Zoom is something we've become accustomed to over the last three years or so, but -- and it's great, but it -- it has a tendency to -- for there to be a little bit of a delay in the transmission sometimes, and it makes it a little easier for us to talk over each other than if we were in the same room, so we just got to be careful about that. Okay?

A. Yes. Understood.

Q. Okay. Now, the other thing that I need to tell you is that I'm going to move through what I have in mind to ask you as expeditiously as I possibly can, but if at any point during the deposition you want to take a break, feel free to say, "Can we take a break?" This is not an endurance contest, and I don't expect that this is going to take more than a couple hours, but -- but, nonetheless, if you need to take a break for any reason, feel free to do that.

What I'm required by our rules to tell you is that if during any break you discuss the substance of your testimony being given in this deposition with anybody, including Visibly's lawyers, I'm allowed

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under our rules to inquire into the substance of that communication, and I'm required also to give you that warning to let you know that -- that if you have that kind of a communication within the -- the context of the deposition, I'm allowed to discover what that is about.

I have no intention today of -- to ask you about communications you've had with Visibly's lawyers at any point prior to the start of the deposition. Don't want to know that and will not ask you any questions about that. But if any communication occurs during the deposition, the rules allow me to inquire into -- into that.

Okay. So any questions about the procedure before we get started?

A. No, sir.

Q. Okay. Are you under the influence of any medication, drug or other substance that would impair your ability to think or understand my questions or to provide truthful testimony today?

A. No, sir.

Q. All right. So if you would, start by just stating your full name for the record.

A. My name is Joel Stonedale.

Q. And, Mr. Stonedale, have you ever been known by any other name?

A. No.

Q. And where do you live?

A. Live in -- outside Smithville, Texas.

Q. And is that where you're from originally?

A. I grew up in Arlington, Texas, spent a lot of time in Austin, Texas, and then moved here a couple years ago.

Q. Okay. How far did you go in school?

A. Law school.

Q. All right. So you -- are you a licensed lawyer?

A. Yes, sir.

Q. All right. And are you -- what -- what position do you hold, if any, at Visibly?

A. I'm Visibly's general counsel.

Q. All right. Okay. So -- and how long have you held that position?

A. Three years. A little under three years. I started in January of 2021.

Q. All right. Have you -- when were you first licensed to practice law?

A. 2011. Summer of 2011.

Q. And were you in private practice for any period of time before joining Visibly?

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A. Yes, sir. After graduating law school, I clerked for a year. I then did three years or a little under three years at a large law firm doing mostly patent litigation. I then worked for a year at the Texas Public Policy Foundation doing public interest litigation. I then moved to the Texas Attorney General's Office, also doing public interest litigation. I then went back to patent litigation for, I think, a little over three years, and then from there went to Visibly.

Q. All right. Have you had an occasion to take a deposition before?

A. Yes, sir.

Q. Okay. Well, forgive me for going through all of that in such basic terms. I did not realize that you were a licensed lawyer.

But have you ever litigated any cases in South Carolina?

A. No, sir.

Q. Are you licensed to practice law in any states other than Texas?

A. No, sir.

Q. Have you ever been licensed in any states other than Texas?

A. No.

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Q. Has your license to practice law ever been suspended or have you been disciplined in any fashion by the Texas Bar Association?

A. No.

Q. Okay. And you said you were in private practice with a larger firm. What firm were you with?

A. McKool Smith.

Q. Okay. And -- but since you've been with Visibly, that -- that has been a -- your full-time job is being -- being Visibly's general counsel, correct?

A. Yes, sir.

Q. Have you ever lived or worked in South Carolina?

A. No, sir.

Q. All right. So your area of practice you mentioned was -- it sounds like mostly patent litigation or intellectual property. Have you ever practiced in any other areas?

A. Oh, I have -- that -- I think it's accurate to say most of my work has been in patent litigation, but I have done various other forms of commercial litigation, regulatory, dealing with various regulatory schemes. The Clean Air Act, Endangered

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Species Act, some of the -- Affordable Care Act. And then, of course, since Visibly -- since joining Visibly, I've been dealing with a great deal of healthcare litigation with the FDA.

Q. Okay. And where did you go to law school?

A. Did you say where or when?

Q. Where.

A. University of Chicago.

Q. And you -- and from -- over what period of time?

A. 2008 to 2011.

Q. And where did you get your undergraduate degree?

A. University of Texas in Austin.

Q. All right. Well, so let's talk about Visibly. I may go back and ask you some of those background questions as they occur to me, but let's talk about Visibly's -- the history of Visibly as you understand it. The company is incorporated where?

A. Delaware.

Q. And in what states does it currently operate?

A. Well, it depends on what you mean by "operate." The employees are scattered across probably 15 states. The base is primarily in

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Illinois. I would say that's a -- we -- we had a physical office in Chicago until 2019 or thereabouts, and then since then, it's been a fully online company, so it doesn't have a physical base of operations.

Q. Okay. So there isn't -- there really isn't a principal place of business as -- as we're talking to each other.

A. Not a physical location. To the extent there's a concentration of employees and business, it would be Chicago, Illinois.

Q. All right. And -- but you -- do you work out of your home?

A. Yes, sir.

Q. And before the office in -- in Illinois was shut down, had the -- had the office always been in the state of Illinois?

A. I believe the company was founded in Illinois, and that was where it had been until that point.

Q. Okay. And you said this earlier. What year did you begin with the company?

A. January of 2021.

Q. And what year did the -- did -- was the company founded?

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A. Founded. I would think it's either 2012 or 2013 in terms of the initial incorporation, that sort of thing.

Q. Okay.

A. Yeah.

Q. And do you know who the -- who the founder or founders were?

A. Aaron Dallek and Steve Lee.

Q. Okay. Are those two people still affiliated with the company?

A. No, sir.

Q. And do you know when -- when they left?

A. Not precisely. I could give you a ballpark range. So I can -- I can tell you with some precision that Steve Lee left in the latter half of 2019.

Q. Okay.

A. Aaron Dallek was before that. I want to say 2017, but my confidence in that is not particularly high.

Q. Okay. Okay. Well, I appreciate at least giving me the ballpark.

Do you know what -- under what circumstances either of them left? Were they bought out? Did they -- did they resign? Were they fired? What --

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do you know what the circumstances were?

A. I could not tell you about Aaron Dallek. I know that Steve Lee was suspended initially, and then I don't know if he after that resigned or was fired, but I know he was initially suspended.

Q. Okay. And do you know why he was suspended?

A. I believe there was dissatisfaction with his -- with his managing of the FDA process the first time around.

Q. Okay. And the company is governed -- does it have a board of directors?

A. Yes, sir.

Q. Okay. And so the decision to suspend Mr. Lee, was that a board decision?

A. I believe so. I would -- I would expect so, but --

Q. Okay.

A. Yes. I think that's very likely.

Q. And Aaron Dallek, I mean, you don't know anything about what -- what the circumstances of his leaving were.

A. No.

Q. All right. We'll talk about the -- the -- managing the FDA process here shortly. So what -- all right. What -- what is the corporate structure

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of the -- of the company? Does it -- does it -- does it have any subsidiaries, or is it just one entity? How -- what's the structure like look?

A. There's just one subsidiary. So Visibly, Incorporated has one wholly-owned subsidiary which is Next Day Contacts, LLC. That's the extent of it.

Q. And is -- was that -- is that subsidiary established by way of some sort of acquisition or a merger of some kind?

A. Yeah. I believe it was an asset purchase acquisition.

Q. And when did that occur?

A. Approximately 2020.

Q. And say the name of the subsidiary again.

A. Next, N-e-x-t, Day Contacts.

Q. Okay. Does that business operate in -- as some -- under some other name, or is -- is that the name that it is known by in the public sphere?

A. It's known as Next Day Contacts in the -- in the public sphere, yes.

Q. Okay. And I assume that's some kind of contact lens supplier.

A. Contact lens retailer.

Q. Okay. And was that company operating as Next Day Contacts prior to the asset purchase?

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A. I believe so.

Q. Has -- well -- and let me go back. When -- when did Visibly -- when did Opternative change its name to Visibly?

A. It was late 2018 or early 2019.

Q. And do you know the circumstances giving rise to the decision to change the name?

A. Yes. It was thought that Opternative conveyed a notion that Visibly wanted to be an alternative to optometry, and that was not the message we wanted to send. Visibly wanted to work with optometrists, be an adjunct they use in their office, for example, when they can't get a patient to come in, things of that nature. And so it was looking to make it easier to partner with optometrists, and having a name like Opternative hinted that it was an alternative to optometry which was not the message they wanted to send.

Q. Okay. So it was really a marketing decision that gave rise to the name change.

A. I don't know if I would characterize that as marketing. I think it was more about clear communication to the potential partners.

Q. Okay. And that was just accomplished by virtue of a name change filing with the Delaware

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Secretary of State?

A. I can't tell you the precise mechanism, but I could tell you that it is not much more complicated than that, if it was any more complicated than that. It didn't -- there was no re-organization or anything of that nature.

Q. Okay. Okay. So today how many employees does Visibly have?

A. 35.

Q. And who is -- does it have a chief executive officer?

A. Yes.

Q. Who is that?

A. Brent Rasmussen.

Q. Okay. And how long has Mr. Rasmussen been with the company?

A. Can I answer that question shortly? I wanted to point out: When I said 35, I should have said approximately 35.

Q. Okay.

A. I'm not entirely certain of what the head count is today.

Q. Yeah.

A. Brent Rasmussen, he has been with the company, I believe, since 20 -- 2017 to 2018. He may

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have started in 2018, but definitely by 2018.

Q. All right. Who are the other officers of the company today?

A. Paul Foley is the chief operating officer and might still be the chief financial officer. Then there's -- Brian Ambers is the head of finance. I don't know if he's the CFO or not technically, but Paul and he both work on finance aspects. Sam Shanley is the head of Next Day Contacts operations. And then Simran Chatrik -- that's S-i-m-r-a-n. I'm attempting to spell this right, and I'm not sure I am.

Q. Okay.

A. C-h-a-t-r-i-k. She is the -- someone with a name that's spelled approximately like that is the head of business development. And let's see. Pann -- oh, it's another difficult name. Pichetsurnthorn. His first name is P-a-n-n. His last name is approximately P-r-i-t-c-h-e-n-t-h-o-r-n. He is the head of product. And, oh, yes. Brandon Varilone. I'm sorry with these names. I just call them by their first names.

Q. Understood.

A. He is our chief technology officer.

Q. Okay. And is Visibly privately held?

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A. Yes.

Q. All right. Do you know who the -- who the owner or owners of the stock are?

A. I know some of them. There are a lot. It's -- there are a lot of owners. There's probably over 100.

Q. Okay.

A. It's quite a diffuse ownership.

Q. Is there -- okay. Is there anyone with a controlling interest?

A. No.

Q. Okay. So no -- no one has greater than 50 percent of the shares.

A. No.

Q. How many people serve on Visibly's board?

A. I believe there are -- so there are seven seats, five of which are currently occupied. So there's only five board members, and there's two seats that are vacant right now.

Q. Okay. Are the folks that serve on the board actively managing the company, or are they outside -- outside folks just serving on the board?

A. A mix of the two. There are three outside people that are fully outside, and then two of the people on the board are Paul Foley, who is our chief

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operations officer, and Brent Rasmussen, who is the CEO.

Q. Okay. Who are the -- who are the outside people?

A. It changed recently. So David Ting who is at Zenni, and then a -- I'm blanking on his name. Another man who works for Johnson & Johnson in his day job. And I'm trying -- I can't remember his name at the moment. And then Peter Carroll who works for Jump Capital.

Q. Okay. I want to ask you about the Next Day Contact operation just briefly and then -- and then get back to Visibly's core business. Next Day Contact, is that a -- is that some sort of an online contacts real -- retailer?

A. Yes, sir.

Q. Okay. And does -- does Next Day Contacts or Visibly manufacture any contact lenses?

A. No.

Q. Okay. So its -- it purchases contact lenses manufactured by others and then sells them via an online platform to the public; is that correct?

A. Correct.

Q. Okay. And had -- to your knowledge, has that been the business model for Next Day Contacts

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from its inception?

A. As far as I know, it has always been a contact lens retailer, never a manufacturer.

Q. Okay. Now -- and does -- other than selling contact lenses via an online platform, is there any other service or product that Next Day Contacts offers to the public?

A. It links to Visibly's vision test, but it doesn't actually offer the vision test, but you -- if you go to the Next Day Contacts site, you can take Visibly's vision test on that site.

Q. Okay. Does Visibly have any relationships with any other contact lens retailers other than -- than its -- its own subsidiary, Next Day Contacts?

A. Yes. Many. I would say a couple dozen at least, maybe -- maybe 50. There are -- there are quite a few where they put a link to Visibly's vision test on Visibly's -- or on their -- on their contact lens retail site.

Q. Okay. And so that's sort of the -- that's sort of the typical way that a customer of one of those companies gets to Visibly's site, by way of a link on those retailers' websites.

A. Yes.

Q. Okay. Now, Visibly, can you describe what

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Visibly's business operations are? I mean, what -- what product or service does it offer to the public?

A. Visibly makes vision testing software.

Q. Okay. And so it offers a service, a vision testing service, to the public, and that's how it generates its revenue?

A. Well, it makes the software that's then used by others to test vision.

Q. Okay. When you say it's "used by others," explain to me how that works.

A. A eye care provider, such an optometrist or an ophthalmologist might use Visibly's software to test the vision of one of their patients, for example.

Q. Okay. And so is the software licensed to the optometrist or ophthalmologist?

A. Yes. The software runs on Visibly's servers, but the -- the optometrist or ophthalmologist has access to a portal to the software where they can see the results of the vision test.

Q. Okay. And what I'm -- what I'm trying to understand is the way that Visibly generates revenue through that -- that sort of operating model. Is it that -- is there a -- is there a fee for access to

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the portal that Visibly charges an eye care professional?

A. Yes.

Q. Okay. Now, is -- is that the only way by which Visibly generates revenue?

A. No. We also -- well, Visibly gets revenue through Next Day Contacts as well.

Q. Okay.

A. Contact lens sales.

Q. Okay. Does Visibly allow or does it provide a service to laypeople that -- to allow them to access its software?

A. Sort of. So it is possible to go to Visibly's -- so, yes, laypeople can on their own access Visibly's software. One way they can do that is to go to Visibly's website and click "Take a Test" and take a vision test.

Q. Okay. And do -- so do they have to pay a fee up front to take the -- take the test?

A. I believe they pay the fee -- when do they pay the fee? At some point they pay the fee. I think it's at the end of the test.

Q. Okay. But -- so that's another way that Visibly generates revenue, is just by -- by laypeople going on Visibly's website and taking the test,

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correct?

A. Right.

Q. Okay. So -- so a layperson could go to Visibly's website, pay a fee, take the test and then, with the results, purchase contact lenses from Next Day Contacts, and -- and -- and Visibly would generate revenue from the fee for taking the test and from the sale of the contacts as well, correct?

MR. MCNAMARA: Objection.

THE WITNESS: Well, no, I don't think so. That's -- I think I oversimplified somewhat.

BY MR. SHEALY:

Q. Okay.

A. If someone were to go to Visibly's website and -- and take the test, they would -- the -- the payment for that would go to Optimized Eye Care, which is a professional corporation that employs optometrists and ophthalmologists. Then -- and Optimized Eye Care via Visibly would send the prescription back to the user, and they could then use that prescription to purchase contacts from wherever they wanted.

Q. Okay. So -- all right. So let me make sure I understand how the -- the payment stream works. Okay. So the layperson takes the test, pays the fee

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via Visibly's website, but the fee goes to another company, Optimize...

A. Optimized Eye Care.

Q. Optimized Eye Care.

And does -- does Visibly have any interest in that company?

A. No. Visibly has a -- Visibly provides management services to that company, administrative services --

Q. Okay.

A. -- but that company is owned by a doctor by the name of David Hillman.

Q. All right. So -- okay. So Visibly, when it provides management services to that company, does it -- does it charge the -- that company for providing those management services?

A. Yes.

Q. Okay. Does -- is there some sort of contractual arrangement by which the fee that is -- that goes to Optimized -- what did you say? It was Optimized?

A. Optimized Eye Care.

Q. Eye Care. Where Visibly receives a portion of that fee?

A. No. Visibly's paid on a standard yearly fee

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for its services.

Q. Okay. Okay. So there's just an arrangement where Optimized Eye Care pays Visibly for both the management services and -- and for having this portal that sends the eye test results to Optimized Eye Care, correct?

A. No. They -- Optimized Eye Care pays for the management fee. There's a -- management services and for -- for billing and for the software license for the vision test.

Q. Okay. All right. So have we talked about all of the ways that Visibly generates revenue?

A. Certainly the vast majority of it. I mean, basically all the revenue Visibly gets is from the vision test one way or another, the origins of -- for licensing the vision test one way or another and -- and for the sale of contact lenses.

Q. Okay. And Optimized Eye Care, where is that company located?

A. Illinois.

Q. It's incorporated in Illinois?

A. It is an Illinois professional corporation.

Q. Okay. And to your knowledge, does it -- it employs optometrists or ophthalmologists to review the vision test results generated by Visibly's software?

A. Some of both.

Q. Okay. It has both optometrists and ophthalmologists --

A. Yes.

Q. -- on its staff? Okay.

A. Yes, sir.

Q. And do the --

A. I should be clear. I don't believe it employs them. I believe they have a contractual relationship.

Q. Okay.

A. I think you said employ, but it -- both -- it has contractual relationships with doctors that are both optometrists and ophthalmologists.

Q. Okay. Now, so is -- if the -- if -- if an optometrist or an ophthalmologist reviews a particular patient's vision test results, is there some mechanism by which a doctor that is licensed in the same state where the patient is performs that review or do you know how that works?

A. Can you repeat the question?

Q. Yeah. What I'm trying to figure out is does Optimized Eye Care direct a vision test to a doctor that is licensed in the state where the patient is

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that took the test to perform the review?

A. Yes.

Q. Okay. And that -- and as you understand it then, if -- if in that medical professional's opinion it's appropriate, they issue a prescription to that patient based on the -- that test result.

A. Yes.

Q. And -- and is there any -- is there any personal interaction between the patient and that medical professional during the process we've just been talking about?

A. What do you mean by "personal interaction"?

Q. Is there any -- does -- does the doctor have any kind of an interview with or any kind of a face-to-face interaction with the patient?

A. Depends on who's using Visibly's software and how and when. And they -- when Optimized Eye Care uses Visibly's software as opposed to an independent ECP, one of the other independent ECPs that use it --

Q. And when you -- let me -- I didn't -- sorry to stop you, but just so our record's clear, when you say ECP, you mean eye care professional.

A. Or eye care provider. I mean typically optometrists or ophthalmologists.

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Q. Okay.

A. I'll try to use those words.

Q. Okay.

A. So I guess there's two -- two main scenarios how the software is used. One is where someone comes online through one of our retail partners or through Visibly, through Visibly's website directly, and -- and they, you know, take the vision test. The information is sent to Optimized Eye Care remotely, and then the doctor at Optimized Eye Care then reviews the information from the vision test, determines whether to send the prescription. Typically there's no face-to-face interaction there. Certainly not through the Visibly software there isn't.

There's another situation where, let's say, a local optometrist has a patient that -- he, you know, can't come into the office for some reason or doesn't want to. For whatever reason, they would prefer not to come into the office, and they -- so they might use the software in that case to remotely assess someone's vision or gather information about the vision remotely, and then that person might later call them in or might not, depending on the results of the test.

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Q. Okay. Is there -- are you aware of any eye care provider that uses Visibly's software to perform an eye -- a vision test inside that eye care provider's office?

A. I'm not aware of a specific individual. Though I suspect some people do that, I couldn't name someone who does that, but I -- I guess I don't know.

Q. Okay. Are you involved in the -- in Visibly entering into contractual relationships with eye care providers?

A. Yes.

Q. Okay. So you're generally aware of who Visibly has contractual relationships with in various places in the country.

A. I'm aware of many of them. I typically don't see a contract unless it has edits that are, you know, interesting enough to send to me. If someone -- if someone on our sales team gives a contract to an eye care provider and they just sign it, I'm not going to see that contract.

Q. Okay. But to what extent were you involved in the drafting of sort of your standard contract with an eye care provider?

A. I have edited our standard template. I'm familiar with it.

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Q. Okay. And has that template evolved over time during the life of -- during Visibly's life?

A. Yes.

Q. Is that a "yes"?

A. It has changed. You know, year to year, it changes.

Q. Okay. Does Visibly currently have any contractual relationships with any eye care providers within the state of South Carolina?

A. Visibly does not have any contractual -- well, it's possible that there are still contracts with South Carolina doctors who are not using the test anymore because it's no longer legal to do so. There were South Carolina doctors using it beforehand. Now, whether those contracts are still running, I guess I don't know. It would have -- this all happened before I came to Visibly.

But I can't say for certain that there are no South Carolina licensed doctors that Visibly does not have a contract with, though I can say for certain that if you tried to use the software and you said you're in South Carolina, it would kick you out. It wouldn't -- you know, it wouldn't let you.

Q. So when you said that it's illegal for a South Carolina eye care provider to use the software, to your knowledge is there anything stopping a South Carolina eye care provider from using the software in conjunction with a comprehensive eye examination?

A. I would have to look more closely at the law to form an opinion on that.

Q. Okay. But you have not to this point formed an opinion about that, correct?

A. If someone could use it in their office?

Q. Yes.

A. No, I have not looked at that.

Q. Okay. Visibly just made the decision that the software would not be made available to eye care providers if the patient was in South Carolina; is that correct?

A. Visibly understood that at least in most use cases that it would run afoul of the -- the law from 2016 in South Carolina and, as a result, told the system that if someone is in South Carolina that it should not -- they shouldn't use the test or at least shouldn't send the information to any doctor for review.

Q. Okay. But -- and -- but Visibly has not looked at the possibility of entering into contracts with South Carolina eye care providers that would require that if the software was used, it was used in conjunction with a comprehensive eye examination.

A. I don't know what our sales team -- if they've -- if they've felt out if there's much interest in that or not.

Q. Okay.

A. I -- you -- the typical use case is not in office. The -- a major advantage of Visibly's software is that someone doesn't have to come in the office. So some -- some -- some people do use it locally, say, within the same county or town or whatever, to have a patient who can't make it into the office be able to get his vision tested by his optometrist or ophthalmologist, but I -- my impression is that there is less demand, if there's any, for having someone be tested in the office with an optometrist by the -- by a doctor.

Q. Okay. And the -- the -- just if you would, kind of walk me through what the -- what the interface is with a patient. Is -- does -- can the patient do the test via a desktop computer?

A. Yes.

Q. Can the patient do the test using a cell phone, a smartphone?

A. Yes.

Q. Okay. And does the test rely on the patient

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to provide feedback about what he or she is able to see or not see?

A. Yes. And I -- I should clarify something. We have two different versions of -- of vision tests. One that uses a computer screen as the -- the eye chart analog and then one that uses a cell phone as a eye chart analog. The one that uses the computer screen, the cell phone -- the person also uses their cell phone as a remote. They sync their cell phone with their computer screen, and they enter the answers to the vision test. You know, it says -- it asks them -- it shows a Landolt C, and that's the optotype, and the optotype is facing one of four directions, and they select up, down, left or right on their cell phone.

There's another version of the test that shows the optotype on the cell phone, and they use their voice to control it from across the room, and they say -- they say up, down, left or right vocally, and -- from -- from a distance, and it based on that feedback assesses -- or provides the information to, you know -- about their visual acuity from a distance.

Q. Okay. And is -- are they -- is the patient required to stand or situate themselves at a certain distance away from whatever screen they're using, where it's their cell phone or whether it's a desktop computer?

A. Yes.

Q. What's -- what is that distance?

A. It's most commonly 10 feet. I don't know if there are any instances where it tells people to move forward. I don't think it does. So, I mean, the starting distance is 10 feet. I know that for sure, and I think it's always 10 feet, but I -- I wonder if there's some iteration when it might ask you to move closer, but I don't -- sorry. I'm trying to -- I've taken the test a bunch of times, but it's never asked me to move closer, but maybe it's because I'm -- I think it's always at 10 feet.

Q. Okay. Does the software have some means of verifying that the person -- the patient is far enough away for -- for there to be a valid result?

A. The software -- there's two ways it gets you to the right distance. It says either you can get a tape measure and measure out 10 feet and then, you know, stand there, or it walks you through a -- if you don't have a tape measure, it walks you through a series of instructions using the size of your foot and taking heel-to-toe steps to get the same distance away.

Q. Okay. All right. And to your knowledge is this sort of -- the two forms of interface that you've just described, has that always been the way a patient has interacted with Visibly's software?

A. I think the explicit instruction to use a tape measure or having that being an explicit option is relatively new. Maybe it was added in the last two years or something like that.

Q. Okay.

A. Of course, everyone always knew that they needed to get 10 feet away, so they could always use a tape measure, but I want to say about two years ago we made that an explicit suggestion, whereas before it said, "Get 10 feet away. Here's how you can do it with your heel-to-toe steps."

Q. Okay.

A. And before my time, I honestly couldn't say. I couldn't speak to how they were doing it before three years ago. I first took the test three years ago.

Q. And I note that you're wearing eyeglasses today. Have you used Visibly's test to renew a prescription for -- for eyeglasses?

A. I have taken the test many times, but I've never actually submitted it to get a renewed prescription.

Q. Okay. What -- for what purpose did you take the test?

A. Just to understand it.

Q. Okay. All right. I want to switch gears for a minute. I many ask you more questions about -- about the mechanics of the test. But I do want to ask you about whether Visibly has been involved in any lawsuits concerning its business operations. Has it been involved in lawsuits?

A. Yes.

Q. How -- how many other than the one we're talking about here today?

A. Let's see. I can walk you through it if that's easier --

Q. Yeah. That would be fine.

A. -- and you can tell me which ones you care about and don't want to hear more about.

Q. Okay.

A. So we are currently in a patent lawsuit against -- against a competitor, Easee. We're suing them for patent infringement in Germany. It's actually utility model infringement. Utility model is a German thing that's a lot like a patent.

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Q. Okay.

A. I imagine you don't care about that, but happy to tell you more if you --

Q. I don't need to know any more details about that, but thank you.

A. We had a lawsuit where Steve Lee, the founder of Visibly, sued Visibly for defamation, and that settled about a month ago. Not a month ago. About a year ago.

Q. Okay. And what -- was the settlement confidential?

A. Probably. I can't remember specifically now --

Q. Okay.

A. -- but they typically are.

Q. Where -- where was that lawsuit brought?

A. In Cook County, Chicago.

Q. Okay. And what were the allegations of -- that gave rise to this -- to a defamation claim?

A. With a high level? You could probably find the complaint online. At a high level, it was that -- so when Visibly suspended Steve Lee, it published a letter, and that letter said that Steve Lee had messed up the FDA process because he didn't -- didn't respond to the feedback offered by

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the FDA. The FDA said, "You need to do A, B, and C," and he didn't adequately do A, B, and C.

Q. Okay. When you say "published a letter," to whom?

A. Oh, sent a letter to the board or, I guess, specifically Brent Rasmussen, the CEO of Visibly, and Visibly's lawyer by the name of Lisa -- Lisa Conmy, who were also named in the lawsuit.

Q. Okay.

A. The two of them were -- they -- the allegation is they published the letter, and by "published" I think he means sent. But for defamation, you got to call it "published."

Q. Yeah, I understand.

A. Sent the letter to the board saying that Steve Lee had -- had messed up the FDA process by not following the FDA's feedback.

Q. Was there any allegation that the letter had been published outside of the company?

A. I don't know if there was an allegation. I'm pretty sure there was no evidence of that. But I'm -- I don't recall there being an allegation. There's definitely an allegation that it was published to the board --

Q. Okay.

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A. -- that resulted in his suspension or firing or whatever it was. I don't recall specifically if he was ever actually fired. But -- and then there were other allegations of more verbal -- they were a little more nebulous, and I can't remember them with specificity but something along the lines of, you know, people in the company after he was suspended had bad-mouthed him, you know, saying he --

Q. Out in the world?

A. Say again.

Q. Out in the world in some way or --

A. I think -- well, at least some of the allegations were that it was within the company, you know, that people within the company had said bad things about him to -- within the company and maybe there was some allegations about out in the world. I can't remember the specific details --

Q. Okay.

A. -- but that was the gist of.

Q. Okay. All right. So that -- that's now resolved.

A. (Witness nodding head.)

Q. Is that a "yes"?

A. Yes. Yes. I'm sorry.

Q. All right. What other litigation are you aware of?

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A. Let's see. There was the lawsuit filed against Warby Parker. This is another IP suit where Visibly sued Warby Parker for breach of an NDA.

Q. Of a non-disclosure agreement?

A. Yes, non-disclosure.

The basic allegations -- this is, again, before my time, so forgive me on the details. The basic allegation was Visibly had shown Warby Parker certain things about its vision test as part of, you know, looking into some sort of partnership agreement, and then Warby Parker developed its own vision test and, the allegation, something along the lines of that process used some of Visibly's confidential information in violation of the non-disclosure agreement.

Q. Okay. Is that lawsuit still pending?

A. No. That was 2017 or 2018.

Q. And do you know how the lawsuit was resolved?

A. Eventually there was a settlement agreement.

Q. Okay.

A. I don't know much of the details about how -- how it went down. I know there was a -- it went on for a while, I think.

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Q. Okay. All right. And what else?
A. I think that's it for litigation.
Q. Okay. So are -- other than the lawsuit that we're currently involved in -- or is -- is Visibly involved in any other litigation? I guess -- I guess the -- the patent suit in Germany is still pending. But is there any other lawsuit pending either against Visibly or where Visibly is the plaintiff in the United States at present?
A. No.
Q. Okay.
A. I am not certain that my recollection of the historical litigation is complete, but I am certain that I know about all the current litigation.
Q. Okay. Okay. All right. I understand that the Illinois Attorney General opened an investigation that -- against Visibly that -- that ended with some sort of settlement. Are you aware of that situation?
A. Yes.
Q. And that settlement agreement was reached in April of this year?
A. That sounds approximately correct.
Q. Okay. Were there any sort of formal proceedings initiated by the attorney general?
A. It depends on what you mean by "formal

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proceedings." There was a civil investigative demand which I understand to be more along the lines of a subpoena almost.
Q. Okay.
A. I wouldn't consider it litigation, but it -- you know, they -- they ask you for documents, and I believe you have to give it to them without, you know -- or maybe you can challenge it like a subpoena. That part happened before my time. The actual civil investigative demand. I was involved in settling it but not the initial process.
Q. Okay. And the -- were there -- did the settlements impose certain requirements on Visibly?
A. Yes. But the requirements were largely redundant with -- with the law.
Q. What do you --
A. But, yeah, the --
Q. I'm not sure I understand.
A. Yeah. The requirements -- so for context, the -- the states alleged that Visibly was -- was misleading consumers because, among other things, they had -- we had listed the device as FDA registered, and that was true. It was FDA registered.
But the states considered that to be

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misleading because someone might confuse FDA registered with FDA approved or FDA cleared or something like that, and that according to the states violated consumer protection laws that say you can't say misleading things, and so Visibly committed to not saying misleading things, but I wouldn't -- it -- essentially the agreement was parallel to what the legal requirements were anyway, so it was not an especially groundbreaking agreement.
Q. So you say "the states." Did other attorneys general join with the attorney general of the state of Illinois in this civil investigation?
A. Yes, sir. Eleven states.
Q. Okay. Who -- do you remember what states they were?
A. Illinois, Nebraska, Texas, Washington, Kentucky and some more. I'm going to start reaching the ends of my memory and get speculative if I go further.
Q. Well, let me see if I can help you because I have a statement up on my other screen issued by the attorney general of the state of Illinois about the settlement. He indicates that Illinois joined with attorney -- or the states of Kentucky, Mississippi, Nebraska, Nevada, Pennsylvania, South Dakota, Texas,

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Vermont, Washington and Wisconsin in participating in the settlement. Does that comport with your memory?
A. Yes.
Q. Okay. It also indicates that Visibly agreed to pay $500,000 to the participating states. Is that correct?
A. Yes.
Q. All right. It says that Visibly agreed not to market or sell any product to consumers unless it could be legally marketed or sold in accordance with the Food, Drug and Cosmetic Act or other FDA authority.
Is that part of the settlement to your knowledge?
A. Yes.
Q. It also indicates that Visibly could not make any representations comparing the safety or effectiveness of any Visibly product to products or services provided in person by medical professionals without possessing competent and reliable scientific evidence substantiating the representation.
Is that a correct recitation of an element of the settlement agreement?
A. I don't have a specific recollection if that's precisely correct, but I think it's at least

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approximately correct --

Q. Okay.

A. -- in their characterization. I couldn't -- I don't specifically recall that.

Q. Okay. And as I -- as I'm reading that, my own interpretation is that there's -- there's some proscription against making a comparative statement about the relative effectiveness of Visibly's software with other means of testing a patient's vision.

Does that sound like approximately what the settlement agreement touched on?

A. I think what it was going for is there's an FDA rule that when you make a comparison along those lines that you have to have a certain level of evidence, and I think the -- the FDA term of art for that is competent and -- and -- competent and reliable or -- I'm not sure of the exact wording.

But there's -- there's a term of art that they have for the level of evidence that you need to make a claim of just about any kind, and so I -- I think what that's getting at is that -- another way of saying we have to adhere by the FDA rule on that subject.

Q. Okay. Today, as we're talking to each other, does Visibly have evidence that meets that standard?

A. Yes. We -- FDA cleared the vision test based on the -- I don't know if "finding" is the right word. FDA came to the conclusion, broadly speaking, that the vision test is as safe and reliable as, you know, the process of testing vision with a ETDRS chart or the -- I'm not sure if that's even the exact right one. An eye chart that was standard in the market beforehand.

So in order to get pre-clearance what Visibly had to do was convince the FDA that we are -- that our device -- and it defines the device as the -- the vision test. That that vision test is substantially equivalent to something else in the market before 1976. That thing is some version of an eye chart. I think we actually used a couple versions of an eye chart.

Q. Okay.

A. So we ran clinical studies, and the FDA agreed with us that it was -- that our vision test was approximately as accurate or -- you know, did -- I can't remember. They have a specific -- they have a specific FDA term of art they use for this, but they -- they concluded that it was comparable enough, I'll put it that way, or as safe and effective or something like that, to the ETDRS eye chart, and I would think that satisfies the competent evidence.

And I'm probably -- I am getting to where I need to take a break.

MR. SHEALY: Yeah. That's -- and so am I. So why don't we --

THE WITNESS: Yeah.

MR. SHEALY: We'll do that right now, and we'll come back in, say -- why don't we just come back in 10 minutes?

THE WITNESS: Sounds great.

MR. SHEALY: That work?

MR. MCNAMARA: Off the record.

MR. SHEALY: Okay. Thank you.

- - -

(There was a recess from 11:12 to 11:24.)

- - -

BY MR. SHEALY:

Q. Okay. Mr. Stonedale, during the break, did you have any communication with any -- anyone else about the substance of your testimony?

A. No.

Q. Okay. All right. I was asking you about the terms of the settlement reached with the attorney generals of some eleven states in April of this year. And -- and you were telling me that the FDA had -- had given clearance to Visibly. Do I understand correctly that that clearance came in August of 2022?

A. That's correct.

Q. Okay. And was that clearance in the form of -- I think it's called a 510(k) letter?

A. It was a 510(k) clearance.

Q. 510(k) clearance. Okay.

Let me show you my screen and ask is this the -- can you see that?

A. Yes.

Q. This is a -- it looks like an 8-page document. Is this the 510(k) clearance from the FDA?

A. It is the -- it's called the 510(k) summary. It is something that's issued along with the 510(k) clearance.

Q. Okay. All right. So this is the -- this is the 510(k) summary that -- that Visibly received from the FDA in -- it looks like on or about August 11 of 2022?

A. Thereabouts.

Q. Okay. All right. I'll mark this as Exhibit 2 to your deposition.

- - -

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(FDA 510(K) Summary Letter marked Defendants' Exhibit Number 2 for identification.)

- - -

BY MR. SHEALY:

Q. And then let me see -- I think -- all right. And did that -- did that come along with a letter of some kind which indicated that Visibly had received the clearance?

A. I think so. I'm not certain.

Q. Okay. Let me -- let me see if I can find -- just hold on one second.

Okay. All right. I'm showing you a -- I think it's two -- two letters. One issued in -- yeah, August 12, 2022. And then a sort of follow-up letter of September 30, 2022.

And are these the communications by which Visibly learned that it had received FDA clearance?

A. I'm not certain that's when we learned it. But those were communications, I guess, formally -- well, I don't know if that's what formally grants it or not, now that I think about it. I guess is -- is your question how we learned?

Q. No. I just --

A. Or is your question just to authenticate these documents?

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Q. I was trying to authenticate these documents.

A. Oh. Yes, they looked authentic to me. I haven't --

Q. Okay.

A. Yeah.

Q. As I -- well -- and as I'm looking at them myself, I see that the August 12 letter -- looks like I don't have all of the pages of that letter in this -- in what I had hoped to be an exhibit. The August -- I mean, the September 30 letter is one page. It just -- and it looks like that was just issued because of a typo in the -- in the August letter. Correct?

A. I think so.

Q. Okay. All right. I'll -- I will -- when we -- we'll take a break again. I'll get a complete copy of the August letter, and we'll -- we'll have these two together marked as Exhibit 3 to your deposition.

Okay. So talk to me, if you will, about, I mean -- so this whole FDA process, because you've mentioned earlier, again, a big dust up with Stephen Lee about not handling that appropriately. Can you sort of tell me what your understanding is about

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what -- what steps Optternative took to -- to be able to market and license its software to the public?

A. And so when you say "Optternative," to me that hints you want me to talk about the first attempt at FDA.

Q. Yeah. I kind of want to walk through the whole -- the whole history.

A. The whole history. Okay.

With the caveat that my recollection is much better on the more recent attempt because I was around --

Q. Right.

A. -- I will -- I'll tell you what I know about the original. So the -- we attempted to do the De Novo process which as -- that is more involved than the 510(k) clearance process.

Q. Okay.

A. And it is the -- De Novo process has a different role. The 510(k) clearance was the appropriate process for what we were trying to do. Why we chose to do the De Novo process is not entirely clear. It was not the right decision.

The -- so the 510(k) -- the 510(k) clearance is easier to understand. It's trying to establish the fact that the device you would like to market is

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functionally equivalent within some standard range in terms of safety and effectiveness as some device that was marketed before 1976, I believe it is. Sometime in the '70s. In any event. Now, that is a -- that took us years and millions of dollars. It is a very involved process, and that's considered the relatively simple one.

The De Novo process, which I have not had to go through, is even more involved because instead of trying to show that -- like, in our case that the -- the vision test is functionally similar, equivalent to a -- to an eye chart, we're trying to create a whole new device category of things that other things can then be in the future equivalent to. So effectively, yeah, it -- then, you know -- huh? Yeah. I don't -- I don't actually know that's true. Scratch that.

So what is very clear is it's a lot more involved. So we chose the more involved route and --

Q. Do you know when that -- when you -- when -- and I guess it was Optternative then, when it initiated that -- that -- the -- its first attempt through the De Novo process?

A. I believe it started in 2016.

Q. Okay.

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A. So to give you the full time line, before 2016 we were operating under the notion -- because we had gotten an email from the FDA saying, "Your device is classified as an eye chart. Eye charts are 510(k), pre-market notification exempt. You don't have to go through a process to market it. You just have to register the device, and you can go on."

Then sometime in 2016, we had a meeting with the FDA where we learned that they had effectively changed their mind, and they no longer -- they did still consider it HOX code. HOX is -- so they did still consider it an eye chart, but they considered it the sort of eye chart that needs to go through a 510(k) clearance anyway, and most eye charts are not required to go through any sort of clearance.

So we were kind of under this exception because -- basically because it worked differently than a normal eye chart. Normal eye chart is a -- just a piece of paper or even a computer screen that you read the lines, whereas we showed the optotypes one at a time, and, you know, there were differences that the FDA later decided were significant enough that we needed to go through the clearance process.

And then we started going through the De Novo process. And there was a lot of back-and-forth.

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You know, the whole -- the whole process with the FDA, I know from experience in the simpler 510(k) process, is very involved. They give you feedback at every step of the way. You know, you need to -- so before you even say, "This is the clinical trial we're going to do," you say, "This is the sort of clinical trial I'm thinking about doing."

And they say, "Oh, okay. I would actually do it like this. That would be better."

And then you say, "Okay. So here's the plan based on what you said."

And then they say, "Well, I would tweak these five things."

And then, you know, it's back-and-forth. Many, many submissions.

Q. And did -- and it looks like -- did Hogan Lovells handle this whole process for -- for Opternative, or did it get involved later with the 510(k) process?

A. I -- so I'm certain that Hogan Lovells was the main firm involved in the 510(k) process, and I think they may have come in and lent a hand at the very end of the De Novo process, but I'm not certain of that.

Q. Okay.

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A. But they were -- they were in charge of the 510(k) process, the main lawyers.

And so there's lots of back-and-forth where the FDA gives you a great deal of feedback on how to design the appropriate clinical trials to -- to demonstrate what they want demonstrated. And the main problem with our attempt at the De Novo process is we didn't take the feedback into account sufficiently. We tried to do things -- we kind of stuck to the original plan despite the feedback telling us that wasn't -- that wasn't the right plan.

You know, they -- so, for example, they said, "You're going to need more eyes," more -- more study participants, I shouldn't say. We always refer to it as "eyes."

But, "You're going to need more individuals in your study, and you're going to need them to have this age distribution, this ethnic distribution, this geographical distribution."

And, you know, we didn't meet those requirements. That's one of the simpler things that they wanted, for statistical purposes, to have the right kind of sample size.

And then there were lot of details about changes in labeling and so forth that -- so that

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process didn't go right because we didn't listen enough, I think, and, ultimately, as it -- so -- okay. So we started that in 2016.

Then in 2017, we got this letter. It's a warning letter saying, you know, you need to be -- you need to have 510(k) cleaning or De Novo clearance or some sort of official clearance from the FDA or approval, rather, and -- and -- or clearance or approval, I should say, actually.

And then we called the FDA and said, "Hey, you know, we were operating under the understanding that we could continue in the market while we're going through this process."

And they said, "Yes, you can."

There's a disconnect between the people doing enforcement and the people doing device classification. So we continued operating as we continued to go through the De Novo process over, I guess, three -- three to four years. It was a while. So from 2016 to 2019. And then in the spring or summer of 2019, the -- you know, the process, I guess, had gone so slowly or for whatever reason they -- I don't know if they lost their patience with us or for some reason. I can't read the FDA's mind.

For some reason, the FDA changed its

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position and said, "Just take it off the market. We -- you know, you -- we are giving up on enforcement discretion to allow you to keep using the software while you go through the De Novo process."

Q. All right.

A. So then --

Q. So this is in -- you think 2019 is when you were given a directive to take the service off the -- off the market.

A. Right.

Q. And -- okay. And did you -- did -- was -- was -- was it still Opternative in 2019?

A. By then, it was Visibly.

Q. Okay. Did Visibly comply with that directive?

A. Yes, sir.

Q. And how long was the service off the market?

A. From approximately the summer, the spring or summer, of 2019 until COVID. When the pandemic started, the FDA changed its mind again, said, "We do not -- you don't any longer need pre-clearance. You can operate under the HOX code." That's the eye chart code. "You can operate under the HOX code as any other eye chart without pre-clearance." They issued this enforcement discretion policy.

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Q. Okay.

A. And so then we started operating again.

Q. Okay. Did -- and was -- was that connected to any kind of emergency powers or emergency authorization issued by the FDA?

A. Yeah. There's a -- they issued a whole policy for COVID. They said, "During COVID -- during the COVID emergency, we're going to effectively suspend certain requirements for certain devices."

Q. Okay.

A. One of those was the requirement that was preventing us from operating.

Q. All right. So that policy was in effect until May of 2023, correct?

A. To some degree, it's still in effect. There's a phase-out, and so I believe the bulk of it goes out of effect in November of this year.

Q. The reason I've asked the question is, was -- did Visibly -- was there ever a point where Visibly had to take the service back off the market for any period of time until it got the 510(k) clearance in August of 2023 -- 2022?

A. No.

Q. Okay.

A. So we -- the entire time Visibly was off the market was from mid 2019 to early 2020.

Q. Okay. And then it's been in the -- it's been operating in the marketplace ever since without interruption.

A. Correct.

Q. Okay. All right. So -- well, so when did -- I guess when did the process start of getting the 510(k) clearance?

A. I mean, it's a little difficult to define when the process starts. But as soon as we were given the opportunity to start operating again, I believe we started planning for getting the clearance that we needed so that when the emergency was over -- at that time, no one knew the emergency was going to last three years.

Q. Right.

A. As soon as the emergency was over, we'd be able to continue operating, so we started to some degree immediately. As far as the actual filings, of course, they took a while to put together.

Q. Okay. All right. And so as we sit here today, Visibly has the clearance it needs from the FDA to -- to operate.

A. Yes. In fact, it's -- it's a -- it's even -- it's even stranger. The FDA, upon clearing Visibly, determined the same day or the day after that online vision tests no longer need clearance. So it seems that through the process of going through 510(k) clearance with Visibly, they determined that the risk was low enough that no -- no clearance was further needed.

So, yes, Visibly got the clearance. We are probably the only online acuity test that will ever get the clearance because the day we got the clearance or the day after, something like, you know, within a day or two, they changed the -- they created a new code called QTO, and this new code, that's what they classified our device under instead of the earlier HOX which is a regular eye chart.

And then they -- they made this QTO category exempt from -- from pre-clearance requirement categorically. So even, like, the HOX was mostly exempt from pre-clearance, but because ours operated differently than a standard eye chart, we had to go through pre-clearance. QTO does not require pre-clearance even for, you know, an online vision test because it's only online vision tests.

Q. Okay. Okay. Thank you for that.

Let me go back to -- there are two more bullet points in the Illinois Attorney General's

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recitation of the settlement that -- that I wanted to ask you about. The third one is -- it says that Visibly would clearly label that its product have not been endorsed by any provider appearing on its "Find a Doctor" feature.

Does that sound like an accurate recitation of one of the elements of the settlement agreement?

A. Yes.

Q. Okay. And has Visibly complied with that part of the settlement agreement?

A. I don't believe we've used the "Find a Doctor" feature in a very long time, so -- so by default, yes.

Q. Okay. So you've just changed the -- made a change to the website to just take that feature off -- off of the website?

A. Well, I don't think it was in response to allegations by the states. I think it -- or maybe it was. It was before my time. I can't say why that was -- that happened. But it's -- for whatever reason, we no longer use that feature.

Q. Okay. And then the -- the last bullet point that the Illinois Attorney General has on -- in the announcing the settlement indicates that Visibly was to disclose that its online vision test is not a

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substitute for an in-person comprehensive eye examination and urged consumers to seek such exams to determine overall eye health.

Has Visibly complied with that aspect -- well, first, is that an accurate recitation of one of the elements of the settlement agreement?

A. As I recall, there's something like that in there. But I -- I don't know if the exact wording is right, but --

Q. Okay. To -- with that caveat in mind, has Visibly complied with that aspect of the settlement agreement?

A. Yes.

Q. Okay. And was -- how -- how has it done that?

A. When you take the vision test, it -- it states that the -- you shouldn't take the vision test if you haven't had an appointment in two years, I believe, or some amount of time. It says we recommend that you get a comprehensive eye exam. I don't recall if it's every one or two years, and that -- that you should go see a eye doctor at least that often.

Q. Okay. Now, the -- the 10(k) clearance that Visibly has received, does it provide a certain -- or

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does it provide certain parameters in terms of an audience for whom the test is deemed appropriate?

A. Yes. They're listed -- the details are listed there in the 510(k) summary.

Q. In the summary?

A. Yes.

Q. Okay. And do you -- do you know off the top of your head what the -- what those details are?

A. There's something along the line -- I don't remember how it's worded. There's something along the lines of people who don't have serious eye health issues. I believe that's in there. And then 18 to 40 age range, and there might be others.

Q. Okay. So let's -- let's look at it again together.

Okay. So if this is the 510(k) summary -- oh, I see. Okay. Here, the intended use, indications for use, this section, where it says --

A. I said 18 to 40. I meant to say 22 to 40.

Q. 22 to 40. Okay.

A. Sorry.

Q. Does -- does Visibly market its device to or its service to individuals that are outside of this age range?

A. It allows individuals to take the test

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outside of that age range, and I'll explain why.

Q. Okay.

A. The -- when -- when the -- so the initial approach was to do the simplest age range first, and below -- so we only got approved or we only got cleared, I should say, for 22 to 40 because we were trying to get through the 510(k) process with creating the fewest complications, and there's complications because the FDA considers adolescence to end at 21.

So if you go below 22, there are additional procedures, and then if you would go above 40, there's additional procedures, and particularly there's concerns about, you know, older populations and -- and presbyopia which tends to happen around 40. That's -- presbyopia is nearsightedness -- sorry -- farsightedness.

So in order to be able to operate on some population, not knowing that this whole category was going to become exempt and wanting to make sure that we got the clearance before the -- the enforcement discretion policy expired with the COVID emergency, we -- we got that relatively narrow age range, and then our plan was to after that provide additional data on over 40s and 18 to 21.

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Q. Okay. So let me make sure I understand --
A. Yeah.
Q. -- your testimony. The -- the clearance that you've received allows you to market the product, as it's called here, to folks who are within the age range of 22 to 40, but you're currently marketing the service to those -- to folks as young as 18 and as old as 55, correct?
A. I don't know if I would say we're marketing it to them. What I would say is if -- if you -- if someone who is 19 comes to Visibly's website and tries to take the test, it will let them. If someone who is 56 tries to come and take the test, the test won't let them take it.
Q. Okay. But it will take -- it will let someone that is 55 take it, correct?
A. Yes, sir. At least 54. I'm not sure -- is 55 inclusive? I'm not certain of that. 54 for sure.
Q. Okay. Is -- is that -- is that appropriate in your mind given -- given the -- the age range that has been cleared by the FDA?
A. Yeah. So that was the next part of it that -- I wanted to give you the history to understand why we made the decision to go with the 22 to 40 because it's that the explanation related. So

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then when we got clearance under this new code that -- where the FDA determined that these sorts of devices don't need clearance at all because they're safe, that also made the -- the process of getting the additional age range clearances unnecessary and redundant.
Q. Okay.
A. So our initial plan was to separately clear 40 to 55, but our -- the -- the doctors we've consulted with think that 55 -- you can go up to 55 without any sort of serious risk and -- and down to 18. So we -- we don't have to then get the clearance for the additional age ranges and submit the additional data for -- you know, specifically on people 40 to 55.
Q. Okay. And who -- does -- who does Visibly consult with for medical decisions like the one you just described?
A. The doctors at OEC and -- and our chief medical officer.
Q. And I don't know. What does OEC stand for?
A. Oh, I'm sorry. Optimized Eye Care. I described them earlier to you.
Q. Okay. Okay. So you rely on the doctors at that company to provide you with advice to the extent

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that there are medical considerations to be made in how your device is marketed.
A. Well, not just them. So we -- we do discuss with them -- of course, they're using the software, so we're always seeking their feedback. If they -- if they were not comfortable using the device on a population, then we couldn't be sending them the information because they wouldn't write the prescriptions, first of all, but, you know, it's good practice to get a lot of opinions. So we discussed -- we discussed with them, and then we also discussed with our chief medical officer, Taylor Tedder.
Q. Okay. And how long has Taylor Tedder been the chief medical officer?
A. Since, I want to say, September of 2022.
Q. And was there a chief medical officer before that?
A. Not in 2022. I imagine, because Steve Lee is an optometrist -- and I'm admittedly speculating now, but because he's an optometrist, I imagine he would have filled a similar role before that --
Q. Okay.
A. -- you know, until 2019 when he left.
Q. Okay. So do you know whether there was a

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chief medical officer from 2019 to 2022?
A. I don't think there was.
Q. Taylor Tedder --
A. I can -- I can tell you there was not -- from 2021 to the fall of 2022, there was not a chief medical officer.
Q. Okay. Taylor Tedder is what kind of doctor?
A. Optometrist.
Q. And licensed in what state or states?
A. I believe California. Might have more than one license, but I know he went to college in Illinois, so he might be licensed in Illinois too. I'm not certain.
Q. Okay. This just occurred to me. You're the general counsel. But do you have any other lawyers that report to you that -- that work for Visibly?
A. Yes.
Q. How many lawyers do you have working under your supervision?
A. One.
Q. And who is that person?
A. His name is Cleve Doty, D-o-t-y.
Q. And where is Cleve Doty licensed to practice?
A. Texas.

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Q. Does Visibly undertake any kind of vetting process in determining what eye care professionals or retailers it is going to partner with in -- in providing its vision test?

A. We leave the medical discretion up to the medical professionals that use the software. We don't -- Visibly doesn't second-guess that. We license the software.

Now, one thing Visibly does do is make sure that the prescriptions go to a doctor that has an active license in the state and isn't on the exclusion list. So, you know, we don't want to be in a situation where we send the information to someone whose license has expired, say, and -- and then they issue an invalid prescription. So we check that the license is valid, not on the exclusion list, but that's the extent of it.

Q. What -- and tell -- describe for me what the exclusion list is.

A. Oh, yeah. There's -- Medicaid and Medicare, and there's some state ones as well, they have these lists of medical providers that they won't operate with for one reason or another. Could be disciplinary actions or some sort of -- something that has called into question that person's

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integrity, and so they just -- they maintain a list of people that the government won't do business with, and we use that list to double-check to make sure the providers aren't on there.

Q. Okay. So, now, with respect to the relationship with Optimized Eye Care, how does -- how does Visibly go about that process of confirming that the medical professionals working for that company or working with that company are both licensed and not on the exclusion list?

A. I don't know exactly how, but we -- we get their license information and its expiration date, and that's put into our system, and the software, before it determines to send information to a given -- for a given provider, checks to make sure that their license is still valid.

Q. Okay. All right. So let -- so -- so with respect to medical professionals that work with Optimized Eye Care, the interface that we just walked through earlier where a layperson goes on to Visibly's website, takes the test and that information is sent to Optimized Eye Care, it -- it doesn't just go to that company to then be distributed to the right eye care professional. In fact, your software sends the eye -- the test result

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directly to a physician affiliated with Optimized Eye Care that is licensed in the state where the -- where the patient is. Is that correct?

A. I can't speak with confidence as to what software does what. I know that -- I know that somehow some software in the system checks the provider's license information to make sure it's still valid, and then somehow that person gets the information. As far as the interworkings of it and who controls what, I couldn't tell.

Q. Okay. But -- but you -- I think you've answered my question about vetting the eye care professionals. You verify that they are licensed, and you verify that they are not on the exclusion list. That's the -- that's the vetting process, correct?

A. That's what -- that's what Visibly does.

Q. Okay. Now, with respect to retailers that you mentioned for -- for contact lenses, are there retailers that also sell spectacles, sell eyeglasses, that Visibly has a relationship with?

A. Yes.

Q. Okay. With respect to those companies, is there some vetting process that Visibly goes through to make sure that those companies adhere to some sort

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of minimal standards?

A. No. Those companies basically just have a link or an API integration -- API is application programming interface -- with Visibly -- to use Visibly's vision test, but those -- they're not providing any sort of medical service. It's -- someone goes to a website to buy glasses or contacts and takes a vision test to renew their prescription if it's expired and -- and then gets their prescription.

But the -- you know, from Visibly's perspective, we deliver the prescription to the customer. We provide no suggestion, so, therefore, there's no need to vet where they -- where they use that prescription. And when I say Visibly provides it, I should say OEC provides the prescription. Visibly kind of stands in the middle and facilitates the transfer of information.

Q. Okay. But, I mean -- but you do have, you said, maybe even 50 different retailers with whom you have a relationship that -- that allows for one of their customers to have a link to Visibly's website to sort of start the process that ends up in someone purchasing either contact lenses or eyeglasses, correct?

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A. Yeah. But from our perspective, the process ends at the -- you know, when they get the prescription.

Q. Okay.

A. And then if they want to buy glasses from anyone they want, that's up to the customer.

Q. Okay. Has any -- has any retailer that Visibly has had a -- had a relationship with ever been the subject of any kind of governmental enforcement action, any kind of litigation that you're aware of?

A. I would imagine that some of the retailers that we -- we service has been subject to some sort of litigation. But I -- I don't monitor what litigation they're involved in.

Q. Okay. That's not a -- that's not a thing that Visibly actively monitors.

A. That's right. Or at least I don't.

Q. Would there be somebody else other than you that -- that would then -- that would take that on on Visibly's behalf?

A. I -- I would imagine -- I don't think there's a formal policy that I'm aware of. But I would imagine that if someone was doing something that we considered abusive or wrong that we would be

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disinclined to renew our contracts with them, you know, if they were defrauded customers or something.

I'm not exactly sure what you're getting at, but I -- you know, I don't think we -- we don't, as a matter of course, investigate online glasses retailers, although the industry is small enough that we probably -- our sales people and our -- other people on the team likely know something about each of the -- at least the larger players, but...

Q. Since you've been with the company, can you recall an occasion where Visibly made a determination -- Visibly or Opternative made a determination to sever a relationship with either an eye care provider or a retailer because of some -- some either professional disciplinary action being taken against the -- a provider or some law enforcement or regulatory investigation or action taken against a retailer?

A. No.

Q. Are you aware of any circumstances in which a Visibly customer reported -- either reported or alleged some sort of adverse health consequence or health event related to or arising from use -- the use of Visibly's software?

A. No.

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Q. Does Visibly have any sort of process for tracking or storing customer complaints related to the online vision test?

A. Yes. Are you familiar with a quality management service or QMS for short?

Q. Not particularly, no.

A. There's a fairly developed ISO standard for medical devices that need to use this QMS service, and part of that QMS service is maintaining observation and analysis of complaints about a medical device in the market, so we have a developed policy for that. At a high level, it consists of getting feedback from wherever we find it. We get the feedback, and we analyze it for complaints that might require some sort of fix or some sort of improvement to ameliorate the problem.

And the main sources where that feedback comes from are from -- our retail partners we hear things from. We have a survey at the end of the test where we ask for feedback, so people might put a complaint in there, and online reviews of the test. Those are typical ways we get information.

Q. Okay. And is there some requirement that that information or the analytics associated with that information has to be reported externally periodically?

A. To -- yeah. So there's -- in certain circumstances, certain circumstances that have never arisen, if there is a serious issue, then we would have to report it. That's never happened. The issues we have found -- excuse me -- are more along the lines of, you know, using the voice test. There's some background noise, and it didn't register. It didn't register the person's voice correctly or there was a difficulty in syncing the phone with the test. Some of them -- more unusual browsers, there have been issues. So there's never been the sort of thing that would have been reported. It's been technical fixes like that that we improve iteratively over time.

Q. Okay. So -- all right. At present how many states is Visibly operating in?

A. 30-something.

(The stenographer asks for clarification.)

THE WITNESS: 30-something.

BY MR. SHEALY:

Q. Okay.

A. Approximately 35.

Q. And are -- the states where Visibly is not operating, other than South Carolina, are they

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states -- are they not -- is the company not operating in those states because of some regulatory issue, or what -- what are the reasons why Visibly is not operating in those states?

A. For the most part, it's some regulatory issue. Other states with laws analogous to South Carolina. Not in every instance, though. I think for a while we weren't operating in a state because we just didn't have any customers there or didn't have any licensed professionals there briefly. But, yeah, for the most part it's regulatory issues.

Q. Okay. All right. So just going back to the FDA process, just -- I mean, just looking at information that seems to be publicly available, I just want to make sure I'm clear on a couple of details. The -- I guess originally Opternative registered the -- what we'll call the device, the software interface, as a Class I device. Is that correct?

A. Yes. Back in 2016 or thereabouts.

Q. Okay.

A. That sound correct. I don't remember if it was Class I or Class II, but I would think -- I would think it was Class I which is what it was ultimately classified as with the 510(k) clearance.

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Q. Okay. But the -- but in October of 2017 is when the company received a warning letter indicating that the FDA thought at that time that it was a Class II device; is that correct?

A. What I can say from memory is that's when we learned -- well, that's when we -- so that's when we got the letter saying we needed to go through a clearance or approval process, and I imagine that's partially because they determined it was Class II, so that --

Q. Okay. And is it your understanding a Class I device is a low-risk device that does not require any kind of pre-market clearance; then a Class II device is considered something that has enough inherent risk associated with it that it needs the -- that pre-market clearance from the FDA?

A. I think it's more complicated than that. I -- partially because we needed clearance and we're determined to be Class I. So it's -- it's not that simple.

Q. Okay. Okay. So it's -- I have -- I have made it more simple than it really actually is in my -- in what I -- in the way I formulated my question, correct?

A. I think so.

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Q. Yeah. Okay.

A. I'm -- I -- it's been a while since I've had to look at the Class I, II, III distinctions, and I can't precisely remember the borders between them, but I do recall that the borders that determined which class those are in are a little indeterminate.

Q. Okay.

A. So reasonable minds could disagree sort of thing.

Q. Okay. Does -- does Visibly have a -- a contractual relationship with a contact lens company known as Hubble?

A. Yes. Yes.

Q. Okay. Are you aware of any issues with the way Hubble operates and any -- any allegations that it fails to verify prescriptions, anything like that?

A. Yes. I recall seeing a news article that Hubble -- oh, I can't remember the details of the prescription or the -- of the issue, but I think there was some issue with them and that verification process of prescriptions and compliance with the FTC rule. Is that -- is that what you're referring to?

Q. I -- you know more about it than I do probably.

A. I -- yeah. I recall seeing something --

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some sort of allegation and -- yeah, I don't know if I'm remembering that it had to do with prescription verification or if I'm getting that from the question, but there was some allegation against Hubble that I recall seeing.

Q. Okay. And -- but has -- has Visibly changed its relationship with Hubble in response to any -- any allegation by anyone, or is it -- does it still maintain the same relationship with Hubble today as it -- as it always has?

A. I remember looking into that and thinking that there was nothing there that prevented our -- the use of our software.

Q. Okay.

A. But I don't remember precisely what the allegations were. I just remember thinking that it -- there was no reason they couldn't continue using our software.

Q. All right. So earlier we talked about all of the litigation that you're aware of that Visibly had been involved in, and then we talked about the civil investigation initiated by the attorney general of the state of Illinois. Are there any other regulatory or -- or other law enforcement actions currently pending that -- that involve Visibly?

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A. No.
Q. And other than what we've already talked about, have there been any other regulatory or law enforcement proceedings lodged against Visibly?
A. Yes. There was a issue in -- I think it was 2016 in Michigan. Michigan has a rule that requires the -- the prescriber of contact lens to -- I can't remember the exact wording. But it's something along the lines of assess the physiological fit, and some doctors had used Visibly's software to issue contact lens prescriptions in Michigan.
And Visibly got a letter from the board of licensing or some sort of state entity in Michigan saying not to make the software available there. And there was a back-and-forth, and ultimately we agreed that the software would not be made available for contacts but could be for glasses because the requirement to assess physiological fit or something along those lines did not require -- did not apply to glasses.
Q. Okay. And other than that in Michigan and the other action taken by the attorney general for Illinois, are there any other investigative or regulatory or law enforcement proceedings that you're aware of that have been initiated against Visibly?

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A. I don't know what you mean by "initiated." Those are the only formal ones. Now, there were -- they have -- we have received questions over the years before I started about how the software works and what it does and some -- from a number of states, and I recall -- and some of this -- they didn't go after Visibly, but they went after -- or they were asking questions about -- you know, asking questions to doctors that used Visibly.
And medical boards and things like that were asking questions, and then -- and there were -- you know, for the most part, it was just asking questions, providing answers, and then, you know, nothing really happened. Michigan was the only one where there was a formal agreement.
Q. Okay. And was there any kind of a fine or a monetary aspect of the agreement reached with Michigan?
A. I don't believe so. That was in 2016. I remember reviewing -- so I've reviewed the agreement, and I don't recall there being any fine.
Q. Okay. Has Visibly incurred any other fines from any -- any other regulatory body that we have not already discussed?
A. I don't believe Visibly has ever incurred a fine from a regulatory body.
Q. Okay. Or a law enforcement body.
A. Or a law -- yes, I don't -- as far as I know, Visibly has never paid a fine.
Q. Okay. Now, we talked about it paying $500,000 as a part of the settlement reached with the state of Illinois, but do you not consider that a fine?
A. No. I consider that the cost of avoiding litigation.
Q. Okay. Has Visibly incurred the cost of avoiding litigation in any other circumstance that we haven't already talked about?
A. No. I'm only aware of two settlements that Visibly has ever been the payor in. The one that you just mentioned with the CID in the eleven states and the -- the issue with Steve Lee, the defamation case we mentioned before.
MR. SHEALY: Okay. All right.
Mr. Stonedale, I think I am fresh out of questions. I will pass the baton to see if Mr. Matthews has some questions for you.
MR. MCNAMARA: Not to interrupt, but you said you wanted to fix the one exhibit that was truncated.

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MR. SHEALY: Yeah. I got -- I have to take a break and go find my secretary, so -- but, yeah, before we close, I will definitely do that.
MR. MCNAMARA: Okay.
- - -
EXAMINATION
- - -
BY MR. MATTHEWS:
Q. Okay. Do you go by Mr. Stonedale?
A. I usually go by Joel, but --
Q. Okay.
A. -- happy to go by Bob if you like.
Q. Well, Joel, I wanted to ask that question because I noticed on your -- your biography on your website, you're referred to as "they." Is that something that you prefer as well? I want to make sure I'm respecting your -- your stuff.
A. I don't know why that is. I -- I use the he/him pronouns.
Q. Well, I got to tell you. It was a little confusing because your bio seemed to indicate that you were not necessarily attuned to that, that you had been with the Texas Attorney General, and you had -- I think you had written things for The Daily Caller. Is that right?

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A. Yes. I --
Q. I don't think The Daily Caller uses pronouns, not like that. So just wanted to make sure I was zeroing in on your preferences.
A. Thank you for the consideration.
Q. Not a problem.
Listen, you indicated that -- I believe that the -- that the vision test states that you should not take the test if you have not had a comprehensive eye exam every two years.
A. I believe that's right.
Q. Okay. I'm looking at that test right now on the internet, and I don't see it. Where could I find it?
A. I believe it's one of the disclaimers that pops up during the -- I can't tell you exactly what screen it's on.
Q. Well, there's a -- there's a little -- there's a whole set of articles on the Visibly website that says "About the Vision Test." And it's got all sorts of discussion about, "How does the online vision test work," and, "Do I need a previous prescription to take Visibly's online vision test?" That sort of thing.
And you essentially say, "Yes, Visibly's

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online vision test is a prescription renewal service, so the doctor will want to know our previous prescription so they will know what they need to renew for you."
And there's a -- you know, Kirby had already talked to you about, you know, the ages you're allowed to do that. I see that your website says, "We enforce an age window of 18 to 55 for our participants on our online vision test."
And you explain why if you're over 55 you -- you do that. You say, "We recommend that those over 55 see a doctor in person to ensure that any of these health conditions that we acquire as we get older are not missed."
Does that -- I know you're not looking at it because I'm looking at it right now. Did you author that?
A. No.
Q. Okay. Who would have authored that warning that you give to your customers?
A. I don't know. It -- I don't know how long -- I don't know when that was written.
Q. Well, I'm -- I'm least likely to be voted to be technically competent. However, during the course of this deposition, I went on the Visibly website,

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clicked on -- you know, it is -- it's under the heading "About the Vision Test." And it's "Visibly Frequently Asked Questions," then just your -- "About Online Vision Test" and "About the Vision Test." And I'll read this into the record.
And the question -- it's under the, I guess -- a frequently asked question would be, "Why do I have to be between 18 to 55 years old to take the vision test?"
And it says it was -- it's from the third paragraph. "Once we reach the age of 55, there's an increasing likelihood of eye and health conditions, and our eye needs go beyond just how well you're seeing, period. Because we want to ensure that our patients' health is at its best, we recommend that those over 55 see a doctor in person to ensure that any of these health conditions that we acquire as we get older are not missed, period."
And I know you're not looking at it right now. You're just going to have to trust me that I read that appropriately. We could always print out a copy of it if we need to.
And my question to you is: Do you -- are you aware who in Visibly would have been reasonable for approving the content of that directive that you give

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to your patients?
MR. MCNAMARA: Objection.
THE WITNESS: At one point it would have been me. It may have also been the chief medical officer.
BY MR. MATTHEWS:
Q. Well, you know, it's funny you mention that. I was going to just say out loud that sounds to me like medical advice, not legal advice. You know, we're not doctors here. So is that something you would have trusted one of your physicians to author?
A. I don't know who authored it.
Q. Well, I know -- yeah, you've told me you don't know who especially doctored it, but, you know, Joel, I know, unless I'm missing my mark, you're not a doctor, right?
A. Correct. I'm not.
Q. Right. And neither am I.
And if you're working at Visibility (sic) and you're a physician and I think you've indicated that at some point you may have approved some of the content that's on your responses to frequently asked questions; is that right?
A. I have approved some of those changes as they've happened over the years.

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Q. Okay.
A. I don't recall the specific.
Q. Even though you don't have a current -- well, I'm putting words in your mouth. Do you have a current recollection of who would have approved that part of what you tell your patients or what I -- the part that I just read?
A. I do not know who authored that or who approved it. I do not specifically recall.
Q. Well, let me ask you the question like this then: Can we agree that that sounds to a layperson like medical advice?
A. No, I don't think so.
Q. Oh.
A. I think it sounds like an --
Q. Go ahead, please --
A. Oh, I think it sounds like an explanation of Visibly's reasons --
Q. Okay.
A. -- because it's -- yeah.
Q. Well, let me ask the question like this. I wouldn't know from anything that someone over 55 -- it would be proper to recommend to someone over 55 to see an in-person -- a doctor in person to ensure that health conditions related to your eye as we acquire

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are not missed. I wouldn't know anything about that. Is it fair to say that you don't know anything about that, why it's 55 or 50 versus anything else?
A. We have -- I have been told by the medical professionals we work with and -- that it is -- the risk of various eye diseases goes up at approximately 55, and --
Q. Okay.
A. And I -- I understand that's why we don't -- you know, we avoid offering the test to those at that age for that reason.
Q. Okay. Do you recall that being Dr. Hillman?
A. I'm sorry?
Q. Was that Dr. Hillman telling you that?
A. I have --
Q. Isn't he the guy that owns the Optimized Eye Care?
A. I have heard -- I've heard Taylor Tedder say that.
Q. Okay.
A. And I believe that opinion has also been attributed to Dr. O'Brien who we often ask about these sorts of things.
Q. Okay. What's Dr. O'Brien's first name?
A. Chris.

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Q. Okay. Are they at all connected with Optimized Eye Care?
A. Yes.
Q. Are they owners of some type?
A. Dr. O'Brien owns Optimized Eye Care of California, which is a separate entity.
Q. Okay.
A. And he also is a contractor with Optimized Eye Care of Illinois.
Q. Okay. How about Taylor Tedder, is he an owner of Optimized Eye Care in any fashion?
A. No. He's a Visibly employee or contractor now.
Q. Okay. And does he have a job title?
A. Chief medical officer.
Q. Okay. Good. Thank you. I missed that. I'm sorry.
So tell me this: Do you think it's likely that Dr. Tedder, as your chief medical officer, would have reviewed and approved the statement that I read to you into the record for your website?
A. I can't say for sure.
Q. Okay. Well, tell me this. If you think he disapproved of it, you better bet that that wouldn't be on your website, right?

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A. I would think he would have -- if he saw it and disapproved of it, I think he would have asked someone to change it.
Q. Right. So we have no information right now that either Dr. O'Brien or Dr. Tedder have any problem with the statement that "Because we want to ensure our patient's health is at its best, we recommend that those over 55 see a doctor in person to ensure that any of these health conditions that we acquire as we get older are not missed."
Sounds reasonable, right?
A. I cannot recall who looked at that before it went on the website.
Q. But you certainly have no objection to it, right?
A. I don't have it in front of me. But it doesn't sound to me like medical advice. My understanding from when you read it was that it was explaining Visibly's position and reasoning. For context --
Q. Well, it -- I think you're right. And I don't mean to cut you off, but I want -- I also don't want you to guess. Is -- the little paragraph that I just read is responding to a frequently asked question that is stated as follows: "Why do I have to

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be between 18 and 55 years old to take the vision test?"

So this is -- again, I'm not trying to ambush you. This is Visibly's explanation of, "Hey, this is why we, you know, restrict our -- the ages in which you can take the test online." Okay?

And it has an explanation about, "For those under 18, we want to ensure that parental consent is given when taking the vision test, so to protect our customers, we require that the minimum age of our participants is 18 years old."

Now, that is something that you probably did say grace over, right? That's just a legal issue. That's not a medical issue at all.

A. Say that again.

Q. It doesn't strike me at all that that's medical advice. You're not talking about anybody's eyeballs. You're talking about, "Hey, if you're not 18 or older, we have a concern about parental consent."

And that's a legal issue, not a medical issue, right?

MR. MCNAMARA: Objection.

THE WITNESS: It could be in certain circumstances.

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BY MR. MATTHEWS:

Q. Right. And you're better safe than sorry. You don't want people who are under 18 taking your test because there's a parental consent issue there, right?

A. I'm not familiar with -- enough with that to say.

Q. Well -- well, then why do you have it here?

A. Why do I have what there?

Q. Why do you have your -- why do you have the prohibition of people under 18 taking your test if you're not concerned about legal issues and parental consent?

A. You're asking why Visibly does not let -- take -- let minors take the test?

Q. Right.

A. That has -- that has been a practice since before I started. It was not my --

Q. Okay.

A. -- recommendation, so I've never looked into whether I thought it was a good idea. It strikes me as safer to avoid those issues with minors.

Q. No. I agree with you. I think you're right.

A. But I -- I've never -- I've never been asked to look into that.

Q. Okay. Cool beans.

A. For context on the FAQ, we have this complaint process I mentioned earlier where we gather --

Q. Right.

A. -- all the complaints, and --

Q. Okay.

A. -- one of the complaints we frequently see -- it's not really a complaint about the device, but one of the things we see is people are dissatisfied when they take the test and -- or they try to take the test and they can't because they're over 55. So some of the negative reviews we've seen have been that this test isn't allowed for people over 55, so I suspect that's the motivation, just connecting the dots, knowing that this has been a source of complaint. I suspect it's there to address -- to explain to people why that is.

Q. Well, tell me this. As a business model, it was okay for people -- in your view for people -- it was okay for people over 55 to -- it was okay in your view for them to take the test. And when I say "your view," I don't mean Joel. I mean Visibility.

If it was okay in your view that it posed no health concerns for someone over 55 to take the test, you would be quite pleased for them to do so, right, because that's just money in your pocket, right?

A. I don't know. That's -- that issue hasn't come up.

Q. Huh. Well, let's use an example. I am over 55, not by a lot, thank you, but I am over 55. I -- I -- as you can see, I wear glasses. And I hate eye exams. I hate people putting stuff in my eyes. I know it's important. I know you got to do it. I just hate it.

I would love to be able to get a new prescription without people sticking stuff in my eyes all the time. But if I tried to use this, I wouldn't be allowed to because -- even though you would otherwise welcome me as a customer, I'd be a paying customer, because -- you guys have a concern that it's better if I see a doctor in person because you don't want me to miss out on getting a health concern identified. Is that fair?

A. That has -- qualifies as one of the many reasons -- or not --

Q. Okay.

A. I won't say "many." I don't know if there's other reasons. What I would say is one concern with

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over 55 is there is a higher probability of eye diseases, eye -- other eye health issues other than visual acuity --

Q. Okay.

A. -- and one of -- lost my train of thought.

Q. I'll give you a minute.

A. Yeah.

I forgot what I was saying. I'm sorry. Keep going --

Q. It happens to everyone. Please don't -- please don't feel ill at ease about that.

A. Yeah.

MR. MATTHEWS: Actually, Joel, thanks for being with us. I'm actually done with my questions. Thank you for being with us.

And, Kirby, I didn't know if you or anyone else had any follow-ups?

MR. SHEALY: Only follow-up I have concerns those exhibits. I think I've got them queued up now as separate documents. So let me show my screen.

THE WITNESS: I'm sorry. Could I correct something I just said? I remember what my train of thought was that I had lost. Would that be okay?

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MR. SHEALY: Sure.

BY MR. MATTHEWS:

Q. Absolutely.

A. Okay.

Q. And at your pleasure.

A. Thank you. Yeah. The -- what I wanted to say was there -- we haven't addressed the issue of what other reasons there might be to not use over 55s. I believe some other online vision tests do, but -- so because we haven't addressed it, I don't want to speak to that, but, you know, one -- one thing I am aware of is that the standard of care as published by the American Ophthalmology Association or whatever trade body that is that represents ophthalmologists --

Q. Right.

A. -- does recommend frequent appointments starting at age 55, and I imagine that would be a source of that advice, and because we haven't gone past that, we haven't evaluated other issues that may arise.

Q. Well, as it happened, Joel -- I don't know if this is a question, but just to give you some comfort --

A. Uh-huh.

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Q. -- in your -- in your own motion for summary judgment, you state that the American Academy of Ophthalmology recommends that patients from age 55 to 64 have an eye health exam once every one to three years, that from age 41 to 40 -- or to 54, they have the examination once every two to four years.

So that -- is that -- that's from an affidavit by Dr. O'Brien. So is that -- is that what you were thinking of?

A. Might be.

MR. MATTHEWS: Okay. Okay. Once again, I'm done.

Kirby, anything else?

MR. SHEALY: Yes.

\- - -

REEXAMINATION

\- - -

BY MR. SHEALY:

Q. So -- all right. I'm going to show you -- do you see the document on my screen that's dated August 12, 2022?

A. Yes, sir.

Q. Okay. And do you see it's two pages in length?

A. Rightly so.

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Q. Okay. And is it your understanding that this -- this letter was the mechanism by which you -- Visibly learned that it had received section 510(k) pre-market clearance for the Visibly Digital Acuity Product?

A. Against, my understanding is this letter is what formally recognizes that decision. I don't know -- I think we -- we may have been told on the phone or something with our contacts with FDA that it was likely to happen. We may have known a day or two early --

Q. Okay.

A. -- something like that, but this is the formal notification.

MR. SHEALY: Okay. All right.

So, Madam Court Reporter, I, I think, earlier indicated that this letter combined with another letter would be Exhibit 3. What I'd like to do is just have this letter by itself be Exhibit 3 to the deposition. Okay?

THE STENOGRAPHER: Yes, sir.

MR. SHEALY: Okay. And I'll send it to you.

\- - -

(Letter Dated 8/12/2022 marked Defendants'

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Exhibit Number 3 for identification.)

- - -

BY MR. SHEALY:

Q. And then Mr. Stonedale, let me pull up the other one. The -- the September 30, 2023, letter I'm now sharing on my screen, do you see it?

A. Yes.

Q. Okay. And this is, again, just the one-page letter correcting the August 12 letter just to correct a typo, correct?

A. Seems to be.

Q. Okay. But these two letters together, am I correct, constitute the formal notification of the section 510(k) clearance for Visibly's Digital Acuity Product, correct?

A. Yeah. I think there may be some additional documents too. They're definitely part of it. There's the 510(k) summary, which is --

Q. Which we've already looked at.

A. Yeah. That lays out the scope. I was going to say, I think there's more than just this, but, yeah, this is the notification, the formal notification.

Q. Okay.

A. Yeah.

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Q. All right. This -- I'll have this letter, the September 30, 2022, letter, marked as Exhibit 4 to your deposition.

- - -

(Letter Dated 9/30/2022 marked Defendants' Exhibit Number 4 for identification.)

- - -

MR. SHEALY: And I'll have that -- both of those sent to you, Ms. Osborne, when we conclude.

And, Mr. Stonedale, I have no further questions for you. Thank you for your time today. Please answer any questions that your counsel may have.

- - -

EXAMINATION

- -

BY MR. MCNAMARA:

Q. Just a couple of quick points of clarification before we wrap up. You were talking to Mr. Shealy about the FDA approval process and all of the feedback the FDA gives and the back-and-forth. Do you remember that?

A. Yes.

Q. And I just want be clear about the nature of the feedback. Is the FDA giving feedback on the design of the device, or is this feedback about something like the design of the clinical studies you're going to provide to prove whether the device works?

A. I -- I think they might in some cases offer feedback about design of device. In our case, the feedback that was offered that I'm aware of was design of the trials. I know in the 510(k) clearance they provided feedback about design of the trials, number of participants, things along -- you know, what statistical tests to use. They also provided feedback about the wording of disclaimers. But I -- I don't think it would be outside FDA practice to, in some cases, offer suggestions about the -- the design of the device itself.

Q. Okay. They talk about the design in some cases, but that wasn't Visibly's process?

A. Yeah. Our -- most of your interaction, anyway, if not all of it, had to do with the design of the trials and labeling. They like to -- they like to provide feedback on labeling requirements, which in some cases might be a feature of the device, depending on...

Q. Okay. You also talked at some length with Mr. Shealy about the settlement initiated by the Illinois Attorney General. Do you remember that?

A. That's right.

Q. One of the provisions you talked about was a requirement that Visibly disclose that it's not a comprehensive eye exam and urge its customers to get a comprehensive eye exam. Am I summarizing that right?

A. Yes. That's what we talked about.

Q. Did Visibly make those disclosures to its customers before the settlement?

A. Yes.

MR. MCNAMARA: Okay. Nothing further.

MR. MATTHEWS: Okie dokie. Thank you so much.

MR. SHEALY: Yep. Thanks.

MR. MATTHEWS: Thank y'all.

- - -

(Witness excused.)

(Videoconferenced deposition concluded at 12:45 p.m.)

- - -

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CERTIFICATE OF REPORTER

I, Deidre Osborne, Stenographer and Notary Public for the State of South Carolina at Large, do hereby certify:

That the foregoing deposition was taken by videoconference on the date and at the time and location stated on page 1 of this transcript; that the deponent was duly sworn to testify to the truth, the whole truth and nothing but the truth; that the testimony of the deponent and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed; that the foregoing deposition as typed is a true, accurate and complete record of the testimony of the deponent and of all objections made at the time of the examination to the best of my ability.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof. Witness my hand, I have hereunto affixed my official seal this 13th day of August, 2023, at Lexington County, South Carolina.

_____

Deidre Osborne, RPR
Registered Professional Reporter
Notary Public
State of South Carolina at Large
My Commission Expires:
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THE STATE OF SOUTH CAROLINA
In The Supreme Court

RECEIVED
Aug 15 2024
S.C. SUPREME COURT

APPEAL FROM RICHLAND COUNTY
Court of Common Pleas

Kristi F. Curtis, Circuit Court Judge

Case No. 2016-CP-40-06276

Opternative, Inc.	Appellant,
v.	
South Carolina Board of Medical Examiners and the South Carolina Department of Labor, Licensing and Regulation	Respondents,
and	
South Carolina Optometric Physicians Association	Respondent-Intervenor

NOTICE OF APPEAL

Opternative, Inc. ("Appellant"), appeals from Judge Curtis' order granting summary judgment, dated July 18, 2024, and received in written form by Appellant that same day. Appellant files this notice directly in the Supreme Court because the decision below issued a "final judgment involving a challenge on state . . . grounds to the constitutionality of a state law . . . where the principal issue is one of the constitutionality

of the law." Rule 203(d)(1)(A)(ii), SCACR. Appellant notes that this case has been before the Supreme Court once before, and the constitutional issues that the appeal raises are significant. *Opternative, Inc. v. S.C. Bd. of Med. Exam'rs*, 437 S.C. 258, 260, 878 S.E.2d 861, 862 (2022) (holding "Opternative, Inc. has constitutional standing to challenge the constitutionality of the Eye Care Consumer Protection Law"). A copy of Judge Curtis' July 18, 2024 Order is attached hereto as required by Rule 203(d)(1)(B)(ii), SCACR.

Respectfully submitted,

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STATE OF SOUTH CAROLINA)	IN THE COURT OF COMMON PLEAS
)	FOR THE FIFTH JUDICIAL CIRCUIT
COUNTY OF RICHLAND)	
)	Civil Action No. 2016-CP-40-06276
Opternative Inc.,)	
Plaintiff,)	
v.)	
)	**ORDER GRANTING SUMMARY JUDGMENT TO DEFENDANT-INTERVENOR**
South Carolina Board of Medical Examiners,)	
South Carolina Department of Labor,)	
Licensing and Regulation,)	
)	
Defendants,)	
and)	
)	
South Carolina Optometric Physicians)	
Association,)	
)	
Defendant-Intervenor.)	

This matter is before the Court on cross-motions for summary judgment filed pursuant to Rule 56 of the South Carolina Rules of Civil Procedure by Plaintiff Opternative Inc. ("Plaintiff") on June 15, 2023, and by Defendant-Intervenor South Carolina Optometric Physicians Association ("SCOPA") on August 7, 2023. Defendants South Carolina Board of Medical Examiners and South Carolina Department of Labor, Licensing and Regulation (collectively, "Defendants") filed a response in opposition to Plaintiff's motion on August 4, 2024. On August 7, 2023, Plaintiff moved to strike SCOPA's motion for summary judgment, and on May 29, 2024, Plaintiff filed a response to SCOPA's motion for summary judgment.

A hearing took place by WebEx on June 3, 2024. At the beginning of the hearing, Plaintiff's counsel informed the Court that Plaintiff's Motion to Strike was withdrawn, and the Court agreed to consider all memoranda and exhibits filed by both parties in support of and in opposition to the motions for summary judgment.

After review of the materials submitted to the Court and consideration of the arguments made

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by counsel at the hearing, and based on applicable law, this Court concludes summary judgment is appropriate against Plaintiff as to all causes of action set forth in the pleadings in this case. Therefore, pursuant to Rule 56, SCRCP, this Court denies Plaintiff's Motion for Summary Judgment and grants summary judgment in favor of Defendants and SCOPA.

BACKGROUND AND PROCEDURAL HISTORY

Plaintiff[1] initiated this action against Defendants on October 20, 2016, seeking a declaratory judgment that portions of the Eye Care Consumer Protection Law, S.C. Code Ann. §§ 40-24-10, *et seq.* ("ECCPL") are unconstitutional because they result in a denial of both equal protection and substantive due process. Specifically, Plaintiff challenges sections 40-24-20(C) and (D) of the ECCPL, alleging these provisions violate Article I, Section 3 of the South Carolina Constitution. It also challenges Section 40-24-10(9) of the ECCPL, which provides that vision assessments:

> may not be based solely on objective refractive data or information generated by an automated testing device, including an auto refractor or other electronic refractive-only testing device, to provide a medical diagnosis or to establish a refractive error for a patient as part of an eye examination.

S.C. Code Ann. 40-24-10(9).

The Court granted SCOPA's motion to intervene on February 22, 2017. Following a brief discovery period, Defendants moved for summary judgment on the basis that (1) Plaintiff lacked standing to challenge the constitutionality of the ECCPL, and (2) even if Plaintiff possessed standing, the ECCPL passes constitutional muster because it bears a reasonable relationship to its legislative purpose that is supported by rational basis. Plaintiff responded with its own Motion for Summary Judgment on September 6, 2017, arguing the ECCPL amounted to "naked economic protectionism" that served no purpose except protecting the financial interests of brick-and-mortar optometrists "all

[1] Plaintiff was called Opternative Inc. at the time the action was commenced but changed its name in 2018 to Visibly, Inc.

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while doing literally nothing to protect the public health or safety." (Pl.'s Mot. Summ. J. 1-2). On October 3, 2017, SCOPA filed a brief in support of Defendants' motion and opposition of Plaintiff's motion.

The circuit court granted Defendants' Motion for Summary Judgment and dismissed Plaintiff's Complaint with prejudice on January 26, 2018, finding Plaintiff failed to demonstrate that it had standing to bring its Complaint. In light of this conclusion, the circuit court expressly declined to address the parties' equal protection and due process arguments regarding the constitutionality of the ECCPL.

On February 23, 2018, Plaintiff filed a Notice of Appeal from the circuit court's order granting summary judgment to the Defendants. On May 5, 2021, the Court of Appeals reversed the circuit court's order, finding Plaintiff had satisfied the requirements for constitutional standing. *Opternative, Inc. v. S.C. Bd. Med. Exam'rs*, 433 S.C. 405, 418, 859 S.E.2d 263, 270 (Ct. App. 2021). The South Carolina Supreme Court affirmed the decision of the Court of Appeals on August 24, 2022. *Opternative, Inc. v. S.C. Bd. Med. Exam'rs*, 437 S.C. 258, 878 S.E.2d 861 (2022). The case was then remitted to this Court for further disposition.

FACTS

I. THE PARTIES

Founded in 2012 by Aaron Dallek and Steven Lee, O.D., Plaintiff is a Chicago-based telehealth company that developed a technology through which individuals can use a computer or smartphone to determine the refractive error of their eyesight without having an ophthalmologist or optometrist in the room ("Technology"). Plaintiff currently offers its Technology in approximately 35 states and, in addition to its remote vision tests, sells contact lenses through its subsidiary, Next Day Contacts, LLC, an online contact lens retailer.

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SCOPA is an association of optometric physicians practicing in South Carolina. Optometrists are independent primary health care professionals for the eye that examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures as well as identify related systemic conditions affecting the eye. Ophthalmologists are medical doctors specializing in eye and vision care, who by study and training are qualified to diagnose and treat ocular diseases, perform eye exams and surgeries and prescribe lenses to correct vision problems. Ophthalmologists who practice in South Carolina are licensed and regulated by the South Carolina Board of Medical Examiners ("BME"), within the Department of Labor, Licensing & Regulation ("LLR").

II. PLAINTIFF'S TECHNOLOGY AND IN-PERSON EYE EXAMINATIONS

Users can access Plaintiff's Technology through Plaintiff's website or, alternatively, they may be routed to Plaintiff's vision test through any one of its dozens of affiliated third-party corrective lenses retailers. Plaintiff's Technology then collects the user's information by soliciting responses to questions and visual stimuli through a computer interface. Plaintiff uses the responses to generate a dataset about the user and his or her ocular refractive error, which—after receiving a fee from the user—it will then send to Optimized Eye Care, Inc. ("Optimized"), a separate corporation that contracts with optometrists and ophthalmologists to review the results and write prescriptions. Once a prescription is generated, Optimized will send it via Plaintiff back to the original user, who can use the prescription to purchase contacts. Plaintiff's Technology does not measure objective data about the user's eyes or eye health, it cannot detect or aid in diagnosing diseases of the eye or systemic diseases, nor does it perform a corneal examination and evaluation.

Conducting comprehensive eye examinations is within the scope of practice of both optometrists and ophthalmologists. Comprehensive eye examinations consist of, but are not limited

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to, the following: a review of the patient's health history; measuring visual acuity, both aided and unaided; performing an examination with a slit lamp of the anterior segments of the eyes and eyelids; performing an internal ophthalmoscopic examination through a dilated pupil, including evaluation of the optic nerve head, macular and peripheral retina; performing a subjective refraction; performing tonometry; evaluating pupils; assessing ocular motility and eye alignment; performing confrontation visual field or similar screening field; performing other tests and procedures as indicated by the patient's chief complaint, case history or objective signs and symptoms discovered during the course of the eye examination; making a diagnosis and formulating a treatment plan; seeking consultation and/or making referrals for assessment/treatment to other health providers as appropriate.

Optometrists and ophthalmologists are under an affirmative obligation to look after the health and safety of their patients, which requires them to use their judgment to determine whether their patients' complaints or symptoms pertaining to their eyesight or eye health are indicators of systemic or body-wide disease processes or pathologies. They are likewise obliged to make such determinations even when the disease processes or pathologies are asymptomatic. It undisputed that optometrists and ophthalmologists are best able to make those necessary determinations through in-person comprehensive eye examinations.

Both optometrists and ophthalmologists are authorized to issue prescriptions for corrective lenses, including spectacles and contact lenses. A contact lens evaluation is a set of diagnostic tests and procedures performed in addition to a comprehensive eye examination. These tests and procedures include a measurement of the corneal curvature (keratometry or corneal topography) and an evaluation of the anterior segment and tear layer of the eye in relation to the contact lens fit. A poorly fit contact lens can cause irritation to the eyes, and the prolonged use of irritating contact lenses can cause pain, scarring, and vision loss even when a patient does not exhibit any symptoms. Such

consequences of a poorly fit contact lens can only be detected by a corneal evaluation. (Shipp Aff., ¶ 14; Robinson Aff., ¶ 12). Typically, a prescriber will not prescribe contact lenses they have not seen on their patient's eyes and will factor in a trial period to evaluate how the lenses are fitting and whether the lenses are causing vision problems. (Shipp Depo. 41:3-12; 53:8 – 54:12).

Certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination. There is also a risk that individuals may mistakenly believe that they have received a comprehensive eye examination after receiving a prescription for spectacles or contact lenses from an ophthalmologist who only relies upon Visibly's Technology. (Shipp Aff., ¶ 15; Robinson Aff., ¶ 15).

In addition to assessing eye and vision problems, an eye examination may be the first opportunity to detect diabetes and other health conditions. Examples include high blood pressure, hypercholesterolemia, and certain inflammatory diseases. Diabetes is currently the nation's seventh leading cause of death in the United States. Diabetes is also a risk factor for heart disease and stroke, and a leading cause of kidney disease and blindness in adults. Early detection can allow early treatment and management of both systemic and eye-related diabetic changes. One of the more debilitating eye-related outcomes associated with type 2 diabetes in adults is vision impairment, including blindness. Diabetes-related eye conditions include, but are not limited to, refractive changes, cataracts, diabetic retinopathy, and glaucoma. Diabetic retinopathy is among the leading causes of preventable blindness in the United States. Most symptoms associated with diabetic eye disease progress slowly, and unnoticeably; therefore, comprehensive dilated eye examinations are necessary to diagnose, prevent and manage these conditions. Importantly, diabetic eye disease can be detected and diagnosed during a routine comprehensive dilated eye examination.

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III. THE EYE CARE CONSUMER PROTECTION LAW

The General Assembly passed the ECCPL on April 29, 2016. Governor Nikki Haley vetoed the ECCPL on May 16, 2016, but on May 19, 2016, the General Assembly overrode the Governor's veto by a vote of 98 to 1 in the House of Representatives and by a vote of 39 to 3 in the Senate. The ECCPL is now codified at S.C. Code Ann. §§ 40-24-10 and 40-24-20.

The ECCPL contains two parts: the first part establishes the relevant definitions, while the second part contains the substance of the Act. Part one of the ECCPL defines a "provider" as "an individual licensed by the South Carolina Board of Examiners in Optometry or the South Carolina Board of Medical Examiners," meaning both optometrists and ophthalmologists are governed by the Act. S.C. Code Ann. § 40-24-10(7). Part two of the ECCPL provides as follows:

> **SECTION 40-24-20.** Valid prescription required to dispense spectacles or contact lenses; penalties.
>
> (A) A person in this State may not dispense spectacles or contact lenses to a patient without a valid prescription from a provider.
>
> (B) To be valid, a prescription must contain an expiration date on spectacles or contact lenses of one year from the date of examination by the provider or a statement of the reasons why a shorter time is appropriate based on the medical needs of the patient. The prescription must take into consideration medical findings made and refractive error discovered during the eye examination. If a provider determines a patient is a suitable candidate for a prescription for contact lenses or spectacles, a provider may not thereafter refuse to issue a prescription for spectacles or contact lenses to a patient.
>
> (C) A prescription for spectacles or contact lenses may not be based solely on the refractive eye error of the human eye or be generated by a kiosk.
>
> (D) Violation of this section constitutes misconduct as provided for in Sections 40-37-110 and 40-47-110. A provider who violates this section is subject to the penalties authorized in Chapter 37, Title 40 or Chapter 47, Title 40, as applicable.[2]

S.C. Code Ann. § 40-24-20.

[2] Chapter 37, Title 40 applies to optometrists. Chapter 47, Title 40 applies to ophthalmologists, among other physicians.

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In sum, the ECCPL establishes a baseline in the standard of care for corrective lens prescriptions such that they must be based upon more than refractive error measurements generated by a computer or smart phone.

APPLICABLE LEGAL STANDARD

I. SUMMARY JUDGMENT

Summary judgment shall be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Rule 56(c), SCRCP. "In determining whether any triable issue of fact exists, the evidence and all inferences which can reasonably be drawn therefrom must be viewed in the light most favorable to the nonmoving party." *Quail Hill, LLC v. Cnty. of Richland*, 387 S.C. 223, 235, 692 S.E.2d 499, 505 (2010) (citation omitted). Even when the evidentiary facts are not disputed, "if the conclusions to be drawn from them are, summary judgment should be denied." *Coker v. Cummings*, 381 S.C. 45, 49, 671 S.E.2d 383, 385 (2008). "Summary judgment is not appropriate when further inquiry into the facts is desirable to clarify the application of law." *Id.*

II. STATUES PRESUMED CONSTITUTIONAL

"Statutes are presumed constitutional, and a law that neither creates a suspect class nor abridges a fundamental right is given only minimal equal protection scrutiny." *Faircloth v. Finesod*, 938 F.2d 513, 516 (4th Cir. 1991) (citing *City of New Orleans v. Dukes*, 427 U.S. 297, 303 (1976)). A statute is presumed constitutional and will not be declared unconstitutional unless its repugnance to the constitution is clear and beyond a reasonable doubt. *Sojourner v. Town of St. George*, 383 S.C. 171, 175, 679 S.E.2d 182, 185 (2009). "Constitutional constructions of statutes are not only judicially preferred, they are mandated[.]" *State v. McGrier*, 378 S.C. 320, 329, 663 S.E.2d 15, 19 (2008)

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(quoting *Henderson v. Evans*, 268 S.C. 127, 132, 232 S.E.2d 331, 333-34 (1977)).

When the constitutionality of a statute is at issue, "every presumption will be made in favor of its validity, and no statute will be considered unconstitutional unless its invalidity leaves no doubt that it conflicts with the constitution." *S.C. Dep't Soc. Servs. v. Sarah W.*, 402 S.C. 324, 334, 741 S.E.2d 739, 745 (2013); *see also Dunes W. Golf Club, LLC v. Town of Mount Pleasant*, 401 S.C. 280, 296, 737 S.E.2d 601, 609 (2013); *McMaster v. Columbia Bd. Zoning Appeals*, 395 S.C. 499, 504, 719 S.E.2d 660, 663 (2011). Accordingly, the burden is on the challenging party to prove the unconstitutionality of the statute. *Home Health Serv., Inc. v. S.C. Tax Comm'n*, 312 S.C. 324, 327, 440 S.E.2d 375, 377 (1994) (emphasis added).

Similarly, "those attacking the rationality of the legislative classification have the burden 'to negative every conceivable basis which might support it.'" *F.C.C. v. Beach Commc'ns, Inc.*, 508 U.S. 307 (1993) (quoting *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 364 (1973)); *accord McLeod v. Starnes*, 396 S.C. 647, 723 S.E.2d 198 (2012) ("[A] classification is presumed reasonable and will remain valid unless and until the party [making an equal protection challenge] proves beyond a reasonable doubt that there 'is no admissible hypothesis upon which it can be justified.'" (quoting *Carolina Amusement Co. v. Martin*, 236 S.C. 558, 576, 115 S.E.2d 273, 282 (1960))).

ANALYSIS

Plaintiff challenges the ECCPL on grounds of equal protection and due process and argues the statute is mere economic protectionist legislation that violates the South Carolina Constitution. In particular, Plaintiff first claims that the ECCPL denies it equal protection of the law because it treats doctors who prescribe contact lenses differently than all other doctors who use telemedicine. Plaintiff further claims that the ECCPL violates South Carolina's due process clause because it does not rationally protect patient health and only serves to insulate brick-and-mortar optometrists from online

competition.

I. SOUTH CAROLINA'S EQUAL PROTECTION CLAUSE

The Court turns first to an analysis of whether the ECCPL violates South Carolina's Equal Protection Clause. "Courts generally analyze equal protection challenges under one of three standards: (1) rational basis; (2) intermediate scrutiny; or (3) strict scrutiny. If the classification does not implicate a suspect class or abridge a fundamental right, the rational basis test is used." *Denene, Inc. v. City of Charleston*, 359 S.C. 85, 91, 596 S.E.2d 917, 920 (2004). The parties do not dispute that the determination of whether the ECCPL violates the Equal Protection Clause turns upon the application of the rational basis test.

"Under the rational basis test, the requirements of equal protection are satisfied when: (1) the classification bears a reasonable relation to the legislative purpose sought to be affected; (2) the members of the class are treated alike under similar circumstances and conditions; and (3) the classification rests on some reasonable basis." *Id.*; *see also Bodman v. State*, 403 S.C. 60, 69, 742 S.E.2d 363, 367 (2013); *Harleysville Mut. Ins. Co. v. State*, 401 S.C. 15, 26, 736 S.E.2d 651, 656-57 (2012); *Sunset Cay, LLC v. City of Folly Beach*, 357 S.C. 414, 428, 593 S.E.2d 462, 469 (2004); *Fraternal Order of Police v. S.C. Dep't Revenue*, 352 S.C. 420, 430, 574 S.E.2d 717, 722 (2002); *Gary Concrete Prods., Inc. v. Riley*, 285 S.C. 498, 504, 331 S.E.2d 335, 339 (1985). South Carolina's equal protection jurisprudence reveals no discernable difference between its application of the rational basis test to questions of equal protection under the South Carolina Constitution and the federal courts' use of the standard to measure equal protection under the United States Constitution.

A. The ECCPL is Reasonably Related to Its Legislative Purpose.

The ECCPL protects the public health and welfare because it upholds the standard of care for eye care professionals in South Carolina and prevents citizens from unwittingly putting their eye

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health at risk by obtaining a prescription for corrective lenses without a comprehensive eye examination. The applicable standard of care for eye care professionals in South Carolina requires them to use their medical judgment to determine whether their patients' complaints or symptoms pertaining to their eyesight or eye health are indicators of systemic or body-wide disease processes or pathologies. As Plaintiff acknowledges, certain diseases of the eye or of the body may go undiagnosed if patients merely elect to purchase corrective lenses using remote eye refraction measurement tools without an in-person comprehensive eye examination. Corrective lens wearers may therefore incur health risks if they forego regular eye exams that would allow the optometrist or ophthalmologist to spot emerging health problems in their early stages.

Plaintiff argues that the ECCPL does nothing to protect the public health and safety, ignoring the evidence in the record to the contrary. For instance, it fails to acknowledge that one-year prescriptions for corrective lenses are consistent with national optometric standards and with extant South Carolina and federal law concerning contact lenses. *See*, *e.g.*, S.C. Code Ann. § 37-25-10 *et seq.*; 15 U.S.C. § 7601 *et seq.*; 16 C.F.R. § 315.1. It likewise glosses over the fundamental requirement of the ECCPL: that corrective lens prescriptions must be based on more than just a refractive examination. *See* S.C. Code Ann. § 40-24-20 (Supp. 2016).

Instead, Plaintiff argues that the ECCPL does not serve its stated purposes because it does not *require* eye-health exams, nor does it *require* eye doctors to check for emerging health problems. Again, this ignores that optometrists and ophthalmologists are already under an affirmative obligation as part of their standard of care to look after the health and safety of their patients, including using their judgment to determine whether their patients' complaints or symptoms are indicative of a latent disease or other issue. The ECCPL need not spell out what particular steps an optometrist or ophthalmologist needs to take during a comprehensive eye examination for it to survive rational basis

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scrutiny. Both the General Assembly and the common law have long recognized that the standard of care for professionals across a wide range of disciplines is too nuanced and fact-specific to be established by legislative act. *See, e.g.*, S.C. Code Ann. § 15-36-100 (Supp. 2016) (expert witness must attest to standard of care and its breach as a prerequisite to bringing a claim for professional negligence); *Dawkins v. Union Hosp. Dist.*, 408 S.C. 171, 758 S.E.2d 501 (2014) (expert testimony required in medical malpractice action). What the ECCPL does is establish a baseline for corrective lens prescriptions, just as other laws and regulations establish minimum requirements in the healthcare context and otherwise. *See, e.g.*, S.C. Code Ann. § 40-33-32 (outlining minimum standards for licensure as a nurse); S.C. Code Ann. § 40-57-135 (establishing minimum standards for real estate brokers-in-charge management agreements); S.C. Code Ann. § 37-15-30 (setting minimum standards for using a contest as a ruse to promote the sale of goods, property or services).

To that end, Plaintiff acknowledges in its disclaimer to potential consumers that its Technology is not available to individuals over the age of 55, stating: "Because we want to ensure that our patients' health is at its best, we recommend that those over 55 see a doctor in person to ensure that any of these health conditions that we acquire as we get older are not missed." In doing so, Plaintiff has instituted its own minimum baseline for the appropriate standard of care regarding the need for in-person eye exams for those over a certain age.

The South Carolina Constitution grants the General Assembly the authority to legislate for the protection of the public health and welfare, and this Court finds the ECCPL does just that by protecting the public from receiving inadequate eye care. Because there is an identifiable risk that the law addresses, Plaintiff has not met its evidentiary burden to overcome the presumption of the ECCPL's constitutionality

B. The ECCPL Treats All Ophthalmologist and Optometrists Alike Under Similar Circumstances and Conditions.

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The ECCPL creates a bright line rule for all ophthalmologists and optometrists to follow. This is not a case in which some ophthalmologists or optometrists are treated differently than others. *See, e.g.*, *Daniel v. Cruz*, 268 S.C. 11, 14, 231 S.E.2d 293, 294 (1977) (holding legislation that treated fortune tellers in one county differently from those in another violated equal protection). Nor are ophthalmologists and optometrists being treated differently from other health care providers, as the ECCPL only applies to conduct that falls within ophthalmologists and optometrists' scope of practice. *See, e.g.*, *Joseph v. S.C. Dep't Lab., Licensing & Regul.*, 417 S.C. 436, 450-53 790 S.E.2d 763, 770-72 (2016) (holding classification which distinguished physical therapists from other licensed healthcare providers had no rational relationship to the legislative purposes of a statute at issue); *Broome v. Truluck*, 270 S.C. 227, 230-32, 241 S.E.2d 739, 740-41 (1978) (holding different statutes of limitations for different professionals involved in making improvements to real property violated equal protection).

Plaintiff argues the ECCPL singles out ophthalmologists from other types of physicians because "dermatologists, cardiologists, endocrinologists, psychiatrists, family doctors, and all other doctors are allowed to prescribe using telemedicine." This comparison is inapposite. These other types of doctors cannot prescribe contact lenses, while eye doctors can. While eye doctors may still prescribe treatment via telemedicine as permitted under South Carolina law and their standard of care, they cannot base a prescription for corrective lenses based solely upon the refractive error measured by a kiosk or computer. In other words, the standard for prescribing corrective lenses is applied uniformly, just like eye doctors, or any other type of doctor, cannot prescribe "drugs to individuals the licensee has never personally examined based solely on answers to a set of questions." S.C. Code Ann. § 40-47-113.

Furthermore, the ECCPL prohibit reliance upon Plaintiff's Technology in the course of

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treating a patient; it merely proscribes writing prescriptions for patients based solely upon the refractive error that the Technology measures. Plaintiff acknowledges that it is possible for eye doctors to use its Technology in conjunction with an in-person eye exam, although it has not attempted to market it for use in that manner because that is not where the "demand" lies. Regardless, South Carolina is not unique in determining it is necessary to protect consumers in this fashion while acknowledging a place for telemedicine. *See e.g.,* Ga. Code Ann. § 31-12-12(a)(5) and (b)(1)(C) (mandating that "[n]o person in this state shall write a prescription for contact lenses or spectacles unless an eye examination is conducted," and defining "eye examination" as a "real-time examination, which includes the use of telemedicine, in accordance with the applicable standard of care of the prescriber, of the ocular health and visual status of an individual that does not consist solely of objective refractive data or information generated by an automated testing device, including an autorefractor or kiosk, in order to establish a medical diagnosis or refractive diagnosis for the establishment of refractive error, conducted with the patient and prescriber in the same physical location or via telemedicine.").

The ECCPL bears a reasonable relation to the State's legitimate interest in protecting the eye and systemic health of South Carolina citizens. The ECCPL's utility in tackling traditional police power concerns easily survives rational basis scrutiny. The distinction between ophthalmologists who write prescriptions for corrective lenses based solely upon Plaintiff's Technology and the ophthalmologists who write prescriptions based upon a comprehensive eye examination is not arbitrary or capricious, but a rational reflection of the statutory standard for appropriate patient care in the realm of eye health. This Court is not empowered to pass judgment upon that standard, except to acknowledge the legislative prerogative to establish it.

C. The Classification in the ECCPL Has a Reasonable Basis.

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In arguing the ECCPL has no rational basis, Plaintiff relies heavily upon *Joseph v. South Carolina Department of Labor, Licensing & Regulation*, 417 S.C. 436, 790 S.E.2d 763 (2016). In *Joseph*, the Supreme Court held that the statute at issue "deprives physicians of the right to practice medicine in the best interest of their patients" by not being able to hire physical therapists. *Id.* at 452, 790 S.E.2d at 771. Plaintiff draws a parallel with that case, claiming the ECCPL deprives ophthalmologists of their right to practice medicine in the best interest of their patients. The comparison fails because the ECCPL addresses a particular public health risk, whereas it was impossible to find any such risk to the public health and welfare that the statute in *Joseph* was allegedly designed to mitigate.

The text of the ECCPL does not prevent ophthalmologists from exercising their medical judgment to write corrective lens prescriptions. If anything, it prevents Plaintiff, and other similar healthcare technology providers, from fulfilling a market desire for convenience, to the detriment of ophthalmologists' patients. *See Denene, Inc.*, 359 S.C. at 97, 596 S.E.2d at 923 ("No one has an unfettered right to pursue a business detrimental to the public health, safety, and welfare."). Unlike the statute at issue in *Joseph*, the ECCPL does not prevent ophthalmologists and optometrists from practicing medicine in the best interest of their patients. To the contrary, the ECCPL prevents corrective lens prescriptions from being issued without an examination that takes into consideration a patient's overall health. Addressing that risk is well within the General Assembly's constitutional prerogative.

Accordingly, this Court concludes Plaintiff has not proved beyond a reasonable doubt that the ECCPL violates the Equal Protection Clause.

II. SUBSTANTIVE DUE PROCESS

Likewise, this Court concludes Plaintiff has not proved beyond a reasonable doubt that the

ECCPL violates its right to substantive due process. The test for a substantive due process claim is "[w]hether [a statute] bears a reasonable relationship to any legitimate interest of government." *R.L. Jordan Co. v. Boardman Petroleum, Inc.*, 338 S.C. 475, 478, 527 S.E.2d 763, 765 (2000). "In order to prove a denial of substantive due process, a party must show that he was arbitrarily and capriciously deprived of a cognizable property interest rooted in state law." *Harbit v. City of Charleston*, 382 S.C. 383, 394, 675 S.E.2d 776, 782 (Ct. App. 2009) (citing *Sunset Cay, LLC*, 357 S.C. at 430, 593 S.E.2d at 470). "The State's deprivation of the property interest must fall so far beyond the outer boundaries of legitimate governmental authority that no process could remedy the deficiency." *Id.*

Although the analysis of Plaintiff's due process claim largely mirrors its equal protection claim, it is nonetheless clear that the ECCPL bears a reasonable relationship to the State's legitimate interest in protecting the eye and systemic health of South Carolina citizens.

The undisputed facts before the Court reveal that the ECCPL's legislative purpose is to protect the public from receiving inadequate eye care. The ECCPL protects the public health and welfare because it prevents citizens from unwittingly putting their eye health at risk by obtaining a prescription for corrective lenses without a comprehensive eye examination. There is no dispute that that undiagnosed diseases of the eye are a public concern, and that certain diseases of the eye or of the body may go undiagnosed if patients forego an in-person comprehensive eye examination. The provisions of the ECCPL are reasonably related to protecting and upholding the applicable statutory standard of care for medical professionals in South Carolina, which requires them to use their professional judgment to determine whether their patients' symptoms are indicators of systemic diseases.

Accordingly, because the South Carolina Constitution grants the General Assembly the authority to legislate for the protection of the public health and welfare, and because the ECCPL does

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just that, the ECCPL is constitutional. Plaintiff has not met its evidentiary burden to overcome the presumption of constitutionality beyond a reasonable doubt.

CONCLUSION

For the above-stated reasons, this Court concludes Plaintiff has not to carried its evidentiary burden to overcome the presumption of the ECCPL's constitutionality beyond a reasonable doubt. Summary judgment is therefore warranted on Plaintiff's claims against Defendants.

Accordingly, for the reasons stated in this Order, the Court hereby grants the Motion for Summary Judgment filed by SCOPA. Plaintiff's claims against Defendants are hereby dismissed with prejudice.

IT IS SO ORDERED.

(*Judge's E-Signature Page to Follow*)

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Richland Common Pleas

Case Caption:	Opternative Inc vs South Carolina Board Of Medical Examiners , defendant, et al
Case Number:	2016CP4006276
Type:	Order/Summary Judgment

So Ordered

s/ Kristi F. Curtis, Circuit Court Judge, No. 2762

STATE OF SOUTH CAROLINA	)	
	)	THE COURT OF COMMON PLEAS
COUNTY OF RICHLAND	)	
Opternative Inc.,	)	
	)	TRANSCRIPT OF RECORD
Plaintiff,	)	2016-CP-40-06276
	)	
-vs-	)	
	)	
South Carolina Board of Medical Examiners, et al.,	)	
	)	
Defendants.	)	

June 3, 2024

Richland, South Carolina

B E F O R E:

HONORABLE KRISTI F. CURTIS, JUDGE

A P P E A R A N C E S:

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Transcribed by Amy Pennica, from Webex

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(WHEREUPON, there were no exhibits marked or testimony taken during this hearing.)

THE COURT: Okay. That brings us to the next several motions on the docket. This is case number 2016-CP-40-06276. This is Opternative versus South Carolina Board of Medical Examiners, et al.

MR. WINDHAM: Yes, Your Honor. My name is Josh Windham. I represent the plaintiff Visibly in this case. And, Your Honor, before we get to the merits of the case, you know, we do have a couple pending motions on the calendar, so I thought it would be useful to, maybe, briefly summarize what this case is all about and how we got here, given it's been pending for almost eight years, and then where our motions currently stand. Because I think, at least our pending motion to strike and our motion to supplement -- those can be pretty easily resolved in light of the notice of SCOPA filed on Friday. Your Honor, this is a challenge --

THE COURT: Okay. Can I stop you just a minute. I need everybody to tell me -- because the parties on this have shifted --

MR. WINDHAM: Yes, Your Honor.

THE COURT: -- from the beginning until now. So I need to know who everyone represents. Mr. Windham, you are here for Visibly?

MR. WINDHAM: That's right. And I'm joined by Robert McNamara at The Institute for Justice and Rayjia Fowler at Nelson Mullins for Visibly.

MR. MATTHEWS: My name is Gene Matthews. I represent the Department of Labor Licensing and Regulation. And the only reason we're in this case is we're the administrative agency -- actually, I think it's the Board of Medical Examiners that's in charge of enforcing the statute that the plaintiff would like to have cleared and constitutional -- and for whatever reason the Attorney General is not a party to this, so it falls to LLR to defend the constitutionality of the statute.

THE COURT: Okay. And that's Mr. McNamara and Ms. Fowler and Mr. Windham all here for Visibly?

MR. WINDHAM: Yes, Your Honor. And the plaintiff name is going to be Opternative in the caption.

THE COURT: Okay. And, Mr. Shealy, you are here for which party, sir?

MR. SHEALY: May it please the Court, Your Honor. I'm here for the South Carolina Optometric Physicians Association, which is an intervener -- was allowed to intervene in the case. And it's, I guess, on your docket, I think -- our motion for summary judgment is the first motion on your docket, but there is a procedural history that we all need to let you know about because there's a complicated history to this.

THE COURT: Sure. So, Mr. Windham, I'll let you start us off. And I did see this has already gone to the Supreme Court and back.

MR. WINDHAM: That's right.

THE COURT: But I'll let you get us started, sir.

MR. WINDHAM: Sure. Okay. Well, given that you're aware of that history, I'll try to be brief in the procedural history, but just so that we're all up to speed --

THE COURT: Well, it looks like you pretty much have the morning since everything else for 9:30 is now resolved, so I'm not in a rush. I'm glad to hear everything that you want to tell me.

MR. WINDHAM: That's great. Okay. This is a challenge to a statute. South Carolina law generally allows doctors to prescribe treatment based on information they collect from patients online. In 2016 the legislature passed the Eyecare Consumer Protection Law, which forbids doctors from prescribing corrective lenses, and only lenses, based on information they collect online. In other words, the Eyecare Law is an exception to South Carolina's broad embrace of telemedicine, and that exception destroyed my client's Visibly's South Carolina business. Visibly created an FDA-cleared online vision test that doctors can use to test patient's vision remotely and decide whether to renew their lens prescriptions. After the Eyecare Law made that illegal, Visibly challenged the law under Article 1, Section 3 of the South Carolina Constitution, which, of course, requires equal protection and due process. Now, as you noted, we are here on remand from the South Carolina Supreme Court's 2022 decision that we've got standing to sue because Visibly's precise

business model and online vision test that doctors can use to renew lenses remotely is forbidden by the Eyecare Law. And so we filed a motion for summary judgment. That was heard in August of 2023, and it remains pending. SCOPA filed a cross motion for summary judgment the business day before the hearing on that matter, and that's on the calendar for today, of course, and that brings me to the other motions on today's calendar.

We've got a motion to strike and a motion to supplement, and our position is that both of those motions are now moot in light of the notice that SCOPA filed on Friday to supplement the summary judgment record. I have one caveat to that, which is that SCOPA's notice is written to apply to SCOPA's motion only. And so we would just ask that, Your Honor, if you're going to resolve the cross motions together, consider all of the evidence attached to both motions for summary judgment and to the responses to the motions for summary judgment, kind of all one big package. And if the Court does that, we certainly have no problem with withdrawing our motion to strike and motion to supplement.

MR. SHEALY: And, Your Honor, I would agree with Mr. Windham and do not have any problem with those items being considered with respect to all party's submissions. We filed the notice to supplement the record on Friday specifically to address the motion to strike that was filed last summer. At that time we had relied upon, in part, an affidavit from one of our expert

witnesses, and there was some dispute about whether that was appropriate for us to do so. Since that time that witness's deposition has been taken. In fact, Visibly filed -- one of its motions was to supplement the record filed in October with that witness's deposition. Out of abundance of caution and because I had not, when I filed our motion for summary judgment, said we're relying on that deposition transcript because I didn't have it. We hadn't taken that deposition yet. I just supplemented to say we're relying also on that deposition transcript. I think all parties were in agreement that that needs to be looked at by the Court to resolve these motions. The other thing we supplemented with was the final version of the deposition transcript of, I think, the caption says Opternative. It was a 30(b(6) deposition of what is now Visibly. At the time we filed our motion, last summer, we only had a rough draft of that, so that was only just to provide the Court with the final version. We agreed Visibly's motion to supplement the record and the motion to strike are both now moot, and there's only one motion, I think, pending -- currently pending before Your Honor.

THE COURT: So everyone's in agreement, then. Mr. Matthews, do you need to be heard on that? That basically everything that's been filed, either in support or in opposition to the motion, be considered for purposes of this motion?

MR. MATTHEWS: Yes, ma'am, Your Honor.

THE COURT: Okay.

MR. SHEALY: Your Honor, what's procedurally anomalous about this is that Judge Clifton Newman heard Visibly's motion for summary judgment and still has that, I guess, nominally under advisement, although he is no longer a sitting South Carolina Circuit Judge. And I don't know if his jurisdiction continues after he has given up his seat, but there's never been a ruling on that. That's the other part of this that I think all of us needed you to be aware of. He's heard one half of these arguments, really. Actually, he's heard all of our arguments previously because when we argued in opposition to that motion we posited the basis for him to rule in the defendants' favor as well. So I don't know how to address that problem.

MR. WINDHAM: I have a thought on that, Your Honor, if I may. I mean, I think because we're the plaintiff in this case, we did file the original motion. That was never decided. What I would like to do for you today is explain why our motion should be granted and SCOPA's cross motion should be denied. And then, of course, Mr. Shealy can, kind of, say his peace as well, and Mr. Matthews, if that's a procedure you're happy with.

THE COURT: Sure. So it sounds like you'd be making the same arguments in opposition to their motion that you would make in support of your motion for summary judgment as well. Is that what I'm hearing from you, Mr. Windham?

MR. WINDHAM: That's right. Except that our response to their cross motion does have some additional evidence attached to

it. I'm happy to go first, or if Your Honor prefers Mr. Shealy -- you know, their motion is on the calendar -- whatever Your Honor prefers.

THE COURT: It really makes no difference to me. But, Mr. Shealy -- well, let me address one thing first. Let me ask, when was this in front of Judge Newman?

MR. SHEALY: I believe it was August 7, 2023.

THE COURT: Okay. And I should know, but I confess I don't know whether he's remaining retired active or whether he is retiring for bigger and better things. I think he's got a pretty -- I think he's doing mediation now. That should be taking up a good bit of his time. If what I've seen is any indication, I think that he'll be highly sought after for mediation, but I don't know if he's remaining on as retired active or not.

MR. MATTHEWS: Ma'am, he is. This is Gene Matthews. He is listed on the JAMS website as an active arbitrator and mediator, and I think he would not be able to do that and continue to be on retired status to hear cases.

THE COURT: Okay. So, Mr. Shealy, I'll be glad to hear from you first since you're first on the docket here, and then, Mr. Windham, I'm going to give you every opportunity to tell me everything you want to tell me.

MR. SHEALY: May it please the Court, Your Honor. So just to return back to the procedural history, the Eyecare Consumer

Protection Law is what we're here about. The General Assembly passed it on April 29, 2016. It's now codified at South Carolina Code Section 40-24-10 and 20. And this was passed, in fact, over Governor Haley's veto. And the plaintiff's lawsuit was filed that fall just a few months after the law went into effect. This is the plaintiff's challenge to the constitutionality of this statute on two basis that claim a denial of due process, and they also claim denial of equal protection. Those -- and so to sort of set the stage from a factual standpoint, Your Honor, there are two sets of professionals in South Carolina that are licensed and authorized to prescribe lenses, corrective lenses, and to treat -- otherwise treat diseases of the eye. Those being ophthalmologists, which are medical doctors, and optometrists, which have a more limited practice. They cannot conduct certain operations -- if you will, surgical procedures -- but they can do a fair number of other things to treat conditions of the eye. And the Eyecare Consumer Protection Law, in essence, says that you can't give someone a prescription for corrective lenses based solely upon a refractive error examination of the eye. And that's me trying to summarize the law. But the point is that Visibly and, I think, now others have developed technology that allows someone to conduct -- self-conduct an examination of the refractive error of their eye using their cell phone. And this technology now has FDA clearance over the span of this lawsuit's nearly eight-year history that now the FDA has, I think, granted

unlimited clearance for that technology. The point of the law, from our perspective and what we believe that the evidence that has been deduced in the discovery process shows, is that if someone is able to get an eyeglass prescription or prescription for contact lenses without undergoing a comprehensive eye examination, diseases of the eye and other systemic diseases will go unnoticed.

The evidence shows that there are certain systemic diseases such as high blood pressure, diabetes that can be diagnosed and sometimes are diagnosed for the first time in an eye examination because they show up -- if you look at someone's retina, they show up in certain conditions in the retina. There are other conditions -- diseases of the eye that are only diagnosed with a comprehensive eye examination. This law, we believe, addresses a public health risk because many, many members of the public, including almost everyone on this Webex, with the exception of me, I believe, wears spectacles. One of the most common medical issues that people have to deal with is getting corrective lenses for their eyes. And I should hasten to say that while I don't have corrective lenses at this point, I probably should. But what this law does is addresses a public health risk that if we don't have it, then people can get corrective lenses and never see an eyecare professional; and, therefore, certain diseases of the eye and certain systemic body diseases get missed. So that is the rational basis for this law. Your Honor, there is no

evidence of any kind of a special classification that our Courts have identified in the past as giving rise to anything other than, you know, a rational basis test. A rational basis test is what applies here for purposes of constitutional analysis. And as Your Honor knows, when we're talking about a challenge to the constitutionality of a statute, every presumption is supposed to be given by the Court to the statute's constitutionality. So it's a high bar for the plaintiffs to carry here. They have to carry it by clear and convincing evidence, and Your Honor is supposed to look at any -- any possible basis for this law to be constitutional before it deems -- before it deems the law to violate the South Carolina Constitution. Here, because of that salient public health risk that this law addresses, it really is a pretty simple inquiry. We've shown through the testimony of Dr. Melvin Shipp through the testimony of Dr. Mark Robinson that this is indeed a legitimate public health risk that this law addresses. And, Your Honor, the arguments that have been advanced in opposition to Opternative's -- I'm sorry -- to SCOPA -- my client is SCOPA -- in opposition to SCOPA's motion go down a lot of rabbit holes, like Visibly's technology is not unsafe. And nobody is taking that position. That's a false, sort of, argument that -- we're not taking the position that Visibly's technology is unsafe. It doesn't matter to us whether the technology works or not. What is being addressed here is the disincentive that South Carolinians would have to visit an

eyecare professional if they can get a prescription for corrective lenses outside of a comprehensive eye examination. And that's what this whole thing boils down to.

We believe there's just no genuine issue of material fact, and Visibly has been unable to up to this point demonstrate that it has been denied equal protection of the laws. The law treats all South Carolina optometrists and ophthalmologists equally. The notion that it treats these doctors differently than other medical professions who wish to use telemedicine is also a false -- it's sort of a false flaw with the law because telemedicine in other contexts allows for a doctor to interact with a patient over a span -- over a spatial -- in other words, they don't have to be right in front of them to have a personal interaction with them and understand what's going on with that patient. But here, what we're talking about is the limited use of a refractive error measurement solely for purposes of giving a prescription for corrective lenses. Those are two totally separate things. And there is a specific health risk that is at issue here that's not at issue in the world of telemedicine in general. Likewise, Visibly has not been able to adduce any evidence of a denial of substantive due process because this is not an arbitrary act on the part of the General Assembly. There is a salient public health purpose, and evidence that we have put before the Court establishes that firmly we believe. And so for those reasons, Your Honor, we would ask that our motion for

summary judgment be granted and that this case be dismissed.

THE COURT: Okay. Mr. Windham, are you going to speak for the group?

MR. WINDHAM: I am, Your Honor. So I want to start by addressing a couple things that Mr. Shealy said, and then, kind of, go into our affirmative case and our broader response. So, first of all, I'm very glad to hear Mr. Shealy disavow the idea that Visibly's technology is unsafe. You certainly get that impression from the introduction to their motion for summary judgment. So I'm happy to hear him say, consistent with all of the evidence in the summary judgment record, that there is nothing unsafe about Visibly's technology as such. And that is why the FDA has cleared Visibly's technology as a safe and effective alternative to an in-person vision test -- eye chart. Now, I also want to address the issue of refractive error. Visibly is not about a doctor using the technology to prescribe based solely on refractive error. Visibly collects medical information from a patient, including -- and this is crucial -- including information on how recently they had a comprehensive eye health exam. And that is one of the most important facts in this case. It is undisputed on this record that patients do not need a comprehensive eye health exam, medically, every single time they interact with an eye doctor. It is undisputed, and the American Academy of Ophthalmology standards lay this out, standards with which both of Mr. Shealy's experts agree that a

patient does not even need a comprehensive eye health exam until they reach the age of 40. They only need it one time. And that's an undisputed fact in this case. And the Court can find that on page 6 of our brief where we kind of cover all that, our response. That's the point of Visibly's technology -- is that in between those comprehensive eye health exams, it is perfectly medically safe for a patient to get limited treatment online, including lenses. And all five eye doctors who testified in this case -- three on SCOPA's side and two on our side -- agreed that it is consistent with the medical standard of care to prescribe lenses in between comprehensive eye exams as long as patients are getting those comprehensive eye health exams. And all five of them have personally done so in their practices. And that's pages 5 to 7 of our response brief.

And with that, I want to kind of go back into legal framework here because this case does really come down to one basic question and one South Carolina Supreme Court decision that resolves that question in our favor. The Eyecare Law treats doctors who want to prescribe lenses differently than doctors who want to prescribe anything else using telemedicine, including anything else for your eyes, like eyedrops. And the question is is it rational to single them out for differential treatment? The answer is no. And the case that tells us that is Joseph from 2016. In Joseph the South Carolina Supreme Court struck down a law that banned doctors from employing physical therapists but

not any other kind of health care professional. It treated doctors who wanted to hire physical therapists differently than doctors who wanted to hire anybody else, and that disparate treatment was irrational, because the supposed reason for it, that conflicts of interest might arise, was a reason that would justify banning doctors from hiring any kind of health care professional, not just physical therapists. The Court refused to indulge the irrational assumption. At the heart of the government's argument, in that case, that physicians hiring physical therapists would act unethically, the Court said we choose to make no such assumption concerning our brothers and sisters in the medical profession. This case is on all fours with Joseph. The Eyecare Law is treating doctors who want to prescribe lenses differently than doctors who want to prescribe anything else under the South Carolina Telemedicine Act, including things like eyedrops.

If you look at page 376 of our appendix, doctors right now are using technologies just like Visibly to prescribe things like eyedrops and eye serums online, consistent with the South Carolina Telemedicine Act. We're talking about the same patients with the same hidden diseases seeing the same doctors. They just can't prescribe lenses, and that is irrational. The only reason SCOPA has given us for the law -- and you heard this earlier -- is that patients who renew their lens prescriptions using Visibly might have hidden diseases that could be uncovered during a

medical exam. Nobody disputes that eye exams are important, but, again, it's also undisputed that patients can get limited care safely in between those comprehensive eye health exams. A concern about hidden diseases has equal force in every other context, whether a doctor's prescribing eyedrops or eye serums or anything else using telemedicine, and it's not just me saying that. SCOPA's own expert, Dr. Robinson, testified that hidden diseases are equally concerning for any kind of, quote, "limited care a patient might get online." That's at pages 352 to -53 of our appendix. And SCOPA's concern here is really just an objection to telemedicine, generally, an objection the legislator deemed irrational when it embraced telemedicine for doctors prescribing any other treatment online, including treatment for your eyes. And yet lenses and only lenses are singled out as the only kind of treatment that cannot be prescribed using telemedicine. SCOPA hasn't given us any plausible explanation as to why lenses are different than drops or any other eye treatment when it comes to hidden diseases. And that's not really surprising because, again, it's undisputed that patients only need an eye exam once by the time they reach age 40. That is the group Visibly serves. It's FDA clearance is for patients who are age 22 to 40. Not only that but, again, all five doctors who testified in this case agreed that you can prescribe that limited care in between comprehensive eye health exams, including lenses. They've all personally done that. In fact, I asked Dr. Robinson

in his deposition, "Would you have any problem, Dr. Robinson, with a patient getting their lens prescription renewed using a technology just like Visibly's as long as they were getting their comprehensive eye health exams before and after that limited care?" He said he would, quote, "not have a problem with it." That's at page 351 of our appendix.

And that's what this case is about, that limited care in between comprehensive eye health exams. I think SCOPA's argument requires the Court to assume that eye doctors who prescribe lenses online but not doctors who prescribe drops or anything else are going to do that when patients need an eye exam, but that is already illegal under the South Carolina Telemedicine Act. That's section 40-47-37, subsection (C)(8). And Joseph tells us that it's irrational to assume that doctors are going to violate the law or act in ways that are going to harm patients. The point of this case is that a patient doesn't need an eye exam every time they interact with a doctor. If you look at Dr. Robinson's testimony, again, he says -- this is at page 349 -- I asked him, "So it's not the case that every time you see a patient for any reason, you're performing this full battery of tests you describe in your affidavit that go with the comprehensive eye exam?" He says, "That's true." And I said, "And whether you perform that full battery of tests depends on the last time the patient got the full battery of tests, right?" And he said, "Yes." Again, that's at page 349 of our appendix.

And that leads me to a final point I want to make. The record here is replete with evidence that SCOPA drafted this law to shut down Visibly. The concern about hidden diseases is not supported by the record because there isn't a reason to single out lenses as opposed to anything else a doctor might prescribe. It's irrational to draw that distinction. But we know from the record that this law was driven by a concern for how Visibly would impact, quote, "the business side of optometry." And that when SCOPA got the law passed, they publicly bragged about destroying my client's business. And if you go to page 320 of our appendix, you'll see a slide where they were asked to present in front of a group about what they had achieved with the law, and you'll see a big red circle with a cross through it and Opternative in the middle. The way they summarize their achievement was destroying my client's business. And in Retail Services in 2017, the South Carolina Supreme Court said that when the only justification supported by the record is economic protectionism, that is unconstitutional. Because that is all we have here, SCOPA's motion for summary judgment should be denied and ours should be granted.

THE COURT: Okay. Mr. Matthews, do you want to be heard, sir?

MR. MATTHEWS: I'd be happy to, and thank you, Your Honor. Well, LLR is the only group here really to have a dog in this fight. We're here too because we must, to protect the

constitutionality of the statute. And whatever sympathies we may have with the plaintiff really run aground of a couple of things. First of all, there's the tried and true legal standard of the legislature says so. The General Assembly is the one that passes the laws. And my good friend Kirby Shealy is correct in pointing out that the Court here has to really, kind of, bend over backwards and approve the work of the General Assembly if it has any reason, even one they didn't think of, which is the standard, frankly, that we think binds the Court and us for that matter. Now, Your Honor, we're going to do whatever the Court tells us. We're just the administrative agency that enforces the statute. And, frankly, I don't think there's been an occasion where the Board of Medical Examiners has had to take this reaction against an ophthalmologist who does something that is allegedly contrary to the ECCPL. I don't know if -- that was certainly the case as of recent years. The case has been going on longer than many of us have been alive. It started in 2016.

We would say two other things. First of all, we think -- we filed a motion for summary judgment back in 2017. And the reason we did -- first of all, standing was our first argument and then the arguments that Mr. Shealy has mentioned, the fact that rational basis tells the due process and equal protection clause arguments of the plaintiff. When our summary judgment motion was first heard by Judge Benjamin, now of the Fourth Circuit, she granted it on the basis of standing only. She didn't address the

others. That was reversed by Appellate Courts and is now back with you. We believe, regardless of what our other beliefs may be, that the legislature did articulate a rational basis. And the legislator had a record, which is, I think, before you, I think even with Mr. Shealy's motion, for summary judgment. The record includes their concerns and the concerns of other physicians that failing to have the annual eye exam when you're supposed to get your prescriptions was enough to alert their concern that undiagnosed diseases of the eye or other diseases might be missed. If that's true, it's constitutional. Period. Because that's irrational basis. There's no suspect class here. We're not dealing with gender or race or national origin. The comments about Joseph as somehow the "get out of jail free" card for the plaintiff, we would simply -- frankly, it's been more recently addressed by SCOPA and its motion, I think on page 17, and would simply address your comments to "Here we are." The one thing that was noticeable about Joseph is -- unlike this case, in Joseph there really wasn't even a hint that there was a public health concern. At least not one that -- I have read the case many times -- there's not one that I can find. Now, again, as SCOPA indicates on page 18, the comparison fails because ECCPL addresses a particular public health risk (inaudible) Shipp and Robinson affidavits whereas it was impossible to find any such health risk, a risk to public health and welfare, in the statute in Joseph that it was allegedly designed to mitigate.

There's also something here that previous judges have voiced some interest in. Nothing in the law forbids an ophthalmologist to use Visibly's technology. They just can't solely rely on it. And that would be -- and that does -- you know, I understand that doesn't jive with Visibly's business model. That's okay. I think Visibly would have an interesting argument: Is the ECCPL good public policy? They may have a good argument. That doesn't matter. Right now they're challenging the legislator's competence -- the legislator's competence to pass the statute, and in that, they fail.

MR. WINDHAM: Your Honor, I'd love to respond to that.

THE COURT: Sure. Let me ask a few questions. Mr. Windham, are you in agreement this is a rational basis test that you've got to overcome here?

MR. WINDHAM: I agree it's a rational basis test. And as SCOPA can see in its brief, that's an evidentiary standard in South Carolina.

THE COURT: And that you've got to -- your standard is by clear and convincing evidence.

MR. WINDHAM: Evidence. Yes, Your Honor. Clear and convincing evidence.

THE COURT: And so let me just see if I'm understanding correctly because it seems to me that what the difficulty or the perceived difficulty with Visibly's business model is that unlike telehealth with the physician -- for whether it's mental health

or any other condition -- I am FaceTiming or I am face-to-face with a physician. I'm communicating with a physician. I'm describing my symptoms, et cetera. I don't know. Maybe I show them my rash. I don't know. As opposed to this technology that allows me to just use this computer program and to, without a physician being involved in it at all, answer my questions. Respond to the prompts on the screen and to do all that without any interface whatsoever with the physician. And then they could just take, you know, what I have punched into the screen, and they can prescribe the lenses without really having any interaction with me face-to-face at all. And so whether that's rational or not rational for me to have that issue with the technology, it seems like that's where the rub really is. Would you agree with that, Mr. Windham?

MR. WINDHAM: I agree that's how they're portraying this case, but I want to make a couple of factual clarifications. First of all, Visibly is not a tool that doctors can use to prescribe or to renew lenses because they don't prescribe lenses. They just renew lense prescriptions. It's not a tool eye doctors can use if a patient has not had a comprehensive eye health exam. There is no way a patient can get a prescription renewed using Visibly from a physician who's using that tool without first having a comprehensive eye health exam. The point of the technology is that you only need a comprehensive eye health exam every certain number of years. So if you're 40 years old, you

need one one time over the course of your entire life. And prescriptions expire annually, and so there's going to be a need for patients to get their prescriptions renewed when it is not medically necessary to get a comprehensive eye health exam. But to address your concern about live interaction. This is what's called "store-and-forward telemedicine," which is when a patient fills out a form, provides information, takes an online test, and sends that information to a physician for review. It is the exact same technology that physicians in South Carolina are currently allowed to use under the South Carolina Telemedicine Act to prescribe eyedrops and eye serums as long as the patient has recently had an eye exam. And that's on page 372 of our appendix. And so the question is not store-and-forward versus live interaction. The question is why are doctors who prescribe lenses being singled out for differential treatment when doctors who prescribe anything else for your eyes can use the same kind of store-and-forward technology according to their medical judgment.

The South Carolina Telemedicine Act forbids doctors from prescribing anything online already if a patient would need a comprehensive eye health exam to prescribe that thing, so the Eyecare Law isn't adding anything to that standard. It is already illegal for a physician to violate that norm. The point of that technology is that you can actually safely prescribe lenses for a patient in between those comprehensive eye health

exams, and that is what every single eye doctor who testified in this case agreed to. So while I agree it's a rational basis test, it's not an irrational basis test. It doesn't allow the government to do irrational things. It still has to be a rational distinction, and that requires the Court to look through the evidence about what is undisputed. And because it is undisputed that a physician can safely prescribe more limited treatment for a patient in between their comprehensive eye exams -- nobody disagrees with that -- it is irrational to single out lenses when doctors can prescribe anything else for you using telemedicine online for your eyes.

THE COURT: Mr. Windham, would you agree that it's not destroying your business model if it is allowing -- I mean, optometrists and ophthalmologists to utilize that technology like -- I guess that would be in place of the, you know, "which is clear" technology. They can still use your technology in place of that.

MR. WINDHAM: No. I disagree with that entirely. The only service that my client offers is a tool that doctors can use to connect with patients to collect the information remotely when they're not in the same room. And the Court of Appeals held, in this case, that the Act, quote, "prohibits Opternative's current business model." That is why we have standing. Because the precise thing that my client wants to do is forbidden by this law. So the idea that we can just change our business model to

do something else is an objection to the standing decision that the South Carolina Supreme Court issued when it was affirming the South Carolina Court of Appeals on that front. And if the Court wants a cite for that, it's 433 S.C. 405, and the pin cite is 414. Our specific business model is forbidden by this law. That is the law of the case.

THE COURT: Well, I understand the business model that you want to employ, using it solely remotely, is forbidden by the Act, but other uses of that FDA-approved technology could be made in the doctor's office, could it not? Is there any reason that you couldn't use it in the doctor's office?

MR. WINDHAM: Well, the technology is not designed to work that way. I suppose some other plaintiff could develop that technology, Your Honor. But the point of the case is that my client's technology could be used by physicians right now under the Telemedicine Act consistent with the Telemedicine Act standards just like any other online tool could be used consistent with the Telemedicine Act standards. The question is why are lenses being singled out for differential treatment. If the idea is the patient may have a hidden disease, any patient seeing any doctor for any reason could have a hidden disease. All patients need comprehensive exams of some sort. If you're a patient who is going to a dermatologist for a skin cream, you know, you have to get annual screenings for your skin. Patients need annual physical exams from their family doctors. And yet

there's no reason why it's unsafe for a doctor to treat you for a cut or pink eye or something like that in between your annual physicals. And that's the point of this case. You know, there are safe occasions where a doctor can prescribe you limited treatment for your eyes in between comprehensive eye health exams. It's legal for anything else a doctor might prescribe, just not lenses, and that's an irrational distinction.

THE COURT: Mr. Shealy, do you want to -- well, first, let me make sure. Ms. Fowler, Mr. McNamara, I don't want to give you short shift. Anything you want to add at this point?

MR. MCNAMARA: No, Your Honor. Thank you.

MS. FOWLER: No, Your Honor.

THE COURT: Okay. Mr. Shealy, so let me ask you this. I mean, it seems to me like a new trend, at least with family medicine, is that physicians want to treat one complaint per visit. So, you know, you have 12 complaints -- and that may be insurance-driven but -- you know, the current trend is, no, we're not going to treat 12 different things on this visit. For this visit you've got to kind of choose your worst, and you're going to be treated on that issue first. And we're not going to hear 12 different complaints in one visit. At least that's the trend as I see. I will tell you I don't go to the doctor unless something is terribly wrong with me. I do have a child in medical school who's doing a family medical rotation right now and who has worked as a medical assistant in high school and

college, and that's what I gather from that limited interaction -- is that that's kind of the trend now -- is we don't want to hear all these different problems. We want you to be treated for one thing when you come in. So are we picking on Visibly to the exclusion of all of the types of medicine?

MR. SHEALY: I don't think so, Your Honor. I mean, the General Assembly is free to address specific issues that are brought to its attention, you know, in different ways. I mean, it may be up to the General Assembly to address what has been brought to the Court's attention by Mr. Windham -- the prescription of eyedrops -- you know, at some point later. What we're looking at is the General Assembly chose to address this particular issue, and what the record shows is that technology that serves to separate a doctor from his or her patient creates perhaps an unintended public health risk. Technology that brings doctors closer to their patient that would not otherwise be able to see the doctor -- that's why this law and the Telemedicine Act are perfectly in sync with each other, because the Telemedicine Act is about bringing doctors closer to their patients who would otherwise not be able to come see them. This is a law that addresses technology that stands in between a doctor and his or her patient. And I just -- Your Honor, the operative language from section 40-24-20(C) is "A prescription for spectacles or contact lenses may not be based solely on the refractive eye error of the human eye or be generated by a kiosk." That's

what -- that's the crux of what the law is addressing. It does not prevent eyecare professionals from using Visibly's technology at all. The prescription can't be based solely upon whatever test result is derived from the use of that technology. You have to have other -- you have to look at the person in a more comprehensive way than just the refractive error of the human eye. And, Your Honor, that's -- again, that's a rational basis for this law. The testimony is uncontroverted that there are diseases of the eye and diseases of the body itself that are diagnosable, and at times first diagnosable through a comprehensive eye examination.

MR. WINDHAM: I just want to make two factual points in response to that, Your Honor. First of all, Visibly is not -- Visibly's physicians, the ones who use its service, do not prescribe based solely on the information collected about refractive error. They prescribe based on that information and also based on information the patient provides about their medical history, the symptoms they have, the medications they're taking, you know, and their most recent comprehensive eye health exam. All of that information is the same information on which an unlicensed, untrained assistant today can collect from a patient in a doctor's office and hand to the physician without the physician ever seeing a patient. And that physician can still prescribe lenses to the patient under the Eyecare Law. And so, really, this is a requirement, not that a patient get a

comprehensive eye health exam every time they interact with a doctor, but it says -- it's really a law that says that the doctor cannot collect the information they need to prescribe lenses based on the automated testing device like Visibly that collects that information online, but it can do it -- a physician can do it when collected by an unlicensed, untrained assistant with a clipboard. And that is undisputed on this record. The other thing I want to note is on page 353 of the appendix to our response, Dr. Robinson, SCOPA's own expert, testified that his concern and the concern about hidden diseases and comprehensive eye exams has equal force as applied to all online care, not just lense prescriptions. And I'll quote, question, "Would you have the same concern if a patient was getting eyedrops through telemedicine?" Answer, "Yes, I would. I think I would. Anything where you're not getting a comprehensive eye exam, I would be concerned about, yes." Doctor Robinson's concern and SCOPA's concern is a concern that applies to telemedicine writ large, to anything a doctor may prescribe for your eyes writ large. The only reason lenses are singled out for differential treatment is that SCOPA succeeded in lobbying legislature for a carveout.

THE COURT: Okay. Anything else from any of the parties?

MR. SHEALY: No, Your Honor.

THE COURT: So I know that you-all have written very comprehensive briefs on this; you've given me a lot of materials

to look at. I will look at all of that closely. I think the main thing that you-all need in this case is you need a final ruling. You've been up to the Supreme Court and now back down, so I think, for better or worse -- I mean, somebody's going to be happy with my ruling; somebody's not going to be happy. But the main thing is you need a ruling so that you can then take that up with the appellate court. So I can assure you I will give you a ruling on the merits, but you'll have to give me a little bit of time to go through all of your materials and look closely at it. You've all done an excellent job at advocating your positions, and so I really appreciate that. That's not always the case. Although, I would say the majority of the time, that's the case; attorneys do a great job. But you-all have done a really good job advocating your position, so that makes my job easier. So I will take this under advisement. I will get you a ruling as quickly as I possibly can.

MR. SHEALY: Thank you, Your Honor.

MR. WINDHAM: Thank you, Your Honor.

MR. MATTHEWS: Thank you, Your Honor.

THE COURT: All right. Thank you-all so much.

CERTIFICATE OF REPORTER

I, Amy Pennica, Certified Verbatim Reporter in and for the State of South Carolina at Large, hereby certify that the foregoing is a true, accurate, and complete Transcript of Record to the best of my abilities to be heard and transcribed of the proceedings had and evidence introduced in the hearing of the captioned case, in The Court of Common Pleas, on the 3rd day of June, 2024.

I further certify that I am neither attorney nor counsel for, nor related to or employed by any of the parties connected to the action, nor am I financially interested in the action.

3rd day of October, 2024

Amy Pennica

Court Reporter

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S.C. SUPREME COURT

CERTIFICATE OF COUNSEL

The undersigned hereby certifies that the Record on Appeal contains all material proposed to be included by any of the parties and not any other material.

January 15, 2025.

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