IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

AMY ELIZABETH WILLIAMS as the PERSONAL REPRESENTATIVE of the ESTATE FOR [redacted], and AMY ELIZABETH WILLIAMS, individually,	)	C/A No. 3:16-cv-00972-MBS
Plaintiffs,	)	**OPINION AND ORDER**
v.	)	
QUEST DIAGNOSTICS, INC., ATHENA DIAGNOSTICS, INC., and ADI HOLDINGS INC.,	)	
Defendants.	)	

Plaintiff Amy Elizabeth Williams, as both Personal Representative of the Estate of [redacted] and individually, (hereinafter collectively, "Plaintiff"), brought the within action against Defendants Quest Diagnostics, Inc. ("Quest"); Athena Diagnostics, Inc. ("Athena"); and ADI Holdings Inc. ("ADI") (hereinafter collectively, "Defendants") in the Court of Common Pleas for Richland County, South Carolina. The action was removed to this court on March 28, 2016. Plaintiff alleges that Defendants negligently performed diagnostic testing on her son ("Decedent"), and that the negligent acts or omissions give rise to claims for wrongful death, a survivorship action, negligent misrepresentation, constructive fraud, civil conspiracy, and violation of South Carolina's Unfair Trade Practices Act.

This matter is before the court on Defendants' motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) filed on June 24, 2016, ECF No. 25. Plaintiff filed an opposition to Defendants' motion on July 25, 2016, ECF No. 28, to which Defendants filed a reply on August 11, 2016. ECF No. 31.

I. FACTUAL BACKGROUND

Decedent was born on August 23, 2005. When he was four months old, he began suffering from febrile focal motor seizures. Decedent's treating clinical geneticists, John McKinley Shoffner, M.D. and Frances Dougherty Kendall, M.D., diagnosed him with probable mitochondrial encephalomyopathy. ECF No. 24 at ¶ 15. Decedent's physicians extracted Deoxyribonucleic acid ("DNA") from a blood sample and provided the DNA to Athena's lab for a SCN1A DNA Sequencing Clinical Diagnostic Test so as to confirm or deny the diagnosis. *Id.* at ¶ 17. Athena issued a SCN1A DNA Sequencing Clinical Diagnostic Report on June 30, 2007 (the "2007 Report"), which indicated Decedent possessed a DNA mutation in the SCN1A gene classified as a "variant of unknown significance." *Id.* at ¶ 19. The glossary included in the 2007 Report defined variant of unknown significance as, "DNA sequence variants that are detected reproducibly, but have not been correlated with clinical presentation and/or pathology in the current literature, nor do they result in a readily predictable effect upon protein structure and function." *Id.* at ¶ 21. In a section entitled "Interpretation," the 2007 Report provided the following information: "This individual possesses a DNA sequence variant or combination of variants in the SCN1A gene whose significance is unknown (missense variant of unknown significance). Testing of the biological parents is strongly recommended to resolve the uncertainty of these test results." ECF No. 24-1 at 7. In a section entitled "Comments," the 2007 Report further stated: "[T]he results of this analysis cannot be definitively interpreted … "; "Testing of the biological parents is strongly recommended (for no additional charge) to help resolve the uncertainty of this sequent variant's pathogenicity and the uncertainty of the predicted phenotype"; "Most mutations that cause SMEI are de novo, or sporadic (arise in the affected individual rather than being inherited) an inheritance pattern that can be confirmed by testing of parents"; "In order

to provide a more comprehensive interpretation of this patient's SCN1A results, Athena Diagnostics is requesting samples from the biological parents of this patient"; and "Athena will perform a target analysis on these samples for variant(s) identified in gene SCN1A only and use the findings to help interpret the patient's SCN1A result(s) at no additional charge." *Id.* at 7, 8, 12. Drs. Shoffner and Kendall and Decedent's treating neurologist, Timothy Scott Livingston, M.D., relied on the classification to administer treatment to Decedent appropriate for epileptic seizures not caused by Dravet Syndrome. ECF No. 24 at ¶ 34.

The mutation in Decedent's SCN1A gene "possessed the characteristics expected of a disease causing alteration," and had been reported and studied as a mutation associated with Dravet Syndrome. ECF No. 24 at ¶ 22. The 2007 Report correctly identified "the transversion in question located on the correct SCN1A gene," but Athena had "simply [] mislabeled" the mutation. *Id.* at ¶ 24. Decedent subsequently passed away on January 5, 2008.

In September 2014, at the request of Plaintiff, Decedent's physicians contacted Athena and Quest to ask for a copy of the 2007 Report. ECF No. 24 at ¶ 43. Before that time Plaintiff had not seen or read the 2007 Report. *Id.* at ¶ 20. On January 30, 2015, Quest and Athena jointly produced a Revised Report ("2015 Report"). *Id.* at ¶ 43. The 2015 Report classified Decedent's DNA mutation correctly as a "known disease associated mutation" consistent with Dravet Syndrome. *Id.* Plaintiff alleges that, because of the error in the 2007 Report, Decedent was not provided with proper medication and treatment, and, in fact, the treatment he received exacerbated his seizures. Plaintiff alleges that Decedent lost his life as a proximate result of Athena's negligent laboratory practices.

At all times relevant to this lawsuit, Athena employed Narasimhan Naga, Ph.D. and Hui Zhu, Ph.D. as Directors of Genetics and Sat Dev Batish, Ph.D. as Chief Director of Genetics. ECF

No. 24 at ¶¶ 7-9. The 2007 Report lists these individuals as those who reviewed the laboratory results and submitted the clinical information. ECF No. 24-1 at 17. Plaintiff alleges that at the time the 2007 Report was issued, Athena employed Joseph J. Higgins, M.D. as the Clinical Laboratory Improvement Amendments ("CLIA") Laboratory Director and license holder, and that Dr. Higgins signed the Report in that capacity. ECF No. 24 at ¶ 10. *See* ECF No. 24-1 at 17. CLIA refers to a "federal certification process for laboratories that perform clinical diagnostic tests on human specimens in the United States." ECF No. 24 at ¶ 27. ADI owns all outstanding shares of Athena. *Id.* at ¶ 6. In 2011, Quest purchased ADI and acquired all of that company's outstanding shares. *Id.*

II. PROCEDURAL HISTORY

Following the removal of this action to federal court, Plaintiff filed an amended complaint with the consent of Defendants. ECF No. 19, 24.[1] Defendants thereafter filed a motion to dismiss, arguing *inter alia* that the amended complaint is barred by the six-year statute of repose applicable to actions brought against licensed health care providers, and that Athena qualifies as a "licensed health care provider," as described by S.C. Code Ann. § 38-79-410. ECF Nos. 25-1 at 18-22, 28 at 16-19. Plaintiff filed a Response, ECF No. 28, to which Defendants filed a reply, ECF No. 31. On January 4, 2017, the court heard oral argument on the motion and took the matter under advisement. ECF No. 34. The court subsequently indicated its inclination to certify to the South Carolina Supreme Court the question of whether diagnostic laboratories are considered health care providers pursuant to S.C. Code § 38-79-410, and heard limited argument from the parties on the

[1] The amended complaint incorporates by reference three exhibits attached thereto: the affidavit of Robert Mullan Cook-Deegan, M.D., ECF No. 24-1; the affidavit of Max Wiznitzer, M.D., ECF No. 24-2; and the "Chairman's Address to Bionomics Limited 2004 AMG," ECF No. 24-3. The 2007 Report and 2015 Report are attached to the affidavits of Drs. Cook-Deegan and Wiznitzer.

topic during a telephone conference held March 2, 2017. ECF No. 36, 39. The court thereafter certified the following question to the South Carolina Supreme Court:

> 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?

ECF No. 40.

On June 27, 2018, the South Carolina Supreme Court issued an opinion answering the certified question in the affirmative. ECF No. 59. The Court held that genetic testing laboratories such as Athena that perform testing at the request of a patient's treating physician for the purpose of assisting the treating physician in detecting an existing disease or disorder constitute licensed health care providers as contemplated by section 38-79-410. *Id.* The court thereafter granted the parties leave to file supplemental briefs addressing whether the amended complaint alleges medical malpractice or ordinary negligence. Plaintiff and Defendants filed their briefs on August 17 and August 24, 2018, respectively. ECF No. 58, 61.

III. LEGAL STANDARD

A Rule 12(b)(6) motion to dismiss for failure to state a claim upon which relief can be granted tests the legal sufficiency of a complaint. *Schatz v. Rosenberg*, 943 F.2d 455, 489 (4th Cir. 1991). While the complaint need not be minutely detailed, it must provide enough factual details to put the opposing party on fair notice of the claim and the grounds upon which it rests. *Bell Atl. Corp. v. Twombly*, 550 U.S 544, 555 (2007) (citing *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Additionally, a complaint must contain factual content that allows the court to reasonably infer the defendant is liable for the alleged misconduct. *Ashcroft v. Iqbal*, 556 U.S 662, 678 (2009) ("A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."). "Facts

that are 'merely consistent with' liability do not establish a plausible claim to relief." *United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 455 (4th Cir. 2013) (quoting *Iqbal*, 556 U.S. at 678). *See* 5 C. Wright & A. Miller, Federal Practice and Procedure § 1216, pp. 235–236 (3d ed. 2004) ("[T]he pleading must contain something more ... than ... a statement of facts that merely creates a suspicion [of] a legally cognizable right of action").

The court must accept the allegations in the complaint as true, and draw all reasonable factual inferences in favor of the party opposing the motion. *Iqbal*, 556 U.S. at 679. However, the court will not accept "legal conclusions couched as facts or unwarranted inferences, unreasonable conclusions, or arguments." *Nathan*, 707 F.3d at 455 (quoting *Wag More Dogs, LLC v. Cozart*, 680 F.3d 359, 365 (4th Cir. 2012)). To determine plausibility, a court is to "draw on its judicial experience and common sense"; and if the court determines that the factual allegations can "plausibly give rise to an entitlement to relief," dismissal is not warranted. *Iqbal*, 556 U.S. at 679. "But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* (citing Fed. R. Civ. P. 8(a)(2)).[2]

[2] In briefing the motion to dismiss, both sets of Parties submitted materials outside of the pleadings. Defendants submitted two scientific articles, ECF Nos. 25-2, 25-3, and, in response and opposition to the articles, Plaintiff submitted a second affidavit signed by Dr. Wiznitzer, ECF No. 28-1. If, on a motion under Rule 12(b)(6), "matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion." Federal Rule of Civil Procedure 12(d). Whether to convert a motion to dismiss is within the discretion of the court. The parties did not ask to convert the motion to dismiss, and the materials they submitted are not likely to facilitate disposal of the motion. Therefore, the court declines to consider these materials at this time.

IV. DISCUSSION

Plaintiff alleges negligence resulting in wrongful death and giving rise to a survivorship action as to Athena only, and claims negligent misrepresentation, constructive fraud, civil conspiracy, and violation of the Unfair Trade Practices Act ("UTPA") as to all Defendants. Defendants assert five grounds for dismissing the amended complaint. First, they argue that the applicable statutes of limitation operate to bar each claim because Plaintiff had constructive notice of her potential claims from warnings and recommendations included in the 2007 Report. Second, Defendants argue that the wrongful death and survivorship actions and claims for negligent misrepresentation and constructive fraud are predicated on the alleged misdiagnosis of Decedent's medical condition in 2007, and are subject to the six-year statute of repose for medical malpractice claims as set forth in S.C. Code Ann. § 15-3-545(A), regardless of when Plaintiff had constructive notice. Third, they contend that the claims for negligent misrepresentation and constructive fraud fail to sufficiently allege justifiable reliance on the alleged false statement. Fourth, they contend that by virtue of their unitary ownership they are incapable as a matter of law of conspiring with themselves; and the conspiracy claim does not set forth additional facts or special damages unique to the alleged conspiracy. Finally, Defendants argue Plaintiff fails to adequately plead that Defendants' wrongful acts affect the public interest so as to state a claim under the Unfair Trade Practices Act. ECF No. 25-1 at 4. The court exercises subject matter jurisdiction pursuant to 28 U.S.C. § 1332, and therefore applies the substantive law of South Carolina. *See Felder v. Casey*, 487 U.S. 131, 151 (1988); *Hanna v. Plumer*, 380 U.S. 460, 465 (1965).

The issue of whether the statute of repose set forth in S.C. Code Ann. § 15-3-545 applies to Plaintiff's allegations of negligence impacts the court's treatment of the predominance of Plaintiff's claims, and thus the court addresses this issue first.

A. S.C. Code Ann. § 15-3-545

Plaintiff's claims for wrongful death, survivorship, negligent misrepresentation, and constructive fraud arise from the misclassification of Decedent's mutation in the 2007 Report as one of "unknown significance." ECF No. 28 at 23. Defendants argue that medical malpractice is "the fundamental nature" of Plaintiff's allegations of negligence surrounding the misclassification, and, as such, these claims are barred by the six-year statute of repose[3] set forth in section 15-3-545.[4] ECF No. 25-1 at 15. Plaintiff asserts in response that the negligence she describes in the amended complaint is "of a nonmedical, administrative, or ministerial, type," and results "from a lack of routine care surrounding the publishing of test results." ECF No. 28 at 23-24. Therefore, the remaining issue dispositive of Defendants' argument under section 15-3-545 is whether Plaintiff's allegations sound in ordinary negligence, or medical malpractice.

The South Carolina Code of Laws defines 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." S.C. Code Ann. § 15-79-110(6). Medical malpractice is a category of

[3] S.C. Code Ann. § 15-3-545 provides, in pertinent part:
(A) In any action, other than actions controlled by subsection (B), to recover damages for injury to the person arising out of any medical, surgical, or dental treatment, omission, or operation by any licensed health care provider as defined in Article 5, Chapter 79, Title 38 acting within the scope of his profession must be commenced within three years from the date of the treatment, omission, or operation giving rise to the cause of action or three years from date of discovery or when it reasonably ought to have been discovered, not to exceed six years from date of occurrence, or as tolled by this section.

[4] "A statute of repose constitutes a substantive definition of rights rather than a procedural limitation provided by a statute of limitation." *Langley v. Pierce*, 313 S.C. 401, 404, 405, 438 S.E.2d 242, 244 (1993) ("[s]tatutes of repose are based upon considerations of the economic best interests of the public as a whole and are substantive grants of immunity based upon a legislative balance of the respective rights of potential plaintiffs and defendants struck by determining a time limit beyond which liability no longer exists.") (citations omitted).

negligence, and, therefore, "the distinction between medical malpractice and negligence claims is subtle; there is no rigid analytical line separating the two causes of action." *Dawkins v. Union Hosp. Dist.*, 758 S.E.2d 501, 503-04 (S.C. 2014) (quoting *Estate of French v. Stratford House*, 333 S.W.3d 546, 555 (Tenn. 2011)). "Rather, differentiating between the two types of claims 'depends heavily on the facts of each individual case.'" *Id.* (quoting *Estate of French*, 333 S.W.3d at 556). In *Dawkins*, cited by both Plaintiff and Defendants, the South Carolina Supreme Court examined the distinct qualities of the two types of claims and offered guidance for determining when an action implicates one rather than the other. Of particular relevance, the Court observed that the medical professional must at all times "exercise ordinary and reasonable care to insure that no unnecessary harm [befalls] the patient." *Id.* at 178 (quoting *Papa v. Brunswick Gen. Hosp.*, 132 A.D.2d 601, 517 N.Y.S.2d 762, 763-64 (1987)). The Court further advised that the statutory definition of medical malpractice "does not impact medical providers' ordinary obligation to reasonably care for patients with respect to nonmedical, administrative, ministerial, or routine care," and "[t]hus, medical providers are still subject to claims sounding in ordinary negligence." *Id.* at 178. By contrast, a medical professional acts in a professional capacity when he or she provides medical services to a patient; and, in so doing, the medical professional must meet the professional standard of care. *Id.* In such instances, "expert testimony is required to establish both the duty owed to the patient and the breach of that duty." *Id.* at 176 (citations omitted).

Defendants argue that the amended complaint asserts allegations of negligence that implicate the provision of professional services and thereby require the proffer of expert testimony. *See* ECF No. 25-1 at 16. Indeed, Defendants assert, Plaintiff attaches to the amended complaint the affidavits of two of Decedent's treating physicians, who each opine as to Athena's duty and breach of care with respect to the misclassification of the mutation. Plaintiff contends in response

that Defendants' failure to accurately classify the mutation "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." ECF No. 28 at 23. She further posits:

> [a]nother possibility might simply be that Athena did not update its database used to compare mutations with other known disease associations or even that Athena'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.

Id. at 23-24. Finally, Plaintiff asserts, and Defendants do not appear to contest, that "[t]he reason(s) Defendants failed to select and promulgate the correct classification is not known with certainty." *Id.* at 23.

The court finds that Plaintiff's claims for wrongful death, survivorship, negligent misrepresentation, and constructive fraud are comprised of allegations sounding in both medical malpractice and ordinary negligence. Plaintiff alleges that Decedent's physicians extracted his DNA and provided it to Athena to perform the SCN1A test "for the very limited purpose of 'detecting an existing disease, illness, impairment, symptom or disorder' on the particular gene where a connection to Dravet would likely be found." ECF No. 24 at ¶ 17. The amended complaint raises allegations that support different theories as to why the mutation was misclassified. First, Plaintiff asserts allegations that appear to implicate the provision of medical services. For example, Plaintiff alleges, "[b]y not providing [Decedent's] doctors with the definitive answer that the mutation was known to be associated with Dravet Syndrome, which was the main reason for conducting the test in question, Defendants breached a duty of care owed to [Plaintiff] by misleading the child's doctors." ECF No. 24 at ¶ 24. Plaintiff also alleges the following:

> the 2007 Report indicates that . . . [Dr.] Batish, reviewed the laboratory results and submitted the erroneous clinical information of [Decedent]. Moreover, Batish is one of the authors of the Harkin et al., 2007 publication . . . , which identifies [Decedent's] mutation as one associated with Dravet. This scholarly paper was submitted and published prior to Athena's issuance of the 2007 Report. As such,

> Batish clearly knew, or should have known, that a mistake was apparent on the 2007 Report.

ECF No. 24 at ¶ 31. As Defendants note, Plaintiff offers the affidavits of Drs. Cook-Deegan and Wiznitzer to support her theory.

However, Plaintiff also asserts a second theory, which sounds in ordinary negligence. She notes that Athena accurately "detected and identified 'a transversion from thymine (T) to adenine (A) at nucleotide position 1237 at codon 413 resulting in the amino acid change of tyrosine (Y) to asparagine (N)." ECF No. 24 at ¶¶ 20, 24. She then alleges that, notwithstanding the proper detection of the transversion, "Athena negligently failed to correctly classify the DNA missense mutation in the decedent's SCN1A gene." *Id.* at ¶ 27. Plaintiff attributes that error to Athena's failure to follow "classification procedures of Athena's CLIA certification," described as follows:

> the laboratory must have an adequate system(s) in place to ensure test results are accurately and reliably sent from the point of data entry to final report destination, in a timely manner and [] the laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.

Id. at ¶ 32. Plaintiff further alleges that "[a]s a result of the various violations of CLIA and the errors in classification cited above, doctors for [Decedent] continued in their mistaken original diagnosis that [Decedent] suffered from a mitochondrial disorder and continued with treatments designed for same." *Id.* at ¶ 33. Finally, Plaintiff argues in opposition to the motion that "[t]he need to update a database, necessary for proper comparative purposes, or the need to ensure the selection of a label that agrees with the information provided 'raise issues that are within the common knowledge and experience of the [fact finder]' and as such raise claims of ordinary negligence." ECF No. 28 at 24 (citation omitted).

The record is unclear as to what caused the staff at Athena to misclassify the Decedent's mutation. While Plaintiff asserts allegations that implicate the inadequate provision of

professional services in classifying Decedent's mutation, she also asserts allegations sufficient to demonstrate that the misclassification of Decedent's mutation could have been caused by ordinary negligence. *See Dawkins*, 758 S.E.2d at 504-05 (observing that differentiating between medical malpractice claims and ordinary negligence claims depends heavily on the facts of each case, and holding that an action against a hospital related to "nonmedical, administrative, ministerial, or routine care" sounds in ordinary negligence). *Cf. Iodice v. United States*, 289 F.3d 270, 277 (4th Cir. 2002) (applying North Carolina law and concluding pleading alleged ordinary negligence in addition to medical malpractice) (citing *Estate of Waters v. Jarman*, 547 S.E.2d 142, 145–46 (N.C. App. 2001) (ruling that when a claim against a hospital "ar[ises] out of clinical care provided by the hospital to the patient," the claim sounds in medical malpractice, but when it "arises out of policy, management, or administrative decisions," it sounds in ordinary negligence)). Indeed, during oral argument counsel for Defendants clarified that Dr. Higgins signed only the 2015 Report, and that he was not employed by Athena in 2007 and did not sign the 2007 Report, which was signed by Dr. Seltzer. ECF No. 35 at 23:1-26:5.[5] In response to questioning by the court as to whether and why Dr. Higgins made the decision to revise the Decedent's classification in the 2015 Report, counsel stated only that the questions implicated Athena's policies and procedures, which counsel was not prepared to discuss and did not believe were relevant to the issues raised in the motion to dismiss. *Id.* at 35:1-5.

The matter should proceed to discovery for the purpose of determining what caused Athena's laboratory staff to misclassify the gene mutation. *See Alexander v. Rite Aid Corp.*, No. 4:11–cv–01406–RBH, 2012 WL 80458 (D.S.C. Jan. 11, 2012) (denying motion to dismiss that

[5] Counsel explained that Dr. Higgins's name is listed on the regenerated 2007 Report because he was the CLIA license holder at the time the Report was regenerated and printed. ECF No. 35 at 25:8-13.

asserted failure to file affidavit of expert as required under S.C. Code Ann. § 15-79-125, where complaint alleged in part that non-pharmacist employees of defendant engaged in ordinary negligence such as improper shelving and keying incorrect information into the computer system). Defendants may renew their argument under section 15-3-545 on motion for summary judgment, if appropriate.

B. Constructive Notice

Defendants also argue that regardless of whether Plaintiff's allegations sound in ordinary negligence, applicable statutes of limitations apply to bar all of Plaintiff's claims because she had constructive notice of those claims approximately eight years before she filed this action. Plaintiff disagrees, and contends she was put on notice of her claims only as of the date she read the 2015 Report.

The Parties agree that the South Carolina Code of Laws imposes a three-year statute of limitations for claims for injury to the person or rights of another, for death by wrongful act, and for fraud, S.C. Code Ann. §§ 15-3-530(5)-(7), for suits alleging medical malpractice, *id.* at § 15-3-545, and for claims brought under the UTPA, *id.* at § 39-5-150. The three-year statute of limitations "begins to run when the underlying cause of action reasonably ought to have been discovered." *Holly Woods Ass'n of Residence Owners v. Hiller*, 708 S.E.2d 787, 793 (S.C. App. 2011) (quoting *Martin v. Companion Healthcare Corp.*, 575, 593 S.E.2d 624, 627 (S.C. App. 2004)). Known as the discovery rule, this principle tolls the statute of limitations until the plaintiff "knew or by the exercise of reasonable diligence should have known that he had a cause of action." S.C. Code Ann. § 15-3-535. The South Carolina Supreme Court explains reasonable diligence as follows:

> an injured party must act with some promptness where the facts and circumstances of an injury would put a person of common knowledge and experience on notice

> that some right of his has been invaded or that some claim against another party might exist. The statute of limitations begins to run from this point and not when advice of counsel is sought or a full-blown theory of recovery developed.

Snell v. Columbia Gun Exch., Inc., 278 S.E.2d 333, 334 (S.C. 1981). The related concept of constructive notice allows for a legal inference that substitutes for actual notice. *City of Greenville v. Washington Am. League Baseball Club*, 32 S.E.2d 777, 782 (S.C. 1945); *Strother v. Lexington Cnty. Recreation Comm'n*, 504 S.E.2d 117, 122 n.6 (S.C. 1998). Under the principle of constructive notice, actual notice is "imputed to a person whose knowledge of the facts is sufficient to put him on inquiry; if these facts were pursued with due diligence, they would lead to other undisclosed facts." *City of Greenville*, 32 S.E.2d at 782; *Strother*, 504 S.E.2d at 122 n.6. "The test for whether the injured party knew or should have known about the cause of action is objective rather than subjective." *Hiller*, 708 S.E.2d at 793. Thus, in applying the discovery rule, the court must determine whether the allegations in the amended complaint demonstrate that a person of common knowledge and experience would have had notice that some right of hers had been invaded, or that some claim against another party might exist. *See id.*

Defendants argue that the warnings regarding inconclusive results and the requests for parental testing contained in the 2007 Report provided constructive notice to Plaintiff of her potential claims, and that "[b]y choosing not to follow-up and not to participate in the additional recommended testing, Plaintiff failed as a matter of law to exercise reasonable diligence." ECF No. 25-1 at 13. Defendants contend that Plaintiff had constructive notice of all of her claims as of the date Decedent's physicians received the 2007 Report, save for the wrongful death action of which Plaintiff had constructive notice as of the date Decedent died. ECF No. at 10-15.[6]

[6] At oral argument, Defendants asserted for the first time and without citing authority that the discovery rule does not apply to the wrongful death statute of limitations. ECF No. 35 at 10:7-19, 17:20-23. The court's independent research did not locate support for this position. *See*

Plaintiff raises several arguments in opposition. First, she alleges she did not review the 2007 Report at the time it was issued or at any time prior to September 2014, when her doctors requested a copy. ECF No. 24 at ¶ 20; ECF No. 28 at 7. Second, she argues that even if the 2007 Report had been available for her to review, "a person exercising reasonable diligence cannot be expected to understand the 2007 Report's complex scientific jargon, reconcile its inconsistencies, and then decide upon a course of treatment." ECF No. 28 at 7. She further argues that Decedent's doctors "should have been able to rely on the technical Results, where the mutation is definitively classified, without regard to the boilerplate disclosures of the Comments section." *Id.* Finally, Plaintiff argues, she was alerted to Defendants' negligence only upon reviewing the 2015 Report in which Athena reclassified the mutation to "known disease associated mutation." *Id.* at ¶ 43.

Statutes of limitations are typically raised as an affirmative defense. "In the limited circumstances where the allegations of the complaint give rise to an affirmative defense, the defense may be raised under Rule 12(b)(6), but only if it clearly appears on the face of the complaint." *Richmond, Fredericksburg & Potomac R.R. Co. v. Forst*, 4 F.3d 244, 250 (4th Cir. 1993) (citations omitted). *See Luberda ex rel. Luberda v. Purdue Frederick Corp.*, No. 4:13–cv–00897–RBH, 2014 WL 1315558, at *7 (D.S.C. Mar. 28, 2014) ("A defendant's statute of limitations affirmative defense can be raised in a 12(b)(6) motion to dismiss; however, it is seldom appropriate to do so."). It is not clear from the amended complaint that Plaintiff knew or should have known that Athena misclassified the mutation as of the date Athena issued the 2007 Report.

Garner v. Houck, 435 S.E.2d 847, 849 (S.C. 1993) (holding that statute of limitations set forth in S.C. Code Ann. § 15-3-545 was triggered subsequent to decedent's death because autopsy results were necessary to identify cause of death and therefore give notice of a possible claim). As discussed throughout this opinion and order, it is not clear on the record before the court that Plaintiff should have known at the time of Decedent's death that the 2007 Report misclassified Decedent's mutation.

Plaintiff alleges that she did not read the 2007 Report until September 2014, ECF No. 24 at ¶ 20, and that she did not know that Athena had misclassified the mutation until Athena revised its finding in the 2015 Report. *Id.* at ¶ 43. She further alleges that up until the time she read the 2015 Report she attributed the Decedent's condition, and ultimate death, to her hereditary genetic makeup. ECF No. 24 at ¶¶ 49-51.

In their reply, Defendants argue that "the pertinent issue is the constructive notice that was provided to the decedent's doctors by the 2007 Report," and that Plaintiff cannot assert liability for Decedent's death as a result of his doctors' reliance on the misclassification and then assert that "it was only when she herself – not her son's doctors – saw the report that the statutory limitations period began to run."[7] ECF No. 31 at 2-3. However, even if knowledge of the 2007 Report is imputed to Plaintiff, it is not clear that she acted unreasonably in relying on the classification. Indeed, as Plaintiff alleges, Decedent's doctors had no "meaningful opportunity for second opinions," because "the process of identifying [Decedent's] particular mutation of the SCN1A gene was, at the time of the 2007 Report, subject to [certain] patents and Athena had the sole responsibility for creating and defining the possible 'Variant Types' listed in the Technical Results . . . ." ECF No. 24 at ¶ 30. One of the cases Defendants cite recognizes that when a condition has been misdiagnosed, the statute of limitations may not begin to run until the mistake is discovered, and instructs that the court must consider the totality of the circumstances. *See*

[7] Defendants cite to several cases to support their contention that "a plaintiff's decision not to participate in additional recommended medical testing constitutes a failure to exercise the required reasonable diligence, and that a plaintiff could be held to have constructive notice of those facts that the additional testing would have revealed." ECF No. 25-1 at 13. However, two of the three cases Defendants cite were decided on motion for summary judgment. *Vitalo v. Cabot Corp.*, 399 F.3d 536, 543-545 (3d Cir. 2005); *Sowell v. Dresser Indus., Inc.*, 866 S.W.2d 803, 806-07 (Tex. Ct. App. 1993). The third case was tried to a jury. *Betts v. Manville Pers. Injury Settlement Trust*, 588 N.E.2d 1193, 1203 (Ill. App. Ct. 1992). Therefore, those cases were resolved after the conclusion of discovery and with the benefit of a fully developed record.

Vitalo v. Cabot Corp., 399 F.3d at 543 ("If a person knows of an injury but is given an incorrect, but nevertheless reasonable, diagnosis, that person may be misdirected as to the injury's cause. In that case, the statute of limitations might not begin to run until the injured person is given a correct diagnosis or should otherwise know the true cause (in light of the totality of the circumstances)"). As discussed in more detail below, there remains a factual dispute, not resolved in the pleadings, as to whether it was reasonable for Decedent's doctors and thereby Plaintiff to rely on the classification provided in the 2007 Report. Therefore, the court cannot find at this juncture that Plaintiff's claims are barred by the applicable statute of limitations. *See Forst*, 4 F.3d at 250 ("Because neither of the asserted defenses appears on the face of the complaint, it is inappropriate to address them in the current posture of the case"). *See also Garner*, 435 S.E.2d at 849 ("If there is conflicting evidence as to whether a claimant knew or should have known he or she had a cause of action, the question is one for the jury") (citing *Santee Portland Cement Co. v. Daniel Int'l Corp.*, 384 S.E.2d 693 (1989)). However, this finding is without prejudice to Defendants raising the affirmative defense on a motion for summary judgment if such defense is supported after discovery.

C. Pleading Deficiencies

Defendants also argue that Plaintiff fails to plead justifiable reliance, a claim for civil conspiracy, or violation of the UTPA.

1. Negligent Misrepresentation and Constructive Fraud

Plaintiff must demonstrate the following elements to establish liability for negligent misrepresentation:

> (1) the defendant made a false representation to the plaintiff; (2) the defendant had a pecuniary interest in making the statement; (3) the defendant owed a duty of care to see that he communicated truthful information to the plaintiff; (4) the defendant breached that duty by failing to exercise due care; (5) the plaintiff justifiably relied

> on the representation; and (6) the plaintiff suffered a pecuniary loss as the proximate result of his reliance upon the representation.

McLaughlin v. Williams, 665 S.E.2d 667, 670 (S.C. App. 2008) (citing *Redwend Ltd. P'ship v. Edwards*, 581 S.E.2d 496, 504 (S.C. App. 2003)). A plaintiff establishes liability for fraud by demonstrating the following elements:

> (1) a representation; (2) its falsity; (3) its materiality; (4) knowledge of its falsity or a reckless disregard for its truth or falsity; (5) intent that the plaintiff act upon the representation; (6) the hearer's ignorance of its falsity; (7) the hearer's reliance on its truth; (8) the hearer's right to rely thereon; and (9) the hearer's consequent and proximate injury.

Id. (citing *Hendricks v. Hicks*, 649 S.E.2d 151, 152–53 (S.C. App. 2007)). "The key difference between fraud and negligent misrepresentation is that fraud requires the conveyance of a known falsity, while negligent misrepresentation is predicated upon transmission of a negligently made false statement." *Id.* at 457 (quoting *Armstrong v. Collins*, 621 S.E.2d 368, 375–76 (S.C. App. 2005)) (internal quotations and citations omitted). Constructive fraud differs from actual fraud only in that intent to deceive is not an element of constructive fraud. *Cheney Bros. Inc. v. Batesville Casket Co.*, 47 F.3d 111, 114 (4th Cir. 1995). While causes of action for fraud and negligent misrepresentation differ, they both contain "the necessary element that the hearer had the right to rely upon the misrepresentation or fraud." *McLaughlin*, 665 S.E.2d at 670 (quoting *Armstrong*, 621 S.E.2d at 375-76).

As discussed above, the claims for negligent misrepresentation and constructive fraud arise from the misclassification of Decedent's mutation in the 2007 Report as one of "unknown significance." ECF No. 28 at 23. Defendants argue that Plaintiff fails to allege justifiable reliance on the misclassification. Specifically, Defendants argue that Plaintiff had "means of knowledge" and access to a definitive diagnosis for Decedent because the 2007 Report stated "repeatedly and with emphasis that the classification was inconclusive and uncertain," and that "parental testing

was 'strongly recommended' in order to confirm or refute that the genetic mutation was pathogenic." ECF No. 25-1 at 24-25. The 2007 Report also stated that Athena "offered to perform genetic testing of the biological parents free of charge, and included a form 'Requisition for Parental Testing' with instructions on how to obtain the free parental testing." *Id.* Plaintiff forewent testing for herself despite the warnings and recommendations contained in the Report, and, thus, Defendants contend, she cannot now claim to have relied on the misclassification. Additionally, during oral argument, Defendants argued that even if Plaintiff did not read the 2007 Report until September 2014, Decedent's doctors' knowledge of the Report should be imputed to Plaintiff. *See, e.g.*, ECF No. 35 at 11:7-13, 12:25-13:9; *see also* ECF No. 31 at 2-3.

In opposition, Plaintiff argues that Decedent's doctors "should have been able to rely on the classification of the variant type listed on the 2007 Reports Technical Results when diagnosing and prescribing a set of appropriate treatments." ECF No. 28 at 26. Plaintiff further asserts that Defendants' argument that reliance on the classification was not justifiable given the stated inconclusive nature of the results "grossly distorts the very nature of the classification system used by Defendants." *Id.* Finally, Plaintiff contends that in revising the classification of Decedent's mutation in the 2015 Report, Athena all but admitted it negligently misrepresented Decedent's mutation in the 2007 Report. *Id.* at 25.

In the amended complaint, Plaintiff alleges that Decedent's doctors expected the test administered by Athena to "clearly confirm whether [Decedent] possessed a DNA mutation linked to Dravet," because the test was "specifically designed and marketed to identify mutations linked to Dravet Syndrome." ECF No. 24 at ¶ 23. Additionally, Plaintiff alleges that Athena licensed and utilized the patent for SCN1A DNA clinical diagnostic testing in the United States, and that because the process for identifying Decedent's particular mutation of the SCN1A gene was, at the

time of the 2007 Report, subject to this patent and because Athena "had the sole responsibility for creating and defining the possible 'Variant Types' listed in the Technical Results," Decedent's doctors had no "meaningful opportunity for second opinions." ECF No. 24 at ¶¶ 28, 30. Plaintiff further alleges that the 2007 Report reflects that Dr. Batish, who had earlier in 2007 co-authored a publication identifying the mutation as one associated with Dravet Syndrome, reviewed the clinical findings and "submitted the erroneous clinical information of [Decedent]." *Id.* at ¶ 31.

"The general rule is that questions concerning reliance and its reasonableness are factual questions for the jury." *Unlimited Services, Inc. v. Macklen Enterprises, Inc.*, 401 S.E.2d 153, 155 (S.C. 1991) (citing *Starkey v. Bell*, 315 S.E.2d 153 (S.C. App. 1984) (holding that "issues of reliance and its reasonableness going as they do to subjective states of mind and applications of objective standards of reasonableness, are preeminently factual issues for the trier of facts")). Plaintiff asserts she was unaware of the warnings and recommendations contained in the 2007 Report because she did not read the Report until September 2014. However, even if knowledge of the 2007 Report and the warnings and recommendations contained therein is imputed to Plaintiff, the question remains whether she acted reasonably in relying on the classification. In light of the allegations regarding Athena's expertise in administering SCN1A DNA clinical diagnostic testing and the lack of opportunity for Decedent to obtain a meaningful second opinion, the court cannot determine as a matter of law that Plaintiff acted unreasonably, or without justification, in relying on the classification stated in the 2007 Report.[8]

[8] Defendants contend in a footnote in their motion that the amended complaint alleges that Quest did not purchase ADI until 2011, and "[t]hus, by the Plaintiff's own allegations, Quest could not possibly have had anything to do with the 2007 report," and that accordingly "the third and fourth causes of action do not plead a valid claim against Quest." ECF No. 25-1 at 24 n.8. However, the record is silent as to whether Quest assumed the liabilities of ADI and/or Athena during the acquisition of those companies' shares. Quest may reassert this argument after discovery, if appropriate.

2. Civil Conspiracy

"A civil conspiracy is a combination of two or more persons joining for the purpose of injuring and causing special damage to the plaintiff." *McMillian v. Oconee Hospital, Inc.*, 626 S.E.2d 884, 886 (S.C. 2006) (citing *Lawson v. S.C. Dep't of Corr.*, 532 S.E.2d 259, 261 (S.C. 2000)). "However, a civil conspiracy cannot exist when the alleged acts arise in the context of a principal-agent relationship because by virtue of the relationship such acts do not involve separate entities," and "it is well settled that a corporation cannot conspire with itself." *Id.* at 564-65 (citing *Perk v. Vector Resources Group, Ltd.*, 485 S.E.2d 140, 144 (Va. 1997); 16 Am. Jur. 2d *Conspiracy* § 56 (2005)).

Defendants assert two arguments for why the court should dismiss this claim. First, Defendants argue that as of 2011, when Quest acquired ADI, they represent one corporation for the purpose of a conspiracy claim, and that the individuals identified in the amended complaint are or were managerial employees of Athena and undertook their allegedly negligent actions in the scope of their employment. ECF No. 25-1 at 25. Second, Defendants argue that Plaintiff "alleges nothing more than a combination . . . [of] the other wrongful acts complained of, and fails to make any allegations of particular harm or special damages resulting from the conspiracy itself apart from the other alleged wrongful actions." *Id.* at 28.

Plaintiff does not contest that "a corporation cannot conspire with itself or with employees of the corporation acting in the course of their employment." ECF No. 28 at 27. Rather, Plaintiff contends that Quest conspired with ADI and Athena prior to the 2011 acquisition, "[a]t some point between the issuance of the 2007 Report and the issuance of the 2015 Report," ECF No. 24 at ¶ 77, and that "[a] jury could well determine that acts in furtherance of the conspiracy occurred on Athena's part prior to the 2011 purchase of the entity by Quest." ECF No. 28 at 28. Additionally,

Plaintiff asserts that "the additional wrongful act(s) alleged by Plaintiffs are the *conspiracy*, *intentional withhold*[ing] and the *cover-up* of the corrected classification by Defendants." *Id.* at 29 (emphasis in original). She asserts that she suffered the following particular harm after the publication of the 2015 Report as a direct result of the conspiracy: "*increased* medical expenses, *additional* mental anguish caused by the delay in the notification of [Decedent's] actual diagnosis and the loss of child bearing years on [her part], as well as the *resulting incurred* medical expenses for the treatment of her severe emotional distress"; "medical costs related to psychiatric care undertaken to help [Plaintiff] cope with this discovery and the knowledge that [Decedent's] death was entirely preventable and proximately caused by the negligence of these Defendants"; and "costs of a [wholly unnecessary] mitochondrial DNA test . . . undertaken in September of 2014 . . . designed to confirm the original mitochondrial diagnosis and the likelihood that such mutation would be passed along to addition children [Plaintiff] might have." *Id.* at 29-31 (citing ECF No. 24 at ¶¶ 75-88) (emphasis in original).

As an initial matter, there is no basis for asserting a conspiracy as of 2011, when Quest purchased ADI. ECF No. 24 at ¶ 6. *See McMillian*, 626 S.E.2d at 886-87. Second, Plaintiff has provided no particularized allegations necessary to find a conspiracy prior to 2011. Plaintiff alleges the following in the amended complaint:

> At some point between the issuance of the 2007 Report and the issuance of the 2015 Report, two or more of the above named Defendants (Athena, ADI, and Quest) acting through their agents and/or executives conspired to intentionally withhold and cover-up the corrected information as reflected by the 2015 Report and as set forth in the "*Factual Background for Relief*."
>
> Upon information and belief, Defendants recognized the significant risks these false reports posed to their respective financial assets and, in response, developed a plan to avoid responsibility for their respective acts by failing to disclose the false statement in the 2007 report to the Plaintiffs and by deliberate concealment of the false report.

> The Defendants discovered the original false representation in the 2007 Report Technical Results that misclassified the mutation at issue, and then engaged in deceitful conduct by intentionally concealing the initial false statement issued in the 2007 report. These intentional acts, in addition to the facts alleged in Plaintiffs' previous causes of action, were done willfully and in furtherance of the Defendants' conspiracy.
>
> These Defendants lied, misrepresented, and actively concealed [Decedent's] actual genetic testing results in an attempt to protect corporate assets and hide their negligent misrepresentation and fraudulent malfeasance . . . .

ECF No. 24 at ¶¶ 77-80. These allegations provide no information as to the actors involved in the alleged conspiracy, the dates of the alleged conspiracy, or the means or method of the alleged conspiracy. As Defendants note in their reply:

> The pleading does not allege any action by Quest prior to the 2011 acquisition of ADI. To the contrary, the Amended Complaint alleges that the purpose of the Defendants' conspiracy was "exclusively to protect corporate assets of defendants Athena, ADI, and Quest." [] The pleading then goes on to allege, as to Quest, that it and Athena "jointly issued the revised 2015 Report . . . and forwarded this revised 2015 Report to [Plaintiff]. []

ECF No. 31 at 13 (quoting ECF No. 24 at ¶ 76). In response to the court's questions during oral argument regarding who was involved in the conspiracy, counsel for Plaintiff stated as follows:

> [H]ere's where the conspiracy comes from, and this is what our thought is. 2007 Athena was a separate entity. Quest purchased them I believe it was 2011. I don't know what Athena communicated to Quest throughout the years, during that courtship before the companies were bought, during the due diligence period, what was communicated during the time when they were two wholly-owned, separate entities, so Quest was a separate entity. I'm not claiming that Quest and Athena have conspired together since they were purchased …. Until I get into discovery, I can't claw back and find out what communications they had. But there's this unknown period, an unknown period, where they *sure could have* communicated this together. So, that's the allegation.

ECF No. 35 at 35:9-25 (emphasis added).

Without additional factual allegations, the mere fact that Defendants corrected the misclassification in the 2015 Report does not support a claim for conspiracy. Quite simply, the amended complaint does not contain enough facts regarding the development of a conspiracy prior

to 2011 "to raise a reasonable expectation that discovery will reveal evidence of illegal agreement," *Twombly*, 550 U.S. at 556.[9] The comments that Plaintiff's counsel offered during oral argument confirm as much. Having so found, the court declines to address Defendants' additional argument that Plaintiff fails to allege wrongdoing and subsequent damage unique to the alleged conspiracy.

3. Unfair Trade Practices Act

The UTPA broadly prohibits any "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." S.C. Code Ann. § 39–5–20. To establish a violation of the UTPA, the plaintiff must demonstrate that (1) the defendant engaged in an unlawful trade practice; (2) the plaintiff suffered actual, ascertainable damages as a result of the defendant's use of the unlawful trade practice, and (3) the unlawful trade practice engaged in by the defendant had an adverse impact on the public interest. *Havird Oil Co., Inc. v. Marathon Oil Co., Inc.*, 149 F.3d 283 (4th Cir. 1998). A trade practice is "unfair" when it is "offensive to public policy or when it is immoral, unethical, or oppressive." *Johnson v. Collins Entertainment*

[9] In their reply, Defendants argue that Plaintiff's contention that an administrative error caused the misclassification is pure speculation. ECF No. 31 at 8. The court notes the difference between the speculative nature of Plaintiff's claim for conspiracy and what Defendants contend is the speculative nature of Plaintiff's allegation regarding administrative error. The amended complaint sufficiently sets forth an injury suffered by Decedent and Plaintiff resulting directly from Athena's failure to properly classify Decedent's mutation. Discovery will aid the parties in determining whether the misclassification was the result of ordinary negligence or medical malpractice, and therefore is appropriate under the Federal Rules of Civil Procedure. *See Twombly*, 550 U.S. at 562 (quoting *Sanjuan v. American Bd. of Psychiatry and Neurology, Inc.*, 40 F.3d 247, 251 (7th Cir. 1994) ("Once a claim for relief has been stated, a plaintiff 'receives the benefit of imagination, so long as the hypotheses are consistent with the complaint'"). The amended complaint does not set forth factual support for the conspiracy claim as framed by Plaintiff. Were the court to allow the conspiracy claim to proceed, it would condone Plaintiff's use of the discovery process to create a claim, rather than substantiate it. *See Iqbal*, 556 U.S. at 678-79 ("Rule 8 marks a notable and generous departure from the hypertechnical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.").

Co., Inc., 564 S.E.2d 653, 665 (S.C. 2002), *overruled on other grounds by Proctor v. Whitlark & Whitlark, Inc.*, 778 S.E.2d 888 (S.C. 2015). *See Beattie v. Nations Credit Financial Services Corp.*, 69 F. App'x 585, 589 (4th Cir. 2003) ("We assume the 'public policy' referred to by the South Carolina Supreme Court is that policy created by applicable common law determinations, legislative enactments or constitutional provisions.") (citation omitted). "An act is 'deceptive' when it has a tendency to deceive." *Health and Promotion Specialists, L.L.C. v. S.C. Bd. of Dentistry*, 743 S.E.2d 808, 816 (S.C. 2013). "The legislature intended in enacting the UTPA to control and eliminate the large scale use of unfair and deceptive trade practices within the state of South Carolina." *Noack Enters., Inc. v. Country Corner Interiors*, 351 S.E.2d 347, 349 (S.C. App. 1986).

"To sustain a cause of action under the SCUTPA, the plaintiffs must establish, by specific facts, that members of the public were adversely affected by [the defendant's actions]." *Bessinger v. Food Lion, Inc.*, 305 F. Supp. 2d 574, 584 (D.S.C. 2003); *see Omni Outdoor Adver., Inc. v. Columbia Outdoor Adver., Inc.*, 974 F.2d 502, 507 (4th Cir. 1992) (holding the UTPA does not apply to "an unfair or deceptive act or practice that affects only the parties to a trade or commercial transaction"). "An impact on the public interest may be shown if the acts or practices have the potential for repetition." *Wright v. Craft*, 640 S.E.2d 486, 501 (S.C. App. 2006) (quoting *Singleton v. Stokes Motors, Inc.*, 595 S.E.2d 461, 466 (S.C. 2004)). Potential for repetition may be demonstrated, among other ways, by showing that (1) the same kind of actions occurred in the past, thus making it likely they will continue to occur absent deterrence, and (2) the company's procedures create a potential for repetition of the unfair and deceptive acts. *Daisy Outdoor Advertising Co., Inc. v. Abbott*, 473 S.E.2d 47, 51 (S.C. 1996).

Defendants argue that Plaintiff's UTPA claim fails because the supporting allegations "show that the challenged conduct took place exclusively within the confines of conduct affecting only the parties to this litigation"; and, more specifically, the allegations do not demonstrate that the challenged conduct "affected other members of the South Carolina public or that it has any credible possibility of repetition with respect to other members of the South Carolina public." ECF No. 25-1 at 31-32.

Plaintiff alleges that Defendants are in the business of performing SCN1A DNA testing for profit, and that they "are among the world's leading providers of diagnostic testing on human tissue and offer services that range from routine blood tests, Pap testing, and white blood cell count, to such complex diagnostic testing as genetic and molecular testing." ECF No. 24 at ¶ 90. Plaintiff further alleges that Defendants "engaged in deceitful conduct by concealing the initial mistake issued in the 2007 report," that Defendants "lied, misrepresented, and actively concealed [Decedent's] actual genetic testing results in an attempt to protect corporate assets and hide their negligence and malfeasance," and that "[t]his concealment not only harmed the Plaintiffs but violated regulatory standards as set for under the CLIA." *Id.* at ¶ 91. Finally, Plaintiff alleges that "Defendants' unfair or deceptive acts are capable of repetition given the nature of Defendants' business and the vast number of people, both in South Carolina and around the country, who depend on the numerous diagnostic tests performed by these Defendants each year." *Id.* at ¶ 96.

As discussed above, there is no factual support in the amended complaint that Defendants conspired to misrepresent the results of Decedent's SCN1A testing, or that Defendants purposefully misclassified Decedent's mutation. However, Plaintiff alleges throughout the amended complaint that Athena breached the CLIA standards of care "for a certified diagnostic laboratory performing high-complexity genetic testing." *See, e.g.*, ECF No. 24 at ¶ 27. Indeed,

Plaintiff alleges that Athena breached the following CLIA standards of care: "the laboratory must have an adequate system(s) in place to ensure test results are accurately and reliably sent from the point of data entry to final report destination, in a timely manner"; "the laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems"; and "the laboratory must maintain an information or record system that includes the date and time of specimen receipt into the laboratory." *Id.* at ¶ 32 (quoting 42 C.F.R. §§ 493.1291(a), 493.1289(a), 493.1283(a)(2)). Finally, Plaintiff alleges that as a result of these violations, Decedent's doctors administered the wrong treatment to Decedent. *Id.* at ¶ 33.

Defendants do not appear to contest that these allegations satisfy the first requirement of pleading a claim under the UTPA, nor do Defendants contest that Plaintiff has alleged actual, ascertainable damages as a result of the alleged unlawful trade practice. Rather, Defendants contend that Plaintiff fails to establish the third element that the alleged unlawful trade practice had an adverse impact on the public interest. However, Plaintiff alleges that hundreds of thousands of people undergo diagnostic testing in Athena's labs, including residents of South Carolina, and that Athena violated various CLIA requirements through the management and operation of its laboratory. While not robust, these allegations suffice to state a claim under the UTPA. *See Daisy Outdoor Advertising*, 473 S.E.2d at 51 (recognizing plaintiff may satisfy the third element by "showing the company's procedures create a potential for repetition of the unfair and deceptive acts"). *See also Iqbal*, 556 U.S. at 679 ("When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief").

Although the amended complaint adequately states a claim for violation of the UTPA, Plaintiff is advised that public harm "must be proved by specific facts." *Network Computing Services Corp. v. Cisco Systems, Inc.*, 152 F. App'x 317, 321 (4th Cir. 2005) (quoting *Jefferies v. Phillips*, 451 S.E.2d 21, 23 (S.C. App. 1994)).[10] After the benefit of discovery, Defendants may renew their argument on a motion for summary judgment, if appropriate.

V. CONCLUSION

For the foregoing reasons, the Motion to Dismiss is GRANTED IN PART and DENIED IN PART. ECF No. 25.

IT IS SO ORDERED.

/s/Margaret B. Seymour
Margaret B. Seymour
Senior United States District Judge

Dated: October 18, 2018
Columbia, South Carolina

[10] Additionally, in determining during discovery whether evidence exists to substantiate the alleged violations of Athena's CLIA license, the parties should also be able to determine whether such violations sound in ordinary negligence or medical malpractice.