

**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.

**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.

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.)

²See *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 suffers 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 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 regimen 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 negligence 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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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' Reply Brief complies
with Rule 211 (b), SCARC.

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