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S.C. SUPREME COURT

THE STATE OF SOUTH CAROLINA
In the Supreme Court

ON CERTIFICATION FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA

Margaret B. Seymour, U.S. District Judge
C/A. No. 3:16-cv-00972-MBS

Appellate Case No. 2017-000787

AMY ELIZABETH WILLIAMS, as the Personal Representative of the Estate for deceased minor, and AMY ELIZABETH WILLIAMS individually,

Plaintiffs,

v.

QUEST DIAGNOSTICS, INC., ATHENA DIAGNOSTICS, INC. and ADI HOLDINGS, INC.,

Defendants.

FINAL BRIEF OF DEFENDANTS

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CERTIFIED QUESTION FOR REVIEW

"Is a federally licensed genetic testing laboratory acting as a 'licensed health care provider' as defined by S.C. Code Ann. § 38-79-410 when, at the request of a patient's treating physician, the laboratory performs genetic testing to detect an existing disease or disorder?"

This Court has previously explained that the answer to this question turns on whether the defendant "provide[s] health care to patients." *Swanigan v. American National Red Cross*, 313 S.C. 416, 419, 438 S.E.2d 251, 252 (1993) ("an institution or person must provide health care to patients to qualify as a 'similar category of licensed health care provider'" under S.C. Code § 38-79-410). Because Defendants were, as Plaintiff concedes in her pleadings, integrally involved in the diagnosis and treatment of the decedent (*i.e.*, they provided health care services to him), Defendants respectfully request that the Court answer the question in the affirmative.

STATEMENT OF THE CASE

Plaintiff is the mother of a child who died on January 5, 2008 as a result of a genetic condition known as Severe Myoclonic Epilepsy of Infancy ("SMEI"). In 2016, Plaintiff filed suit against the Defendants alleging negligence in diagnostic testing performed in 2007, nine years before she filed her complaint.

According to Plaintiff's Amended Complaint, two of the decedent's treating physicians extracted deoxyribonucleic acid ("DNA") from the child and requested that the Defendants test the DNA for the purpose of "detecting an existing disease, illness, impairment, symptom or disorder." (Am. Compl. at ¶ 19). The Defendants[1] performed the tests and provided the child's treating physicians with the results of the tests.

At the Worcester, Massachusetts laboratory of Defendant Athena Diagnostics, the highly specialized genetic test was reviewed and interpreted by board certified medical geneticists. Athena Diagnostics is licensed and regulated by Centers for Medicare and Medicaid Services (CMS) as well as the Commonwealth of Massachusetts' Department of Public Health. CMS regulates all laboratory testing performed on humans in the United States (except research) through the federal Clinical Laboratory Improvement Amendments (CLIA).

The 2007 test results (attached to Plaintiff's Amended Complaint) state repeatedly, and explicitly, that the test results are inconclusive and that the uncertainty could be resolved if Plaintiff and the decedent's biological father provide the Defendants with samples of their own DNA for testing (at no charge to the Plaintiff):

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[1] Testing was performed solely by the Defendant, Athena Diagnostics, Inc. For ease of reference, all Defendants will be referred to herein collectively as "Defendants."

- "Interpretation[:] This individual possesses a DNA sequence variant or combination of variants in the *SCN1A* gene whose significance is unknown (missense variant of unknown significance). **Testing of the biological parents is strongly recommended to resolve the uncertainty of these test results.**" (emphasis in original)

- "Testing of the biological parents is strongly recommended (for no additional charge) to help resolve the uncertainty of this sequent variant's pathogenicity and the uncertainty of the predicted phenotype." (emphasis added)

- "Most mutations that cause SMEI are de novo, or sporadic (arise in the affected individual rather than being inherited) an inheritance pattern that can be confirmed by testing of parents." (emphasis added)

- "In order to provide a more comprehensive interpretation of this patient's SCN1A results, Athena Diagnostics is requesting samples from the biological parents of this patient. Athena Diagnostics will perform a target analysis on these samples for variant(s) identified in gene SCN1A only and use the findings to help interpret the patient's SCN1A result(s) at no additional charge." (emphasis added)[2]

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[2] The SCN1A gene is one of an estimated 20,000-30,000 genes in the human genome. A DNA sequencing test analyzes the sequence of chemical components of a particular gene of a patient and compares it against the normal sequence of that gene to determine if there are any mutations, or variants, in the genetic sequence. Variants may be benign or pathogenic, but many variants have not yet been determined to be either benign or pathogenic – the identification, analysis, and compilation of gene variants is still very much a work in progress. In the case of the Plaintiff's child's test, at the time the test was performed in 2007, the mutation found had not been classified by Athena Diagnostics as either pathogenic or benign, hence the designation of "Variant of Unknown Significance" or "VUS". The essence of the Plaintiff's case is that this classification was erroneous and that Athena Diagnostics knew or should have known at the time that the decedent's variant was correlated with SMEI and therefore pathogenic. In her Amended Complaint, Plaintiff suggests that her claim is supported by the fact that in 2015 she and a doctor and a genetic counselor were provided by Athena Diagnostics with a revised report reclassifying the child's variant from a Variant of Unknown Significance to a Pathogenic Variant, *i.e.*, a Known disease-associated mutation. (Am. Compl. ¶¶ 47, 82; *see also* Pl. Brief at 5). That was, however, nearly eight years after the 2007 test that classified the variant as a Variant of Unknown Significance. Variant classifications can and do change over time with advances in genomics, a field that experienced exponential increases in knowledge over the 8 years that had passed since the original classification. Recently, the online publication *GenomeWeb* published an article highlighting the complexity of the variant classification process and the significant strides in development that were and are still being made:

> "Today's world is quite different from the past. The pace of discovery is amazing," Carl Barrett, VP of translational science within AstraZeneca's Oncology Innovative Medicine division, told GenomeWeb. "We'll probably do

Notwithstanding the repeated, emphatic warnings in the 2007 report that the test results were uncertain and inconclusive, that SMEI was a possible outcome, and that genetic testing of the biological parents was "strongly recommended" and would be done by the Defendants free of charge, the Plaintiff did not submit her own DNA, or that of the biological father, for testing.

Plaintiff now alleges that, because of the "misdiagnosis" in the 2007 report, her son's doctors continued to treat him using sodium channel blocking medications, which is standard for seizures not caused by SMEI but which can worsen seizures in patients with SMEI. (Am. Compl. ¶¶ 33-34) The Plaintiff asserts that "[a]s a proximate result of Athena Diagnostics, Inc. negligent diagnosis and failure to accurately advise selection of appropriate therapy, the decedent lost his life on January 5, 2008 due to a traumatic seizure." (Am. Compl. Ex. A, ¶ 23 (emphasis added))[3]

The question before this Court is whether the Defendants were providing health care to the decedent when, at the behest of the decedent's treating physicians, the Defendants performed diagnostic tests on the patient's specimen and then advised his physicians of the results of the

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> more [whole-genome and exome sequencing] this year than we've done in all of history, time, and science."

Ray, *Drug and Diagnostic Industries Warm to Sharing Genomic Data, With Some Caveats and Challenges*, GENOMEWEB (June 20, 2016). The article further notes the complexity in analyzing variant data, even today: "Given the pace of genetic discoveries ... journals are struggling to adjudicate via peer review whether variants are truly associated with disease and whether they are publishing replicable data." *Id.* at 2. "Doing this well, creating this data, is really difficult ... because there is no one definitive source." *Id.* at 9 (quoting Steven Kafka, President of the cancer genomic testing firm Foundation Medicine).

[3] The quoted language comes from one of the affidavits of medical doctors that Plaintiff attached to her Amended Complaint in support of her claims. Plaintiff's Amended Complaint incorporates those affidavits "as if set forth herein verbatim." (Am. Compl. ¶ 11) Defendants deny, in the strongest terms, the allegations of the Amended Complaint, but accept them for the purposes of this application only.

DNA testing for purposes of assisting them in diagnosing and determining the appropriate course of treatment for the patient.

Respectfully, it is clear that they were, and the certified question should be answered in the affirmative.

ARGUMENT

I. The Defendants Provide Health Care to Patients and Thus Are Entitled to the Protections of S.C. Code Ann. § 15-3-545(A).

Whether the Defendants provide health care to patients matters because South Carolina law establishes a six-year statute of repose for actions for medical malpractice. S.C. Code Ann. § 15-3-545(A). The statute provides that:

> In any action ... to recover damages for injury to the person arising out of any medical, surgical, or dental treatment, omission, or operation by any licensed health care provider ... acting within the scope of his profession must be commenced within three years from the date of the treatment, omission, or operation giving rise to the cause of action or three years from date of discovery or when it reasonably ought to have been discovered, not to exceed six years from date of occurrence ....

Id. (emphasis added). The corresponding definition of "licensed health care provider" in South Carolina Code § 38-79-410 covers all manner of persons and entities that provide a wide variety of health care services, and is expressly open-ended:

> "Licensed health care providers" means physicians and surgeons; directors, officers, and trustees of hospitals; nurses; oral surgeons; dentists; pharmacists; chiropractors; optometrists; podiatrists; hospitals; nursing homes; or any similar category of licensed health care providers.

S.C. Code Ann. § 38-79-410 (emphasis added).

A. This Court Has Implicitly Agreed With Many Others That The Defendants' Services At Issue Constitute The Provision of Health Care Services.

South Carolina courts have not directly addressed the issue of whether claims of negligence relating to medical laboratory results sound in medical malpractice by licensed health care providers, but numerous courts from other jurisdictions have. These courts have uniformly concluded, as might be expected, that the determination turns on the extent to which the services provided play a role in the diagnosis, treatment or care of the patient whose specimen is being tested.

New York state and federal courts, for example, have repeatedly held that clinical laboratory reporting that bears on the diagnosis, treatment or care of the patient sounds in medical malpractice, not general negligence. As the New York Court of Appeals explained,

> Although the services of a medical doctor and a laboratory are divisible, they act as collaborators, not antagonists. Their work is interrelated, and ... the analysis performed by a laboratory is supplemental to and bears directly upon the course of medical treatment to be provided. A proper diagnosis can facilitate recovery while an incorrect analysis can spell prolonged affliction.

Calvin v. Schlossman, 74 A.D.2d 265, 269 (N.Y. App. Div. 1980) (concluding that a private medical lab that had misinterpreted a patient's pap smear was subject to the state's mandatory medical malpractice statutory scheme).

Thus, the analysis begins with the non-controversial and common sense proposition that "conduct may be deemed malpractice, rather than negligence, when it constitutes medical treatment or bears a substantial relationship to the rendition of medical treatment by a licensed physician." *Scott v. Uljanov*, 541 N.E.2d 398, 370 (N.Y. App. Div. 1989) (emphasis added). Applying this rationale in a case involving one of the Defendants in the instant case, the New

York Appellate Division reasoned that "laboratory services ... performed at the direction of a physician are an integral part of the process of rendering medical treatment" and therefore that "a claim stemming from the rendition of such services is a medical malpractice claim." *Annunziata v. Quest Diagnostics Inc.*, 127 A.D.3d 630, 631 (N.Y. App. Div. 2015).

Citing *Annunziata,* the court in *B.F. v. Reproductive Medicine Assoc. of N.Y., LLP*, 136 A.D.3d 73, 80 (N.Y. Sup. Ct., App. Div., 2015) similarly held that "defendants [laboratory's]' screening of plaintiffs' egg donor, even if it could plausibly be viewed as not constituting medical treatment itself, indisputably bears a substantial relationship to the rendition of medical treatment by a licensed physician and therefore, under our precedents, constitutes medical malpractice."

In *Price v. Benedict Community Health Ctr.*, 1998 U.S. Dist. LEXIS 16748 (N.D.N.Y Aug. 11, 1998), the court held that claims against a clinical laboratory based on a cytotechnologist's failure to properly interpret a pathology specimen sounded in medical malpractice because the activities undertaken and results rendered bore a substantial relationship to the rendition of medical treatment by a physician. *Id.* at *10. In arriving at this conclusion the Court noted, *inter alia,* that the laboratory's services required special skills not ordinarily possessed by lay persons. *Id* at *10, *citing. Barresi v. State of New York*, 232 A.D.2d 962, 649 N.Y.S.2d 207 (1996); *Smith v. Pasquarella*, 201 A.D.2d 782, 607 N.Y.S.2d 489 (1994).

Likewise, two Georgia decisions have recognized that "[a]lthough complaints against professionals may state claims based on ordinary as well as professional negligence, where the allegations of negligence involve the exercise of professional skill and judgment within the professional's area of expertise, the action states professional negligence." *Walls v. Sumter Regional Hosp. Inc.,* 666 S.E.2d 66, 69 (Ga. Ct. App. 2008); *Stafford-Fox v. Jenkins,* 639 S.E.2d

610, 614 (Ga. Ct. App. 2007). In *Stafford-Fox*, for example, the court held that a claim framed as one for ordinary negligence against a physician's professional organization based on the conduct of its nonprofessional employees who allegedly failed to place certain test results on a patient's chart or bring other information to the attention of a treating physician still sounded in medical malpractice. The court reached this conclusion because the plaintiff's damages "still arose out of the misdiagnosis by [the physician] involving the exercise of medical skill and judgment."

Similarly, in *Khadim v. Laboratory Corp. of Am.*, 838 F. Supp. 2d 448 (W.D. Va. 2011), the federal district court held that a laboratory corporation that had provided erroneous "prenatal genetic testing results" fell under the definition of "health care provider" in the applicable Virginia statute. In particular, the court concluded that the statute's inclusion of "a corporation, partnership, limited liability company or any other entity ... which employs or engages a licensed health care provider and which primarily renders health care services" included the defendant LabCorp. 838 F. Supp. 2d at 461, 467 (quoting Va. Code § 8.01-581.1) (emphasis added); *see also Johnson v. Superior Court*, 124 Cal. Rptr. 2d 650, 662 (Cal. Ct. App. 2002) (rejecting argument that physicians providing genetic screening services at tissue bank were not acting as health care providers).

Likewise, the Texas Court of Appeals held that a pathology lab that had failed to detect the presence of a melanoma in a lesion removed from a patient's skin and submitted to the lab for analysis was protected by a statute of limitations governing "health care liability" claims against "health care providers." *Hogue v. Propath Laboratory*, 192 S.W.3d 641, 644-45 (Tex. Ct. App. 2006).

All of these jurisdiction that have carefully considered this issue have arrived at the same logical conclusion - if the services at issue bear a substantial relationship to the rendition of a medical diagnosis, care and/or treatment to a patient by a licensed physician, the provision of health care services is implicated and allegations that the services were negligently performed thus constitute claims of medical malpractice.

Importantly, this Court has implicitly reached the same conclusion. In *Swanigan*, this Court held that the Red Cross is not functioning as a health care provider when it simply engages in the wholesale "collection and processing" of blood and plasma. *Swanigan,* 313 SC at 419 ("the collection and processing of blood does not constitute providing health care to patients.") Rather, this Court held that "an institution or person must provide health care to patients to qualify as a 'similar category of licensed health care provider.'" *Id.*

In reaching its conclusion in *Swanigan*, this Court cited to other courts' similar holdings that the Red Cross is simply the supplier of a product (blood) and is not a health care provider. For instance, the *Swanigan* opinion cites *Silva v. Southwest Fla. Blood Bank, Inc.,* 601 So.2d 1184 (Fla. 1992). In *Silva,* the Supreme Court of Florida held that "Southwest [the blood bank] played no role in determining the nature of the plaintiff patients' illnesses ... Southwest was merely the supplier of a product." Likewise, the *Swanigan* Court cited with approval the Wisconsin Supreme Court's ruling in *Doe v. American Nat'l Red Cross,* 176 Wis.2d 610, 500 N.W.2d 264 (1993) holding that "[t]he Red Cross plays no role in the diagnosis, treatment or care of patients. The Red Cross is the supplier of a product that is used by health care providers in their treatment of patients."

Together, these cases make clear that an entity that merely supplies products for use in health care is not a health care provider, but an entity that plays a "role in determining the nature

of the plaintiff patients' illnesses," or that plays a role "in the diagnosis, treatment, or care of patients," is a health care provider. The question certified by the District Court in the instant case sets forth that the Defendants are not the suppliers of a product but, instead, are a "federally licensed genetic testing laboratory" who were acting "at the request of [the] patient's treating physician" to "perform[] genetic testing to detect an existing disease or disorder." On its face, the Defendants respectfully submit that the certified question along with the *Swanigan* holding compel the conclusion that a laboratory that is (a) acting at the behest of a patient's treating physician (b) to perform genetic testing on the patient in order (c) "to detect an existing disease or disorder" is clearly providing health care services to that patient.

B. The South Carolina Legislature Has Defined "Health Care" To Include Entities That "Diagnose or Treat Human Disease," and "Health Care Providers" Includes The Defendants Under S.C. Code Ann. § 38-79-410.

While South Carolina's medical malpractice statute of repose does not define "health care," the term is defined elsewhere in the Code, in provisions addressing health care powers of attorney. There the South Carolina legislature recognizes that "health care" means "a procedure to diagnose or treat human disease, ailment, defect, abnormality, or complaint, whether of physical or mental origin." S.C. Code Ann. § 62-5-504. Applying this definition, the conclusion of the Court in *Swanigan* that the mere provision of a product used in health care, such as blood, does not qualify as "health care" follows as naturally as does the conclusion that the Defendants' services do constitute "health care." As Plaintiff's own pleadings repeatedly allege, the genetic testing provided to Plaintiff's son was unquestionably "a procedure to diagnose or treat a human disease."

Indeed, Plaintiff's Amended Complaint repeatedly alleges that her son's doctors relied on Defendants' "expert diagnosis" in order to decide how best to treat her son. (Am Compl. ¶¶ 23-

26, 34, 38) In the affidavits attached to and incorporated in her Amended Complaint, Plaintiff's own experts opine that Defendants' wrongdoing was their alleged "failure to correctly diagnose" and alleged "failure to accurately advise selection of appropriate therapy." Cook-Deegan Affid. ¶¶ 9, 23; *see also* Witnitzer Affid. p.2. Accepting the allegations of the Amended Complaint as true, the Defendants analyzed the patient's specimen at the behest of the treating physicians, Defendants diagnosed a potential disease, and Defendants advised the treating physicians on the appropriate course of treatment for the decedent. Analysis, diagnosis, and treatment form the very core of the provision of health care and have been expressly recognized by the South Carolina legislature in Section 62-5-504 as the provision of "health care."

For these reasons, Plaintiffs' *ejusdem generis* argument regarding S.C. Code Ann. §38-79-410's definition of "Health Care Providers" is misplaced and must be rejected. Under this doctrine of statutory interpretation, when in a statute, a "general word of phrase follows a list of specific persons or things, the general word or phrase will be interpreted to include only persons of things of the same type of those listed." And this is precisely why medical geneticists and the clinical laboratories they work for are included in the list or doctors, hospitals and other medical professionals who provide services to patients -- the service that the Defendants provide, like those individuals and entities listed, bear a substantial relationship to the rendition of medical treatment of patients.

Critically, Plaintiff downplays the obvious fact that the services rendered by Defendants in this case are ultimately provided by board certified medical professionals, and by a laboratory that is strictly regulated by state and federal agencies tasked with the protection of patients' health and heath care rights. The report at issue in this case was based on the interpretation and analysis of medical geneticists certified by the American Board of Medical Genetics. Athena

Diagnostics' laboratory is licensed and regulated by CMS through the CLIA regulations, as well as the Commonwealth of Massachusetts Department of Public Health, Division of Health Care Facility Licensure and Certification. The very mission of CMS – the primary regulatory body governing the Defendants' work - is focused on the safe and effective provision of health care to patients.[4]

For all of these reasons, the legislature clearly intended to include clinical laboratories such as the Defendants within the protections of S.C. Code. Ann. §15-3-545(A), because the laboratory services provided directly relate to the provision of patient health care.

C. Plaintiff Repeatedly Concedes That Defendants Were Providing Health Care And That Her Claims Sound in Medical Malpractice.

In addition to the overwhelming support of the statutory language case law addressing these issues, the fact that Defendants were providing health care to the patient in this case is put to rest by the Plaintiff's own allegations.

First, throughout the Amended Complaint and the affidavits of the medical professionals incorporated into that Complaint, Plaintiff alleges that the Defendants were negligent in "diagnosing" the decedent's medical condition and in "failing to advise" the decedent's doctors of "appropriate therapy" to treat the child. (*See, e.g.,* Am. Compl. ¶¶ 54, 62, 66-67, 71-72) Plaintiff's allegations also make clear that Defendants' DNA testing services were sought by the decedent's attending physicians for the purpose of "detecting an existing disease, illness,

[4] CMS's "[m]ission is to serve Medicare and Medicaid beneficiaries. The CMS vision is to become the most energized, efficient, customer friendly Agency in the government. CMS will strengthen the health care services & information available to Medicare and Medicaid beneficiaries and the health care providers who serve them." https://surveyortraining.cms.hhs.gov/BHFS/M1/M1S1_180.aspx [last viewed; August 30, 2017] (emphasis added).

impairment, symptom or disorder." (Am. Compl. ¶ 17 (emphasis added)). In the Amended Complaint, Plaintiff asserts that she "sought treatment for [decedent's] condition from a variety of service providers." (Am. Compl. ¶ 12 (emphasis added)) In January 2007, "[i]n an attempt to more accurately diagnose the exact nature of [decedent's] condition," a series of tests were performed, including genetic tests, "at the direction" of two physicians employed by Horizon Molecular Medicine of Atlanta, Georgia, as "treating clinical geneticists." (Am. Compl. ¶¶ 14-15) "As part of the process of dismissing Dravet Syndrome [SMEI]," a blood sample was taken from the decedent and his DNA was extracted from the sample. (Am. Compl. ¶ 17) The extracted DNA was then provided to Athena Diagnostics' laboratory for the purpose of "detecting an existing disease, illness, impairment, symptom or disorder." (Am. Compl. ¶ 17 (emphasis added)). According to Plaintiff, Athena Diagnostics then issued a "Sequencing Clinical Diagnostic Report" that was in error. (Am. Compl. ¶¶ 19, 22)

Second, Plaintiff supports the allegations in her Amended Complaint with the affidavits of Dr. Robert Cook-Deegan and Dr. Max Wiznitzer.. Both affiants are doctors of medicine. Dr. Cook-Deegan holds an appointment in internal medicine in the Duke University School of Medicine, and Dr. Wiznitzer serves as a "pediatric neurologist" at "Rainbow Babies and Children's Hospital" and is "board certified by the American Board of Pediatrics in Pediatrics and board-certified by the American Board of Psychiatry and Neurology both in Neurology, with special qualification in Child Neurology, and in Neurodevelopmental Disabilities." (Am. Compl. ¶¶ 11, 38)

Dr. Cook-Deegan opines in his affidavit that Athena Diagnostics "breached the standard of care of a CLIA-certified diagnostic laboratory performing high complexity genetic testing by its negligent failure to correctly diagnose the DNA missense mutation in the decedent's SCN1A

gene." (Am. Compl. Ex. A, ¶ 9 (emphasis added)) Dr. Cook-Deegan further asserts that "[a]s a proximate result of Athena Diagnostics, Inc.'s negligent diagnosis and failure to accurately advise selection of appropriate therapy, the decedent lost his life on January 5, 2008 due to a traumatic seizure." (Am. Compl. Ex. A, ¶ 23 (emphasis added))

Furthermore, the first affidavit of Dr. Witnitzer, which is incorporated by reference in ¶38 of the Amended Complaint, characterizes Athena Diagnostics' actions as "**Negligent Failure to Properly Diagnose SMEI And Treat Appropriately.**" (Am. Compl., Ex. 2, p. 2 (emphasis in original)) The Amended Complaint cites to Dr. Witnitzer's medical conclusion "that if [the decedent's] SMEI condition had been properly diagnosed and had [he] received appropriate care for the treatment and management of SMEI, [he] would not have suffered the fatal seizure on January 5, 2008." (Am. Compl. ¶38)

In addition to the above allegations, Plaintiff also alleges that the Defendants violated the Health Insurance and Portability Accountability Act of 1996 ("HIPAA"). (Am. Compl., ¶ 47) Notably, HIPAA explicitly includes the Defendants in its definition of "health care providers:"

> The Administrative Simplification of HIPAA and their implementing regulations apply to three types of entities, which are known as "covered entities" .... A laboratory, as a health care provider, is only a covered entity if it conducts one or more covered transactions electronically....

CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports, 79 Fed. Reg. 7,291, (Feb. 6, 2014) (emphasis added). As one commentator has explained:

> "[h]ealth care" is very broadly defined in the [HIPAA Privacy] Rule as "care, services, or supplies related to the health of an individual," including preventive, diagnostic, rehabilitative, or maintenance care, and services, assessments or procedures concerning the person's physical or mental condition or status. This includes the performance of lab services on tissue or biologic samples to determine an individual patient's diagnostic status or potential exposure to a disease or condition.

Hodge, Jr., James G., The HIPAA Privacy Rule and Public Health Laboratories – Guidance Prepared for the Association of Public Health Laboratories, http://www.schs.state.nc.us/hipaa/references/APHL_HIPAA_Guide1-for-Public-Health-Labs.pdf.

In sum, throughout the Amended Complaint and the attached affidavits, Plaintiff and her experts repeatedly allege that the Defendants were providing health care to the decedent. They cannot be fairly heard now to disavow that obviously correct position in order to sidestep S.C. Code. Ann. § 15-3-545(A).

II. Plaintiff Improperly Asks this Court to Add Additional Terms to the South Carolina Legislature's Definition of "Health Care Provider."

In an attempt to avoid the consequences of the statute of repose, Plaintiff improperly asks this Court to add language to the legislature's definition of "health care provider." Although the statute contains none of this suggested language, the Plaintiff asks this Court to hold that a "licensed health care provider" must be (1) "licensed by LLR" (Pl. Brief at 8); (2) "have direct interactions with patients" (Pl. Brief at 8); and (3) "provide twenty-four hour medical and surgical care." (Pl. Brief at 9) The statute, of course, requires none of these things.[5]

Not only does the statute not require any of the additional terms that Plaintiff urges upon this Court, the legislature expressly lists examples of "licensed health care providers" that meet

[5] Without belaboring the point, Defendants would note that Plaintiff's focus on *ejusdem generis* sheds no light on the question before the Court. This Court in *Swanigan* held that each of the legislature's examples in section 38-79-410 share the characteristic of providing health care to patients. *Id.* ("The enumerated persons and institutions in section 38-79-410 are all within the same general kind or class of persons and institutions that provide health care to patients.") Thus, the question now before the Court is whether Defendants in the instant case provide health care to patients – not whether they are open twenty four hours a day or have a certificate from DHEC.

none of Plaintiff's suggested requirements. For instance, section 38-79-410 expressly lists "directors, officers, and trustees of hospitals" as health care providers. These directors, officers, and trustees are not licensed by LLR, do not have direct interactions with patients, and do not provide twenty-four hour medical and surgical care. Similarly, most dentists, chiropractors, optometrists, and podiatrists do not provide twenty-four medical and surgical care, but the legislature expressly lists them as examples of health care providers.

Likewise, many health care providers never interact with their patients but – like the Defendants here nonetheless, provide essential health care services to patients. Health care providers that do not directly interact with patients include, but are not limited to (1) "directors, officers, and trustees of hospitals" who are explicitly named and included in the statutory definition of "Licensed health care provider;" (2) partners in a medical practice who may consult with a treating physician about the treating physician's patient, the patient's illness, disease, injury, or lab results; (3) a specialist who may be asked by a treating physician for a second opinion or to review his or her initial diagnosis; (4) a radiologist who examines x-rays or reviews MRI results[6]; or (5) a geneticist or laboratory who is asked by a treating physician to examine a patient's DNA to help inform the physician's diagnosis and course of treatment for the patient. None of these would meet Plaintiff's suggested standards yet all clearly provide health care to patients and should be considered licensed health care providers.

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[6] A 2017 survey conducted by the Radiology Society of North America reveals that 73% of radiologists report "that time or workload frequently prevented them from communicating directly with patients" (http://pubs.rsna.org/doi/figure/10.1148/radiol.2017162056) A 2016 article in the *Journal of the American College of Radiology* describes the typical radiologists' lack of patient interaction: "By definition, we radiologists are consulting physicians ... we are typically disconnected from our patients ... Radiologists assist primary providers in the diagnosis, treatment, and follow-up of patients, just as consultants work with companies to identify reasons for declining profitability or poor consumer engagement." *Journal of the American College of Radiology*, What Radiology Can Learn from the Management Consulting Industry, February 2016 http://www.jacr.org/article/S1546-1440(15)00952-7/fulltext) (emphasis added).

Indeed, numerous courts have recognized that health care is often provided by individuals and entities that do not have direct interaction with the patient. For instance, the United States District Court for the District of New Jersey held that the medical malpractice statute of limitations governs a claim against a genetic screening laboratory against whom the plaintiffs alleged negligence in the lab's screening of the plaintiffs' embryos at the request of the plaintiffs' treating physician. *Grossbaum v. Genesis Genetics Institute,* 2011 WL 2462279 (D.N.J. 2011). The district court specifically rejected the argument, asserted by Plaintiff here, that a doctor-patient relationship is necessary in order to give rise to a medical malpractice claim, and specifically disagreed that this was the meaning of *Rodriguez v. Saal*, 43 A.D.3d 272, 841 N.Y.S.2d 232 (2007), which the Plaintiff cites in support of her position. (Pl. Brief at 12) After summarizing *Saal* and another New York case that, like *Swanigan,* involved a blood bank's blood-testing procedures, the District Court explained:

> [T]he defendants in these cases [*Saal* and the blood bank case] did not provide medical diagnostic treatment to particular patients. ... The Court of Appeals of New York distinguished between medical malpractice and negligence claims for purposes of the statute of limitations in [the blood bank case], explaining that "a claim sounds in medical malpractice when the challenged conduct constitutes medical treatment or bears a substantial relationship to the rendition of medical treatment by a licensed physician[.]" ...
>
> Here ... it is undisputed that the Genesis Defendants provided genetic diagnoses of Plaintiffs' embryos, with the understanding that Plaintiffs would rely on their diagnoses for purposes of conceiving a child that would not be afflicted with [cystic fibrosis]. ... Unlike a blood bank's screening process, which plays no role in the designation of specific units of donated blood for specific patients, Genesis Defendants performed specialized diagnostic tests on the Grossbaums' embryos for purposes of determining whether those embryos could be implanted. ... **Genesis Defendants thus played an integral part in the medical reproductive treatment provided to Plaintiffs, because ... their [genetic screening] tests were the only part of the process that had the potential of diagnosing flaws** with embryos prior to pregnancy.

Id. at *9-*10 (emphasis added; citations omitted).

The same is true of the instant case. According to the Plaintiff's own allegations, the Defendants performed specialized diagnostic testing on this specific patient's specimen in order to "detect[] an existing disease, illness, impairment, symptom or disorder." (Am. Compl. ¶ 17) Defendants then requested that this specific patient's biological parents (including the Plaintiff) provide a specimen for testing in order to resolve the uncertainty surrounding the testing of their child. These health care services were plainly being provided for the benefit of this one individual patient.

The allegations of the Amended Complaint, the attached affidavits, the decisions of other courts, and the examples listed by the legislature all lead to the conclusion that the Defendants in this case, who analyzed the child's specimen for the purpose of assisting in the diagnosis of his disease and informing his course of treatment, were very much engaged in providing health care to the decedent.[7]

[7] Like *Saal, Morgan v. Lab Corp. of Am.*, 65 Mass App. Ct. 816, 844 N.E.2d 689 (2006), cited by Plaintiff at page 12 of her brief, is clearly distinguishable from this case. *See Morgan,* 65 Mass App. Ct. 816, 821, n.7-8 (Plaintiffs alleged that lab administrator committed ordinary negligence in failing to telephone doctor with test results and court held that allegations did not include "an allegation of a missed diagnosis."). Similarly, Plaintiff's suggestion that Defendants' position is tantamount to claiming that a state highway trooper administering a test to measure the blood alcohol level of a DUI suspect is a "health care provider" (Pl. Brief at 15) ignores the fact that in Plaintiff's hypothetical, the state trooper's administration of such a test does not relate to healthcare at all. *See B.F. v Reproductive Medicine Assoc,* 136 A.D.3d 73, 80, n.5 (distinguishing ordinary negligence claims arising out a forensic toxicology test required as condition of probation because neither side contended that the drug test performed by the laboratory bore any relationship to a course of medical treatment), *citing Landon v Kroll Lab. Specialists, Inc.* 91 A.D.3d 79 (N.Y. 2011), *aff'd*, 22 N.Y.3d 1, 999 N.E.2d 1121 (2013).

III. Plaintiff Cannot Recast Her Claims As General Negligence.

In a last ditch effort to avoid the statute of repose, Plaintiff brazenly attempts to recast her claims as sounding not in medical malpractice (as they are clearly and exclusively cast in the Amended Complaint and medical affidavits attached thereto) but some form of general negligence arising out of a ministerial scrivener's error or "organizational negligence."[8] (Pl. Brief at 16-17) In doing so, Plaintiff hopes to convince this Court that Defendants were not doing what they clearly were – providing healthcare services to decedent and decedent's physicians, which clearly distinguish Defendants from the blood bank in *Swanigan*.[9]

Plaintiff's transparent effort to squeeze the "square peg" in this case into *Swanigan's* "round hole," should be rejected for several reasons. First, the District Court has certified a very specific question – whether the Defendants were "acting as a 'licensed health care provider' as defined by S.C. Code Ann. § 38-79-410 when, at the request of a patient's treating physician, the laboratory performs genetic testing to detect an existing disease or disorder?" Defendants respectfully submit that question can and should be answered in the affirmative, regardless of how the Plaintiff now attempts to re-characterize her allegations.

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[8] In addition to the compelling reasons to reject this argument, as discussed *infra*, is the fact that it amounts to a "straw man" devoid of any support in Plaintiff's Amended Complaint or otherwise. To now contend, contrary to the allegations of the Plaintiff's own pleading, that Defendants' alleged negligence may have been the result of a merely ministerial error, is nothing more than pure speculation posited only to steer this Court from the obvious conclusion (and Plaintiff's position heretofore) that her claims sound in medical malpractice.

[9] Here, even accepting the Plaintiff's speculation that a scrivener's error of a "routine administrative type" contributed to the Defendants' report, Plaintiff's damages resulted from the Defendants' alleged "negligent failure to correctly diagnose ... and failure to accurately advise selection of appropriate therapy," as Plaintiff herself pleads in the Amended Complaint. (Am. Compl., Ex 1, ¶¶ 9, 23)

Second, as noted above, Plaintiff has already clearly cast her claims as sounding in medical malpractice and prior to Defendants' motion to dismiss, never asserted that those claims "may have resulted from a routine scrivener's error" or other mere ministerial error (Pl. Brief at 17 (emphasis added)). Perhaps most indicative of this is the Plaintiff's acknowledgment that her claims cannot be understood or evaluated absent multiple affidavits of medical experts which she attached to her Amended Complaint and referenced throughout. As this Court is well aware, medical expert affidavits are required to allege and support claims of medical malpractice. This Court recently explained that the distinction between professional negligence and ordinary negligence is often made "by determining whether expert testimony is necessary to aid in the jury's determination of fault, particularly with respect to the 'duty' and 'causation' elements of the claim." *Dawkins v. Union Hosp. Dist.*, 408 S.C. 171, 177, 758 S.E.2d 501, 504 (2014). "In general," the court explained, "if the patient receives allegedly negligent professional medical care, then expert testimony as to the standard of that type of care is necessary, and the action sounds in medical malpractice." *Id.*, 758 S.E.2d at 504 (citing various decisions from other jurisdictions). Here, of course, the Plaintiff has offered the affidavits of two medical doctors to support her claims that a standard of care applicable to the Defendants was breached and that the breach was the proximate cause of the decedent's death. The face of Plaintiff's Amended Complaint and the affidavits attached thereto demonstrate that specialized medical knowledge and medical expert testimony is necessary to even allege her claims, and further, that Plaintiff has recognized this fact from the inception of this case.

Finally, Plaintiff's contrived argument is clearly intended to divert the focus of the proper analysis at issue; *i.e.*, whether the genetic testing results at issue and the reasons giving rise to them – the sole focus of Plaintiff's negligence claims – played a role in the diagnosis, treatment

or care of the Plaintiff's decedent. That they did is inarguable and immutable, such that even if improper recording of the results or failure to update its databases played any role in how the decedent's variant was classified (and there is no evidence that they did), these claims nonetheless will always sound in medical malpractice. *See, e.g., B.F. v. Reproductive Medicine Assoc. of N.Y. LLP,* , 136 A.D.3d 73, 80 (rejecting plaintiff's attempt to claim general negligence by framing the claim as focusing on the decision as to which test to order); *Scott v. Uljanov,* 521 N.E.2d 398, 370 ("conduct may be deemed malpractice rather than negligence, when it constitutes medical treatment or bears a substantial relationship to the relationship to the rendition of medical treatment by a licensed physician"); *Annunziata v. Quest Diagnostics Inc.,* 127 A.D.3d at 631 ("laboratory services ... performed at the direction of a physician are an integral part of the process of rendering medical treatment" and therefore "a claim stemming from the rendition of such services is a medical malpractice claim."); *Walls v. Sumter Regional Hosp. Inc.,* 666 S.E.2d 66, 69 (Ga. Ct. App. 2008) ("[a]lthough complaints against professionals may state claims based on ordinary as well as professional negligence, where the allegations of negligence involve the exercise of professional skill and judgment within the professional's area of expertise, the action states professional negligence."); *Stafford-Fox v. Jenkins,* 639 S.E.2d 610, 614 (Ga. Ct. App. 2007) (claim framed as one for ordinary negligence against a physician's professional organization based on the conduct of its nonprofessional employees who allegedly failed to place certain test results on a patient's chart or bring other information to the attention of a treating physician still sounded in medical malpractice because plaintiff's damages "still arose out of the misdiagnosis by [the physician] involving the exercise of medical skill and judgment.").

For these reasons, Plaintiff's attempt to recast her claims as possibly sounding in nonmedical negligence should be rejected.

CONCLUSION

For all of the reasons discussed above, this Court's holding in *Swanigan,* and the detailed analysis from other courts on this issue, Defendants respectfully submit that this Court should answer the certified question in the affirmative and hold that a federally licensed genetic testing laboratory is acting as a 'licensed health care provider' as defined by S.C. Code Ann. §38-79-410 when, at the request of a patient's treating physician, the laboratory performs genetic testing to detect an existing disease or disorder. The claims asserted by Plaintiff here do not involve the provision of a product *en masse* that is used by a treating doctor. This case, rather, involves claims – as the certified question acknowledges – that treating physicians specifically requested and then relied on the expertise and analysis provided by specialists in a federally licensed genetic testing laboratory relating to a specific patient in order to diagnose and determine the course of treatment of the patient. Such action is clearly the provision of "health care" as found in South Carolina Code § 38-79-410.

Respectfully submitted,

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September 1, 2017

THE STATE OF SOUTH CAROLINA
In the Supreme Court

ON CERTIFICATION FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA

Margaret B. Seymour, U.S. District Judge
C/A. No. 3:16-cv-00972-MBS

Appellate Case No. 2017-000787

AMY ELIZABETH WILLIAMS, as the Personal Representative of the Estate for deceased minor, and AMY ELIZABETH WILLIAMS individually,

Plaintiffs,

v.

QUEST DIAGNOSTICS, INC., ATHENA DIAGNOSTICS, INC. and ADI HOLDINGS, INC.,

Defendants.

CERTIFICATE OF COUNSEL

Counsel for Defendants certifies that the Final Brief of Defendants complies with Rule 211(b), to the extent this certification is applicable to briefs filed in response to certified questions of law.

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S.C. SUPREME COURT

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PROOF OF SERVICE

I certify that I have served this 1st day of September, 2017, the Final Brief of Defendants on counsel for the Plaintiffs by depositing copies of same in the U.S. Mail, first class postage prepaid, addressed as shown below:

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