W Y C H E

Attorneys at Law

October 12, 2017

VIA HAND DELIVERY

The Honorable Daniel E. Shearouse
Clerk, South Carolina Supreme Court
1231 Gervais St.
Columbia, SC 29201

Re: *Amy Elizabeth Williams as the Personal Representative of the Estate for Christian Jacob Millare, and Amy Elizabeth Williams Individually vs. Quest Diagnostics, Inc., Athena Diagnostics, Inc., and ADI Holdings, Inc.*
Appellate Case No: 2017-000787

Dear Mr. Shearouse:

Enclosed please find the original and six copies of Exhibits A and B to the Motion to Submit Additional Materials to the South Carolina Supreme Court which were inadvertently omitted from the Motion when filed with your office on October 3, 2017 in the above matter.

If you have any questions, please do not hesitate to contact me.

Respectfully submitted,

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Enclosures

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EXHIBIT A

Final Brief of Plaintiffs

THE STATE OF SOUTH CAROLINA
In the Supreme Court

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

Trial Judge: Margaret B. Seymour, United States District Judge

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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 PLAINTIFFS AMY ELIZABETH WILLIAMS AND THE ESTATE OF DECEASED MINOR

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CERTIFIED QUESTION FOR REVIEW

By order dated May 4, 2017, this Court agreed to answer a question of law certified to this Court by the United State District Court for the District of South Carolina. The question certified to this Court reads as follows:

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?

Stated slightly differently by way of a counter-statement for review, the question before this Court is whether a *certified* clinical laboratory, which fails to properly classify a genetic mutation, necessarily acts within the statutory definition of a "licensed health care provider" as set forth by S.C. Code. Ann. § 38-79-410 (2015)? Amy Elizabeth Williams as the Personal Representative of the Estate for a deceased minor (below the age of fourteen, hereinafter the "Minor") and Amy Elizabeth Williams ("Amy") individually, respectfully request that this Court reaffirm prior precedent, built on a well respected rule of statutory construction, and answer this certified question in the negative.

STATEMENT OF THE CASE

The underlying action arose originally in the South Carolina Court of Common Pleas in Richland County. Amy is the mother of the Minor, (collectively Amy and the Minor hereinafter referred to as "Williams"); subsequently, the Richland County Probate Court appointed Amy as the personal representative of the Minor's estate. In this capacity, and in her own individual capacity, Amy brought suit against Quest Diagnostic, Inc., ADI Holding Company, Inc., and Athena Diagnostics, Inc. (collectively "Quest"), related to certain genetic tests performed on the Minor associated with his epileptic condition; the results of which were then reported to the Minor's physicians.

On March 28, 2016, Quest removed the state court action to the United States District Court for the District of South Carolina, pursuant to federal diversity jurisdiction, 28 U.S.C. § 1332, and the matter now pends with the District Court with case number 3:16-cv-00972-MBS. Upon removal, Quest did not Answer the allegations of Williams' Complaint; instead, Quest filed a motion to dismiss Williams' action pursuant to Federal Rule of Civil Procedure 12(b)(6). Several legal theories supported Quest's motion; however, the only relevant theory in the instant certified question relates to whether Quest qualifies as a "licensed heath care provider" under S.C. Code § 38-79-410.

Each party extensively briefed the above question, and on, January 4, 2017, the Honorable Margaret B. Seymour heard oral arguments. At the close of the hearing, Judge Seymour took the matter under advisement. Thereafter, on March 2, 2017, Judge Seymour Judge Seymour held a conference in chambers (and by phone) to discuss the certification of a question of law to this Court for guidance on the legal issues presented in Quest's motion to dismiss.

Pursuant to South Carolina Rule of Appellate Court Rules: Rule 244, SCACR, on March 30, 2017, Judge Seymour certified the question currently before this Court, finding that "[i]t appears that the South Carolina Supreme Court has not squarely addressed the question of whether diagnostic laboratories are licensed health care providers within the meaning of S.C. Code Ann. § 38-79-410." On May 9, 2017, this Court agreed to accept the certified question for review. This proceeding followed.

STATEMENT OF FACTS

The Minor was born on August 23, 2005, and developed normally and relatively healthfully throughout his first four months. By December 23, 2005, at his four month check-up, the Minor's health records indicate that he began suffering from febrile focal motor seizures. The Minor's physicians initially believed these seizures were resulted from a metabolic disorder caused by a failure of his cells' mitochondria to function properly. As such, the medical treatments given to the Minor included the prescription of drugs known as sodium channel blocking medications.

In order to confirm this mitochondrial disorder, and rule out other possible medical conditions such as Dravet Syndrome, a blood sample was taken from the Minor and sent to Quest for testing. The deoxyribonucleic acid ("DNA") tests results reported to the Minor's physicians indicated that he did possess a genetic mutation but one only of "unknown significance." These findings were forwarded to the Minor's physicians in the 2007 Sequencing Clinical Diagnostic Report (the "2007 Report").

With the results appearing on their face to be inconclusive, the Minor's physicians continued to treat him with sodium channel blocking medications, and further inquiries into Dravet Syndrome were abandoned. Tragically, sodium channel blocking medications can

exacerbate Dravet Syndrome; a condition, later confirmed, from which the Minor suffered. As a result, the Minor passed away, on January 5, 2008, after suffering a severe epileptic seizure.

In the Complaint, Williams asserts several claims for relief against Quest; however, the gravamen of the Williams' causes of action relate to the assertion that Quest negligently misclassified, otherwise accurate, genetic test results and then published this mistake in the 2007 Report. For clarification, the isolation and assessment of the relevant gene (SCN1A), along with the identification and description of a mutation found on the Minor's particular gene, appears to have been executed correctly and without error.[1] Moreover, William's Complaint asserts that the section of the 2007 Report labeled "Technical Results" appears to be "methodologically accurate" and to correctly identify the mutation in question located on the correct SCN1A gene. As such, Quest's work in this regard does not form the basis for any cause of action asserted by Williams.

The actions of Quest that underlie Williams' theory of negligence relate to what happened, or did not happen, next. Quest, with the correct genetic information in hand, simply failed to label, or classify, this mutation properly and then published this misclassification in the 2007 Report provided to the Minor's physicians. As alleged by William's Complaint, Quest should have classified the Minor's mutation as a "disease associated mutation" in that portion of the Technical Results used to described the "Variant Type." Instead, the Technical Results of the 2007 Report, published by Quest, label the variant type as "Variant of unknown significance."

[1] Specifically, Williams acknowledge that Quest correctly identified a "transversion for thymine (T) to adenine (A) at nucleotide position 1237 at codon 413 resulting in the amino acid change of tyrosine (Y) to asparagine (N)" (technically expressed as "1237T>A, Y413N") on a particular section of the Minor's genes known as SCN1A.

As support for the contention that the original classification of the 2007 Report was in error, Williams notes that in, January of 2015, Quest produced a Revised Report ("2015 Report"). The 2015 Report reclassified the Minor's DNA mutation as a "known disease associated mutation" consistent with Dravet Syndrome. Moreover, the Minor's particular transversion (*i.e.* missense mutation) is, and was at the time, well understood within the genetics field to be associated with Dravet Syndrome – a severe form of epileptic encephalopathy also known as *Severe Myoclonic Epilepsy of Infancy*. At least two clinical publications established the foundation necessary to link the Minor's SCN1A mutation with Dravet Syndrome: *Berkovic* et al., 2006 and *Harkin* et al. 2007.

Not only was the association of the Minor's particular mutation with Dravet Syndrome well known within the broader genetic research community, this mutation's association was known to Quest. Quest's Chief CLIA Laboratory Director, Sat Dev Batish, PhD, reviewed and authorized the publication of the 2007 Report along with its Technical Results. Moreover, Dr. Batish is one of the coauthors of the *Harkin* et al., 2007 publication referenced above, wherein the Minor's mutation is identified as one associated with Dravet Syndrome, and Quest's issuance of the 2007 Report occurred subsequently to the publication of *Harkin* et al. 2007 and *Berkovic* et al. 2006 studies.

ARGUMENT SUMMARY

As discussed briefly above, the instant certified question arises from Quest's attempt to dismiss Williams' Complaint by claiming status as a "licensed healthcare provider" under South Carolina statute, S.C. Code Ann. § 38-79-410. Quest's motion to dismiss reasons that the medical malpractice statute of repose (S.C. Code § 15-3-545(A) (2005)) – only available to licensed health care providers – bars recovery under the facts alleged by the Complaint. Quest

asserts that since their alleged mistake occurred more than Six (6) years prior to the initiation of this action, no recovery may be obtained by Williams. To support the contention that Quest is a licensed healthcare provider in previous arguments, Quest relied on a broad dictionary definition of "health care," wherein "any field" concerned with the "restoration of health" would qualify.[2]

By way of rejoinder, Williams first would note that resort to such an outside source is unnecessary since this Court has already found in *Swanigan v. Am. Nat'l Red Cross*, 313 S.C. 416, 438 S.E.2d 251, (S.C. 1993) that the legislative intent of the statute in question to appears to be clear on its face. Instead, Williams posits that instant action is one of ordinary negligence and not medical malpractice and is the result of improper and/or inadequate administrative oversight of published Technical Results in the 2007 Report. Further, the statutorily understood "licensed healthcare provider" is a much more limited term by design and does not encompass every salubrious activity or service. In the only prior instance, where this Court undertook to address the scope of the statute at issue, this Court created an analytical guide premised upon a well established rule of statutory construction that, if used again, would control the result here. Furthermore, while different jurisdictions tasked with similar questions related to the definition of healthcare providers and/or the scope of medical malpractice statutes have reached varying results, the results reached by those courts were often determined by the particular language of that state's statute or a different tradition of case law regarding medical malpractice.

ARGUMENT

1. South Carolina's Exclusion of Diagnostic Testing Laboratories from the Definition of Licensed Health Care Providers is Premised on the Application of a Long Established Rule of Statutory Construction, *Ejusdem Generis*.

[2] Quest has previously relied on the definition of "health care" (two words) found in Webster's College Dictionary, 2d ed., p. 599 (1997).

The definition of "Licensed health care provider" provided by S.C. Code Ann. § 38-79-410 (2015) states as follows:

"'Licensed health care provider' 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*." (emphasis added). The dispute at the center of this certified question turns on how broadly or narrowly the phrase "any similar category of licensed health care providers" applies to a person or entity connected to the health care of an individual.

Fortunately, a means of answering this question has already been provided by this Court, which held that "[w]hen the Legislature uses words of particular and specific meaning followed by general words, the general words are construed to embrace *only* persons or things of the same general kind or class as those enumerated." *Swanigan* at 419, (emphasis added); (citing *State v. Patterson*, 261 S.C. 362, 200 S.E.2d 68 (1973) which held that "[g]eneral words in a statute must be construed in context and, under the doctrine of *ejusdem generis*, the meaning of such words may be restricted by words of specification which precede them on the theory that if the legislature had intended the general words to be used in their unrestricted sense, there would have been no mention of the particular class.") (*See also Black's Law Dictionary* (10th ed. 2014) E*jusdem generis* is "a canon of construction that when a general word or phrase follows a list of specific person or things, the general word or phrase will be interpreted to include only persons or things of the same type as those listed.").

Within this analytical framework, in order to be placed within this "similar category licensed health care providers," Quest must compare reasonably well with those specifically listed licensed heath care providers directly named, or enumerated, by the statute, such as:

doctors, nurses, dentists, hospitals and/or nursing homes. With regard to the very first Twelve (12) examples provided by statute, each one refers to individual persons, and by and large, most of these examples describe recognized professional services. Concomitantly, all these professional services are regulated and licensed by various boards overseen and administered by the South Carolina Department of Labor Licensing and Regulation ("LLR").[3] As a corporation and as a laboratory performing tissue sample testing, Quest is neither an individual nor is this entity licensed by LLR or any other South Carolina state agency.

Moreover, Williams argues that each of the Twelve (12) individual professionally licensed occupations listed in this statute, the majority have direct interactions with patients, whereby each is responsible for a comprehensive and intimately interconnected scope of health issues and patient care. Similarly, as in the case of directors, trustees, and officers, these individuals are responsible for promulgating and enforcing policies and procedures governing patient care while such patients receive treatment at one of the enumerated healthcare provider institutions (*i.e.* hospitals and nursing homes). Also, these healthcare administrators typically are involved in the hiring, selection, retention, and training of professionally licensed healthcare providers.

Conversely, a laboratory, like Quest, conducts very limited-in-scope tests on tissue samples. Such an organization has no interaction with patients. A laboratory's duty merely is to perform its narrowly tailored test, on tissue or other sample, and report accurate results to a patient's health care providers. As such, Quest does not compare favorably with any of the listed individuals within the category of "licensed health care providers."

[3] For a list of those professional occupations whose licensing boards are administered by Department of Labor Licensing and Regulation, Division of Professional and Occupational Licensing, see S.C. Code Ann. § 40-1-40 (2011).

Turning to the listed institutions, – hospitals and nursing homes – fortunately such institutions are precisely defined in the relevant medical malpractice code sections:

> "Hospital" means a licensed facility with an organized medical staff to maintain and operate organized facilities and services to accommodate two or more nonrelated persons for the diagnosis, treatment, and care of such persons over a period exceeding twenty-four hours and provides medical and surgical care of acute illness, injury, or infirmity and may provide obstetrical care, and in which all diagnoses, treatment, or care are administered by or performed under the direction of persons currently licensed to practice medicine and surgery in the State of South Carolina. This term includes a hospital that provides specialized service for one type of care, such as tuberculosis, maternity, or orthopedics.

S.C. Code Ann. § 15-79-110(4) (Supp. 2016).

> "Nursing home" means a licensed facility with an organized nursing staff to maintain and operate organized facilities and services to accommodate two or more unrelated persons over a period exceeding twenty-four hours which is operated either in connection with a hospital or as a freestanding facility for the express or implied purpose of providing skilled nursing services for persons who are not in need of hospital care. This term does not include assisted living, independent living, or community residential care facilities that do not provide skilled nursing services.

S.C. Code Ann. § 15-79-110(7) (Supp. 2016). For purposes of comparison, at least in the instant analysis both Quest and the above defined licensed health care providers are both institutions and entities. As such, Quest may operate a standing facility and organize a staff; however, Quest utterly fails to demonstrate the remaining material elements of either definition.

By contrast, Quest does not provide twenty-four hour medical and surgical care; Quest does not treat acute illness, injury, or infirmity; Quest does not accommodate (*i.e.* house) two or more nonrelated persons for such care and treatment; Quest does not offer skilled nursing services; nor does Quest conduct any similar business in this state under license from the South Carolina Department of Health and Environmental Control ("DHEC") as is required of all

hospitals, nursing homes, and ambulatory surgical facilities operating in South Carolina.[4] Quest may be a certified diagnostic laboratory and regulated by a particular body of federal regulations, the CLIA, but Quest is not licensed by any South Carolina state agency as a medical provider or health care provider. Moreover, Quest's argument for inclusion within this statute ignores the many opportunities, since its enactment for the legislature to expressly expand this definition to include outside testing laboratories.[5]

2. South Carolina Does Not Recognize a Laboratory's Negligence as a Form of Medical Malpractice.

The controlling case on the question of whether Quest is a "licensed health care provider" and therefore subject to the provisions of the South Carolina's medical malpractice statute of repose is *Swanigan v. Am. Nat'l Red Cross*, 313 S.C. 416 (S.C. 1993), as referenced above. In 1985, Mr. Swanigan, whose estate was represented by his wife in a wrongful death action, underwent heart surgery during which time he received a blood transfusion. Before Mr. Swanigan received that blood the American Red Cross (the "Red Cross") ostensibly collected, tested, and categorized (*e.g.* type O negative, type AB positive) the blood in question. *Id.* at 418. Tragically for Mr. Swanigan, the blood he received was contaminated with Human Immunodeficiency Virus also known as HIV. As a result, he later developed Acquired Immunodeficiency Syndrome ("AIDS"), which took Mr. Swanigan's life in 1991. *Id.* More than Seven (7) years after the transfusion, Mr. Swanigan's wife brought an action claiming that the

[4] For a list of facilities that are required to obtain a DHEC license before providing care for two or more unrelated persons see S.C. Code Ann. § 44-7-260 (1976, as amended). *Also see* the State Certification of Need and Health Facility Licensure Act, S.C. Code § 44-7-120, noting the declaration of purpose to require "the licensure of facilities rendering medical, nursing, and other health care."

[5] The legislative history indicates this act was originally codified as S.C. Code § 38-59-110 (1976, as amended) and then recodified in 1987-1988.

Red Cross was negligent "based on its failure to adopt *proper testing and screening* procedures." *Id.*at 420 (emphasis added).

The Red Cross countered this charge by asserting "that because the transfusion of blood is considered a 'medical service'..." that, in turn, the Red Cross should be considered a "licensed health care provider" and, therefore, the relevant limiting statute – the statute of limitations in this case – should bar Mr. Swanigan's action. This Court, exercising the same rules of statutory construction, *ejusdem generis*, and means of comparison set forth above, found held "that the Red Cross is not included in the definition of 'licensed health care provider' in section 38-79-410." *Id.* at 419-20.

In prior arguments, Quest has cited to a Virginia District Court decision wherein that court concluded that the Virginia statute's inclusion, within the definition of a licensed health care provider, of "a corporation, partnership, limited liability company or any other entity ... which employs or engages a licensed health care provider" necessitated subsuming the defendant laboratory within such category. See *Khadim v. Laboratory Corp. of Am.,* 838 F. Supp. 2d 448 (W.D. Va. 2011). The problem with this argument is twofold. First, the Court in the *Khadim* case was asked to interpret a Virginia statute, which differs substantially from the one in South Carolina.[6] Second, and even more importantly, the consideration of whether or not an entity employs "licensed health care providers" has been expressly rejected in South Carolina as part of the analysis of whether the entity is itself licensed health care provider. [7]

[6] Va Code § 8.01-581.1 (2015) expressly *includes* within the definition of "licensed heath are provider, those entities that employ or are owned by other individual licensed health care providers. This is not the case under the South Caronia statute.

[7] Clinical laboratories that perform tests on human tissue must be "certified" pursuant to the Clinical Laboratory Improvement Act, 1988, ("CLIA") as amended 42 U.S.C. § 263a, and the regulations promulgated pursuant to this Act, 42 C.F.R. § 493.1 *et seq*. The legislative history

In *Swanigan*, the Red Cross argued that "because licensed physicians, nurses, and other medical professionals are employed at all levels of the blood collection process" that the Red Cross should be considered a licensed health care provider" under the very same statute at issue here, S.C. Code § 15-3-545(A). *Swanigan* at 420. In response, this Court held that "the mere employment of health care professionals is not sufficient to make an employer a 'licensed health care provider.'" *Id.*

Moreover, the recognition of laboratory work as really some form of health care and the treatment of any laboratory negligence as a form of medical malpractice are hardly a universal assessment. For example, in *Morgan v. Lab. Corp. of Am.*, 65 Mass. App. Ct. 816, 818, 844 N.E.2d 689, 693 (2006) *cert. denied*, the Massachusetts Appellate Court found that a laboratory corporation's failure to notify the plaintiff's doctor of "a significant change in the anticoagulation level of [plaintiff's] blood" negligently cased that plaintiff to suffer "life-threatening or 'panic' values for which he required immediate medical attention." The Court further held that there was no need to instruct the jury on the medical malpractice statutory cap of damages since plaintiff's claim is "based upon traditional negligence principles rather than medical malpractice tenets." *Id.* at 824.

Similarly, a more recent New York Court found that an organ donor network's "testing and screening procedures" for donated organs was not "any type of medical treatment" and that "a cause of action sounding in medical malpractice... must be predicated upon the existence of an express or implied physician-patient relationship." *Rodriguez v. Saal*, 43 A.D.3d 272, 274, 841 N.Y.S.2d 232, 235 (2007) (citing *McKinney v. Bellevue Hosp.*, 183 A.D. 2d, 563, 564, 584

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indicates that the original 1967 Act underwent a substantial amendment in 1988 wherein references to "licensed" and "unlicensed" laboratories as well as "exempt" laboratories were removed and replaced with a mechanism for recognizing "certified" and "accredited" laboratory facilities.

N.Y.S. 2d 538 (1992)). Moreover, this Court cited to a number of out-of-state precedent reaching a similar conclusion. And, among the precedent this Court cited to *Doe v. American Nat'l Red Cross,* 176 Wis. 2d 610, 618, 500 N.W.2d 264, 267 (1993) (which concluded "that neither the Red Cross nor pharmaceutical companies are subject to the medical malpractice statute of limitations because they do not provide health care to others"). Further, in *Swanigan,* this Court summarized the findings of the Supreme Court of Wisconsin as finding "the Red Cross does not qualify as a health care provider *because it plays no role in the care of patients*." (emphasis added). *Swanigan* at 419.

Yet, despite these statements by the Courts, one could certainly make an argument that these and similar entities (*e.g.* Quest and the Red Cross) have some role in final health outcomes of patients. After all, the delivery of blood – properly screen for communicable diseases, and correctly categorized by blood type, and stored and transported in an effective manner – will all have a very real impact on the health of a patient. Williams would argue that the distinction between heath care providers and entities like Quest relates the scope of care required by treating physician and/or hospital owes to its patient as opposed to those required by a testing laboratory or blood screener.

3. Unlike the Parties Enumerated in S.C. Code Ann. § 38-79-410, a Genetic Testing Laboratory Does Not Have the Relationship Between a Patient and a "Health Care Provider" Contemplated by the Statute.

"Medical services differ from other types of commercial activity because of the very personal nature of the service rendered." *Coggeshall v. Reproductive Endocrine Associates of Charlotte*, 376 S.C. 12, 18, 655 S.E.2d 476, 479 (2007). This Court plainly stated in *Swanigan* that "an institution or person must provide health care to patients to qualify as a 'similar category

of licensed health care provider.'" *Id.*, 313 S.C. 419, 438 S.E.2d at 252. Accordingly, the Red Cross did not qualify for protection under the statute of repose because "it plays no role in the care of patients." *Id., citing Doe v. American Nat'l Red Cross*, 176 Wis.2d 610, 500 N.W.2d 264 (1993). *Swanigan* recognizes that to qualify as a health care provider, the party must have a relationship with the patient beyond simply assisting the primary caregiver in treating that person. This distinction explains the specific enumeration of the professions and entities subject to the statute of repose, and why Quest is excluded from it.

For example, in the doctor-patient context, this Court has recognized that "The relation is a consensual one wherein the patient knowingly seeks the assistance of a physician and the physician knowingly accepts him as a patient." *Roberts v. Hunter*, 310 S.C. 364, 366, 426 S.E.2d 797, 799 (1992), *quoting* 61 AM. JUR. 2d *Physicians Surgeons* § 158 at 290 (1981). As such, state law requires that the doctor-patient relationship have a nexus between an actual physician and an actual patient. This Court has clarified the nature of the personal relationship between a doctor and patient in the course of defective breast implant litigation:

> Although the breast implant procedure requires the use of a product, the implant, the health care provider is fundamentally and predominantly offering a service. The provider must have medical knowledge and skill to conduct the procedure. *He must advise the patient of the medical consequences and must recommend to the patient the preferable type of procedure.* The product may not be purchased independently of the service. (emphasis added). *In re Breast Implant Product Liability*, 331 S.C. 540, 547, 503 S.E.2d 445, 448-49 (1998).

Unlike the doctor-patient relationship, Quest has no such interaction, relationship or consultation with a patient. At a physician's request, Quest receives samples, tests those samples, and submits the testing results to the requesting physician. Quest does not "advise the patient about the medical consequences" associated with those test results, nor does it "recommend to the patient the preferable type of procedure." That role is left to the actual

"health care provider" who has a personal relationship with the patient and can provide those services, as contemplated by the statute.[8] As such, without the personal relationship with a patient, Quest is not in the "similar category" of professions identified in section 38-79-410 and subject to its coverage.

Conversely, Quest does not have the interaction and relationship with patients provided by hospitals and nursing homes, which are included in the ambit of the statute of repose. The existence of a "brick and mortar" laboratory does not transform Quest into the type of entity for which it seeks comparison. As noted above in Argument 1, above, those institutions must provide "twenty-four hour medical and surgical care" or "skilled nursing services" which can accommodate "two or more" unrelated persons. Accordingly, Quest is not in a "similar category" as those entities so as to qualify for consideration as a "licensed health care provider."

Basically, Quest asks this Court to rule that providing genetic testing services *per se* qualifies it as a "licensed health care provider." Quest's broad construction of "health care provider" extends the statute of repose to the performance of *any* services of a potential medical nature, regardless of the relationship of the parties. Such an extension of the scope of the statute would lead to absurd results. By extension, a state highway trooper administering a test to measure the blood-alcohol level of a DUI suspect would qualify as a "health care provider" under Quest's formulation. As this Court recognized in *Swanigan*, the legislature plainly did not intend such a result. Therefore, this Court should not undermine legislative intent by extending the coverage of the statute of repose to testing entities and laboratories such as Quest.

4. The Actions of Quest Constitute Ordinary Negligence, Not Medical Malpractice

[8] As discussed in Argument 2, *supra*, this Court previously has rejected the proposition that the mere employment of physicians and nurses by the Red Cross transformed that entity itself into a "health care provider" subject to the statute of repose.

While the South Carolina Federal District Court notes in its Order of Certification that Williams' causes of action arose from "the error in the 2007 Report" that caused the Minor to be denied proper medication, the Order does not speak to how such error occurred. However, Williams would argue that the malfeasance asserted in the instant action is one of ordinary negligence, as opposed or a newly discovered from of medical malpractice. The exact reason(s) Quest failed to select and promulgate the correct classification will be developed during discovery and potentially a trial on the merits of the case. And, the claims Williams has asserted against Quest, for its misclassification, result from a failure of administrative oversight by Quest.

South Carolina, and most other jurisdictions, acknowledge that "medical malpractice is a category of negligence, the distinction between medical malpractice and negligence claims is subtle; there is no rigid analytical line separating the two causes of action... [and] differentiating between the two types of claims 'depends heavily on the facts of each individual case.'" *Dawkins v. Union Hosp. Dist.*, 408 S.C. 171, 176, 758 S.E.2d 501, 503-04 (S.C. 2014) (citing *Estate of French v. Stratford House*, 333 S.W.3d 546, 555 (Tenn. 2011) (internal citations omitted)).

According to the South Carolina Code:

> "Medical malpractice" means doing that which the reasonably prudent health care provider or health care institution would not do or not doing that which the reasonably prudent health care provider or health care institution would do in the same or similar circumstances.

S.C. Code Ann. § 15-79-110 (6) (Supp. 2016). Yet, "[t]he statutory definition of medical malpractice... does not impact [licensed health care] providers' ordinary obligation to reasonably care for patients with respect *to nonmedical, administrative, ministerial, or routine care.* Thus, [licensed health care] providers are still subject to claims sounding in ordinary negligence." *Dawkins* at 178 (emphasis added). As mentioned above, Williams does not assert that the highly specialized and technical aspects of isolating and inspecting the SCN1A gene or the complex

analysis used to describe the Minor's particular SCN1A gene mutation was performed incorrectly, nor does Williams assert that such activities give rise to any of the causes of action asserted in the case at bar.

Williams' claims of negligence arise from the misclassification of the Minor's mutation as one of "unknown significance." The association of the Minor's mutation with Dravet Syndrome was well established and known to Quest. Quest's Chief CLIA Laboratory Director, Dr. Batish, coauthored a peer reviewed publication noting the connection of the Minor's mutation and Dravet Syndrome. Yet somehow, Quest failed to properly classify, or label, the "Variant Type," within the 2007 Reports' Technical Results. Such a failure may have may have resulted from a routine scrivener's error, whereby a laboratory technician simply failed to select, or write in, the correct category after reviewing correct results. Another possibility might simply be that Quest did not update its database used to compare mutations with other known disease associations or even that Quest's database may have had corrupted information or information that was entered into the database in such a way as to make the ensuing comparative search ineffective.

In either scenario, Quest failed to implement adequate oversight and procedural safeguards as well as administerial controls necessary to prevent the false reporting of information in conflict with what was known, or should have been known, by Quest. Such a claim against Quest "is based on its failure to adopt proper... procedures *at the organizational level.*" *Swanigan* at 420 (emphasis added). Williams' action does not arise against the actions of its medical employees (*e.g.* physicians) neither does it arise against the technical quantity of the laboratory work performed by its genetic researchers.

The organizational negligence described above, which appears directly responsible for Williams' damages, are of a nonmedical, administrative, or ministerial, type or result from a lack of routine care surrounding the publishing of test results. *Dawkins* at 178. The need to update a database, necessary for proper comparative purposes, and the need to ensure the selection of a label that agrees with the information provided, and the need to create adequate administrative oversight of published Technical Results "raise issues that are within the common knowledge and experience of the [fact finder]" and as such raise claims of ordinary negligence. *Bryant v. Oakpointe Villa Nursing Ctr., Inc.*, 471 Mich. 411, 414, 684 N.W.2d 864, 867 (2004) (quoting *Dorris v. Detroit Osteopathic Hops Corp.*, 460 Mich. 26, 594 N.W.2d 455 (1999) (brackets in original)).

CONCLUSION

Given the forgoing, Williams argues that South Carolina case law and statutory construction clearly excludes Quest from the definition of "licensed health care providers." As such, the Six (6) year statue of repose, relevant to medical malpractice actions, has no bearing on this case or the claims asserted by Williams, and this Court should answer the above certified question in the negative by finding that Quest does not meet the statutory definition of licensed health care provider under S.C. Code. Ann. § 38-79-410 (2015).

(Signature Page to Follow)

Respectfully submitted,

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Columbia, South Carolina

THE STATE OF SOUTH CAROLINA
In the Supreme Court

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

Trial Judge: Margaret B. Seymour, United States District Judge

---

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

To the extent such certificate is applicable to briefs filed in response to a certified question of law accepted by the Court, counsel certifies that Plaintiffs' Final Brief complies with Rule 211 (b), SCARC.

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THE STATE OF SOUTH CAROLINA
In the Supreme Court

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

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I certify that I have served the Final Brief of Plaintiffs upon the addressees listed below by depositing a true copy in the United States Mail, First Class postage prepaid, on July__, 2017.

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July 3, 2017
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EXHIBIT B

Reply Brief of Plaintiffs

THE STATE OF SOUTH CAROLINA
In the Supreme Court

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

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REPLY BRIEF OF PLAINTIFFS AMY ELIZABETH WILLIAMS AND THE ESTATE OF DECEASED MINOR

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I. OPENING

Amy Elizabeth Williams ("Amy") as the Personal Representative of the Estate for a deceased minor (below the age of fourteen, hereinafter the "Minor") (Amy and the Minor hereinafter collectively referred to as "Williams") submits this reply brief to rebut the arguments proffered by Defendants, Quest Diagnostic, Inc., ADI Holding Company, Inc., and Athena Diagnostics, Inc. (collectively "Quest"). For the reasons set forth herein, as well as those articulated in Plaintiff's Final Brief, the arguments of Quest should be rejected, and the certified question forwarded to this Court by the South Carolina Federal District Court should be answered in the negative.

II. QUEST'S RELIANCE ON THE AMENDED COMPLAINT

A. Certain References by Quest to the Amended Complaint and the Attachments Thereto Should Be Stricken Pursuant to Rule 244(b) SCACR.

Williams objects to Quest's repeated inclusion of materials and evidence not submitted by the certifying Federal District Court, much of which is taken out of context and has little bearing on the certified question before this Court. Specifically, Williams objects the belabored references to the Amended Complaint as well as the attached evidentiary materials and supporting affidavits. Rule 244(b) SCACR, provides that '[t]he Supreme Court will not consider any document or other evidentiary materials unless the certifying court has submitted those materials... In the event a party believes that additional materials from the record before the certifying court are necessary, it shall notify the Supreme Court and the certifying court so that the certifying court can determine if the additional materials will be submitted."

This appellate rule also has a provision allowing the Supreme Court to seek additional materials from the records. However, in the context of a certified question, a litigant has no ability to unilaterally add materials to the record of a certified. This rule "contemplates that the South Carolina Supreme Court will base its answers to the questions certified exclusively upon the findings of fact by the District Court..." *Johnson v. Collins Entm't* Co. 333S.C. 96, 508 S.E.2d 575 (1998). Since Quest has made no motion or request either to this Court or to the Federal District Court to supplement its submission, Quest's references to such materials are improper and should be stricken from its brief.

B. Quest Inappropriately and Inaccurately Characterizes the Amended Complaint.

Without waving this objection nor the request that portions of Quest's Final Brief be stricken, Williams does take this opportunity to expressly reject the assertion that the Amended Complaint, or the attached affidavits, act to concede the argument that Quest provided health care or that that the entirety of Williams' claims for relief sounds in medical malpractice. Quest's selective parsing of the Amended Complaint, which takes words and phrases out of context, is inappropriate. In particular, Quest attempts to mislead the Court by insinuating that the phrases "diagnosing," "appropriate therapy," "failing to advise," and "expert diagnosis" appear within the Amended Complaint itself through misleading references to paragraph numbers within the Amended Complaint. None of these phrases appear anywhere on the Amended Complaint, and certainly cannot be found at the paragraph citations listed by Quest. Some of these phrases may be found in the statements by affiants, which are attached to the Amended Complaint.

However, Williams disputes the notion that a casual reference made by an affiant to the diagnostic assistance offered by Quest definitively or dispositively acts to designate Quest as a "Licensed health care provider" under South Carolina law. The affidavits of Robert Cook-Deegan, M.D., who specializes in the field of genetic ethics as a professor at Duke University, and Max Wiznitzer, M.D., who is a pediatric neurologist with specialized knowledge regarding Dravet Syndrome, are intended to assist in the establishment of a scope of duty owed by geneticists to those individuals relying upon their findings and to connect the prescription of sodium-channel blocking medications to the eventual death of the Minor. The use of medical experts does not, by itself, require this matter to sound in medical malpractice.[1]

"Expert testimony may be used to help the jury to determine a fact in issue based on the expert's specialized knowledge, experience, or skill and is necessary in cases in which the subject matter falls outside the realm of ordinary lay knowledge." *Watson v. Ford Motor Co.*, 389 S.C. 434, 445, 699 S.E.2d 169, 175 (2010). In this new field of genetics, where the scope of duty has not been previously established in this state, then the opinion of such experts will be very valuable in demonstrating negligence on the part of Quest should this matter proceed forward to an evidentiary phase.[2] Quest's only duty was to advise whether the Minor's mutation had any known links to diseases, Dravet Syndrome in particular. What no one disputes is that the 2007 Sequencing Clinical Diagnostic Report (the "2007 Report") makes no link to Dravet Syndrome. That connection, or link, was not published until 2015 after the death of the Minor.

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[1] *State v. Commander*, 396 S.C. 254, 265-66, 721 S.E.2d 413, 419 (2011) (holding that a physician may offer an opinion on the cause of death in a criminal trial.)

[2]See *Savannah Bank, N.A. v. Stalliard*, 400 S.C. 246, 251, 734 S.E.2d 161, 163-64 (2012) setting forth the four elements of negligence as the establishment of a duty of care owed to a plaintiff, the breach of that duty by a negligent act or omission; a negligent act or omission resulted in damages to the plaintiff; and that damages proximately resulted from the breach of duty.

C. Quest's Use of Other Contested Materials in the Statement of the Case.

Williams also objects to Quest's inclusion of highly contested matters within that portion of the Final Brief of Defendants titled, the Statement of the Case in violation of SCACR 208(b)(C), ("The statement shall not contain contested matters."). Among such contested matters include the proposition that further parental testing would have assisted in the Minor's Diagnosis of Dravet Syndrome. Quest refers to the 2007 Report, that was referenced but not included within the District Court's certified question. Quest then makes reference to certain disclosures appearing in body of that report, the details of which are never mentioned in the certified question. The first of these states: "Most mutation that cause SMEI (i.e. Dravet Syndrome) are de novo, or sporadic (arise in the affected individual rather than being inherited."

Another disclosure contained within the 2007 Report, conveniently ignored by Quest, states that "Missense mutations causing the severe phenotypes associated with SCN1A mutations (SMEI or SMEB) are usually (>90%) de novo, meaning that the mutation arose in the affected individual, and is not detected in the biological parents." This technical jargon effectively means that there is a greater than Ninety percent (90%) chance that the mutation at issue arose in the child and was not inherited, or passed along, from the child's parents. As such, the inclusion of arguments that parental testing would have corrected Quest's negligent misclassification of the Minor's genetic disorder is highly contentious and of little relevance to the instant certified question.

III. REPLY TO QUEST'S REMAINING LEGAL ARGUMENTS

A. Providing Diagnostic Information Does Not Equate to the Provision of Health Care.

Williams has never argued that Quest, or other genetic testing laboratories, have no connection to the health care outcomes of patients and expressly acknowledged as much in its prior brief. Instead, Williams suggests that genetic information, which Quest was retained to provide, would have been just a single tool in a doctor's metaphorical medical-bag, a tool designed solely as assistance to diagnosis. Moreover, such testing is just one diagnostic tool with regard to Dravet Syndrome, and other analytical or investigative options exists for doctors seeking to determine whether a patient sufferers from Dravet. In fact, Dravet Syndrome was first described by a French medical doctor, named Charlotte Dravet, as far back as 1978 and long before such genetic testing options were available. See *Epilepsia* Volume 52, Issue Supplement s2 Version of Record online: (4 APR 2011). As more fully described in the Final Brief of Plaintiffs, Dravet Syndrome is a brain dysfunction, where seizures begin to manifest in the first year of life in an otherwise healthy infant.[3] From this and other symptoms, doctors can make a diagnosis of Dravet Syndrome.

However, once a correct diagnosis has been made, Quest plays no role in the short or long term health care of the patient. Quest is not called upon to develop or prescribe drugs or other therapies, to the manage side effects and possible pain associated with treatment, or to assess the effectiveness of such treatments and the associated risks; Quest plays no role in assessing complications that may arise if a patient suffers from more than one ailment or in the development of a unique treatment regiment based on the individual needs and concerns of a patient. Such are the exclusive roles of health care providers.

[3] The Epilepsy Foundation (http://www.epilepsy.com/learn/types-epilepsy-syndromes/dravet-syndrome) (Last visited 2017)

So, the negligence, about which Williams complains, is not that Quest failed to provide Williams with a definitive medical diagnosis and course of treatment. Instead, Williams complains that Quest's failure to update its databases of genetic mutations known to be associated with Dravet Syndrome had the effect of misleading the Minor's doctors, who then, in turn, prescribed an inappropriate drug treatment (sodium-channel blockers) that caused the Minor's death.

B. Quest Requests That This Court Assume the Authority of the Legislature and Extend the Protections of Medical Malpractice Laws to a New Industry.

The medical malpractice statutes in South Carolina, and virtually every state, arose and evolved from a desire by the legislatures to enact certain tort reforms believed necessary to preserve the economic viability of vital industry: the health care industry. In response to a supposed "crisis of availability," and later a "crisis of affordability," many state legislatures passed reform measures to ease these supposed crises.[4] In the instant question, Quest requests that this Court expand the medical malpractice protections, which are currently only available to a well understood set of "licensed health care providers," to an entirely new industry: genetic testing and research. Since medical malpractice, as a distinct form of tortious negligence, arises as a creature of civil statutory law, adherence to a well known rule of statutory construction in the interpretation of that statute would only be reasonable. See *Dawkins v. Union Hosp. Dist.*, 408 S.C. 171, 176, 758 S.E.2d 501, 503-04 (S.C. 2014) (holding that "medical malpractice is a category of negligence").

[4] William R. Padget, *Damage Limitations in Medical Malpractice Actions: Necessary Legislation or Unconstitutional Deprivation?*, 55 S.C. L. Rev. 215, 217; Also see *"Doubling-Down" for Defendants: The Pernicious Effects of Tort Reform*, 118 Penn St. L. Rev. 543, 545 noting that "tort reform began as a response to insurance crises and health care providers' dissatisfaction with personal injury litigation and its method of 'jackpot justice.'"

Yet, in the Final Brief of Defendants, Quest makes little to no effort to compare its facilities to those listed "Licensed health care provider" as provided by S.C. Code Ann. § 38-79-410 (2015), such as hospitals and nursing homes, while still seeking the protection of the medical malpractice statute of repose set forth in S.C. Code Ann. § 15-3-545, Actions for medical malpractice. Looking to the code reveals that South Carolina has defined "Medical malpractice" as "doing that which the reasonably prudent *health care provider* or *health care institution* would not do or not doing that which the reasonably prudent *health care provider* or *health care institution* would do in the same or similar circumstances." (emphasis added).

Again, the code is instructive and should be controlling. The definition of "Health care provider" as provided under S.C. Code Ann. § 15-79-110(3) "means a physician, surgeon, osteopath, nurse, oral surgeon, dentist, pharmacist, chiropractor, optometrist, podiatrist, or any similar category of licensed health care provider, including a health care practice, association, partnership, or other legal entity." This definition seems to directly refer to individuals, who are licensed health care practitioners and the legal entities these practitioners form. No hint at the inclusion of genetic researchers or the companies formed by geneticists can be gathered from a reading of this code section.

Regarding health care institutions, South Carolina has codified a definition here as well, where "Health care institution" is defined as "an ambulatory surgical facility, a hospital, an institutional general infirmary, a nursing home, and a renal dialysis facility." *Id.*(2). With the code going into such detail, if the legislature had intended to include genetic testing laboratories or genetic research facilities, then one would expect at least some reference. However, nothing in the code suggests that the South Carolina legislature believed that genetic testing facilities

warranted the protections currently available in this state through the various medical malpractice statutes.

Of special note, while reasonable minds may differ as to whether an abortion clinic provides health care, abortion clinics are expressly excluded from the definition of an ambulatory surgical facility, which in turn acts to exclude these facilities from the definition of Health Care Institution. *Id.*(1). Such facilities would otherwise meet the "substantial relationship test" proffered by Quest since the services at issue bear a substantial relationship to treatments provided by a licensed physician. (Def. Brief p. 9) Once again, the detail and precision of the legislature in designating those entities, professional practitioners, and facilities that may be subject to the protections of the medical malpractice statutory regime, including the statute of repose, indicates that a stricter and more narrowly tailored review of scope of S.C. Code Ann. § 38-79-410 (2015) is warranted. This also suggests that the well established rule of statutory construction, *ejusdem generis,* previously relied upon by this Court was the correct analytical (or diagnostic) tool and should be controlling yet again.

C. Defendants Argue Against Precedent by Demanding a New "Substantial Relationship Test."

The majority of Quest's arguments in support of this new "substantial relationship test," arise from a series of holdings from the state of New York and the legal traditions surrounding that states medical malpractice statutes as well as the unique series of case law interpretations of that statute which date back decades. In particular, Quest highlights *B.F. v Reproductive Medicine Assoc. of N.Y., LLP* 136 A.D.3d 73 (2015) which reflects on the work and supervision performed by physician-defendant, Alan Copperman, M.D., while he was employed at Reproductive Medicine Associates of New York, LLP, also a defendant. As the Supreme Court

of New York, Appellate Division notes "[t]his case arises from defendants' alleged failure to screen an egg donor for [a genetic disease] before implantation of the donor's fertilized egg into the plaintiff mother." *Id.*

In referring to this case, Quest argues against precedent. The underlying claims in *B.F.* relate to a failure of the defendants to properly process collected human tissue and screen for a disease. These accusations mirror those asserted against the Red Cross in *Swanigan*, screen blood (*i.e.* tissue) for disease. *Swanigan v. Am. Nat'l Red Cross*, 313 S.C. 416, 420, 438 S.E.2d 251, 252 (S.C. 1993). The fact that the New York appellate courts arrived at a categorically opposing result from *Swanigan* suggests a very different analytical framework must exist in the determination of what constitutes medical malpractice. If the supply and processing of an egg, needed for in vitro fertilization, has a substantial relationship to the rendition of medical care, then little argument can be made to distinguish the supply of blood, which can be just a vital in the overall health outcomes for patients.

D. Quest Falsely Conflates Medical Laboratory Testing by Licensed Physician Pathologists with Genetic Testing.

Quest notes that the Texas Court of Appeals found that a pathology laboratory was subject to the unique statute of limitations available to "health care provider" in Texas. *Hogue v. Propath Laboratory, Inc.*, 192 S.W.3d 641 (Tex. Ct. App. 2006). What Quest neglects to mention is that one of the defendants in that case, ProPath Services, "is a group medical practice of pathologists." *Id.* As such, in *Hogue*, the Texas Court is analyzing whether the work of physicians, who specialize as pathologists – and those who work under the supervision of

physicians (Propath Laboratory, Inc., which merely prepared the slides used by the physician pathologist) – qualified as "health care providers." *Id.*

Williams concedes that the work relating to patient care of the doctors, physician-pathologists, hospitals, and any "Health care institution," as defined by S.C. Code § 15-79-110(2), would likely qualify each as a "licensed health care provider" S.C. Code Ann. § 38-79-410. However, in the instant action, the primary actors accused of negligence are geneticists, who failed to uphold professional and ethical standards relevant to geneticists and who do not report to physicians or act under the supervision of physicians or other clearly established licensed health care providers.

Similarly, it is unclear how the analysis of another New York case, *Price v. Benedict Cmty. Health Ctr.*, U.S. Dist. LEXIS 16748 (N.D.N.Y. Aug. 8, 1998) would differ from that of Hogue or what bearing the analysis of *Price* would have on the arguments of Williams. Quest correctly notes that the *Price* court held that claims arising from the failure of a cytotechnologist to properly interpret the results of a pap smear were governed in the New York State, medical malpractice statutes. Cytotechnologists are not doctors but they work under the direction and supervision of a licensed physician-pathologist. *Price* at *13.

The State of South Carolina has a similar statutory framework governing pathology and cytopathology services, which are required to be performed or supervised by a physician or other licensed health care practitioner. S.C. Code § 44-132-10 *et seq.* Once again, Williams concedes that the work of the doctors, physician pathologist, hospitals, and any "Health care institution," as defined by S.C. Code § 15-79-110(2), would likely qualify for the protections offered to a "licensed health care provider" under the relevant statute of repose. S.C. Code Ann. § 15-3-545.

Such work would certainly fall within the realm of medical malpractice if it were undertaken as "Delegated medical acts" under S.C. Code Ann. § 40-47-20. However, such an analysis does nothing to indicate how the specialized work of genetic researchers should be treated under this state's medical malpractice statutes. Williams suggests that the granting of a special category of tort claim protections to an entirely new industry, such a medical malpractice or a worker's compensations regime, must originate with the legislature.

E. Quest Reaching to the Probate Code for a Definition of Health Care Cannot Overcome the Statutory Limitations of the Medical Malpractice Statute.

Reference to the broad definition of "health care" as set forth in the Probate Code, Title 62 of the South Carolina Code, does little to expand the explicit and implicit limitations on the scope of entities and practitioners included within the definition of "Licensed health care provider" as provided for in the various medical malpractice provisions. The only connection Quest has to this Probate Code Section definition "health care" is as an assistant to a physician in the diagnosis of a disease. Of course, the definition of "diagnosis" within this section of the Probate Code can be viewed both narrowly and broadly.

Under S.C. Code Ann. § 40-47-20(36)(e), which defines the "Practice of Medicine" as allowed by physicians, who are licensed by this state's board of medical examiners, includes the "rendering a written or otherwise documented medical opinion concerning *the diagnosis or treatment of a patient...*" S.C. Code Ann. § 40-47-20 (Lexis 2017). When Williams has used the words "diagnose," "diagnostic," or other derivations of this word, with respect to the actionable failures of Quest, Williams has done so in a broad context, where words in question have a more general meaning and are akin to analysis or investigation. Quest's use and description of

"diagnose" appears indistinguishable from the outright practice of medicine, which is currently the exclusive purview of licensed physicians. As such, one tends to get the impression the Quest would have its Ph.D. holding geneticists treated indistinguishably from medical doctors and allow these geneticists to diagnose patients in manner described above in § 40-47-20(36)(e), "Practice of Medicine."

F. No Additional Terms Are Sought to Be Added by Williams.

Williams has argued for the application of the plain meaning of "licensed health care provider" using traditional rules of statutory construction. No additional terms or limitations to the definition have been sought by Williams, and such a claim is a gross distortion of Williams' argument. As noted in the Final Brief of Plaintiff, the application of *ejusdem generis* requires that "[w]hen the Legislature uses words of particular and specific meaning followed by general words, the general words are construed to embrace only persons or things of *the same general kind or class as those enumerated.*" *Swanigan* at 419, (emphasis added); (citing *State v. Patterson*, 261 S.C. 362, 200 S.E.2d 68 (1973).

In determining whether Quest, or any other entity seeking the protections of medical malpractice, is of the "same general kind or class as those enumerated" within the statute, a natural comparison, or contrast, follows. *Id.* The review of how well Quest compares with those listed persons, practitioners, entities, and institutions set forth in S.C. Code § 38-79-410 adds no additional terms to qualify as a licensed health care provider. Such a review merely stems from the inherent characteristics of those enumerated within the statute. Nothing else needs to be added.

Further, while this Court did note that "[t]he 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," such a holding arises from a plain reading and application of the statute in question and not a resort to Quest's "substantial relationship test." *Swanigan* at 419. While a hospital's directors, officers, and trustees are enumerated within the statute, no one would suggest that these individuals offer health care in the common sense. And, the mere appointment of an individual as a hospital director, officer, or trustee does not require such an individual engage in activities that will "bear a substantial relationship to the rendition of medical diagnosis, care and/or treatment to a patient." (Def. Brief p. 9).

Williams has previously speculated that the legislature's inclusion of a hospital's directors, trustees, and officers, with the definition of Section 38-79-410 occurred because these individuals are responsible for promulgating and enforcing policies and procedures governing patient care while such patients receive treatment at one of the enumerated healthcare provider institutions (*i.e.* hospitals and nursing homes). As such, these individuals are just as prone to suit as the hospitals and warrant similar protections. However, none of these individuals would be required to diagnose diseases, provide care or treatment to patients, or be certified by the American Board of Medical Genetics to qualify as "licensed health care providers." The definition given by the legislature clearly designates as much.

G. Further Discovery May Suggest That Williams' Claims Against Quest Arise as Ordinary Negligence.

As discussed *supra*, the expert affidavits used by Williams are not part of the materials supplied to this Court as part of the certified question and Williams objects to the reference of

same within the Final Brief of Defendants. The inclusion of a physician's affidavit regarding cause of death does not force a claim into the realm of medical malpractice. *State v. Commander*, at 265-66. Williams utilizes these affidavits to provide an expert opinion regarding the cause of death and its connection to the prescription of sodium-channel blocking medications.

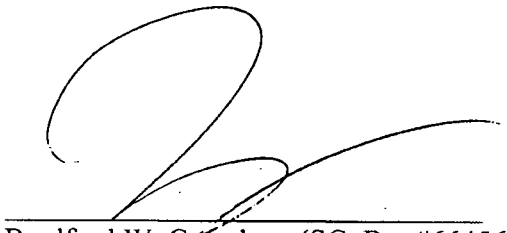
The question of how this misclassification occurred is entirely different and presently does not rely upon the opinions of experts. No Answer to the Complaint has been provided by Quest and no discovery conducted. Williams' claims of negligence arise from the misclassification of the Minor's mutation as one of "unknown significance." The association of the Minor's mutation with Dravet Syndrome was known to Quest, and yet, Quest did not classify, or label, the Minor's mutation correctly. Exactly why this happened has had no opportunity to be explored. The suggestion that the cause may lie with Quest due to "its failure to adopt proper... procedures *at the organizational level*" is perfectly reasonable at this early stage in the litigation. *Swanigan* at 420.

IV. CONCLUSION

As argued here and in the Final Brief of Plaintiffs, South Carolina case law and statutory construction clearly excludes Quest from the definition of "licensed health care providers" and Quest's brief does little to demonstrate points of comparison between a genetic testing laboratory and a hospital, nursing home or other health care institution. Further, even if this Court were to expand the definition of licensed health care provider to include a genetic test laboratory, then without additional information regarding how the Minor's classification errors occurred, no Court would be able to determine whether the negligence alleged arose as ordinary negligee or as medical malpractice. As such, Williams respectfully requests that this Court find that the

expansion of medical malpractice protection to the field of genetics rests within the purview of the legislature and answer the District Court's certified question in the negative.

Respectfully submitted,



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Defendants.

PROOF OF SERVICE

I certify that I have served the Reply Brief of Plaintiffs upon the addressees listed below by depositing a true copy in the United States Mail, First Class postage prepaid, on September__, 2017.

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