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### I. INTRODUCTION

From a legal perspective, is a clinical laboratory a healthcare provider? Physicians are clearly healthcare providers who owe their patients the associated fiduciary duties. It is less clear, however, which—if any—legal duties genetic testing labs owe to the individuals who seek their services.

The question of whether clinical genetics laboratories are healthcare providers for legal purposes may be thornier than it could initially appear. Clinical genetics laboratories perform multiple tasks. Most significantly, they sequence genetic samples and then interpret the results. As “next generation sequencing” has become more accessible,<sup>1</sup> labs can generate and interpret more sequence data for a growing number of clinical indications.<sup>2</sup> While

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<sup>1</sup> See Sara H. Katsanis & Nicholas Katsanis, *Molecular Genetic Testing and the Future of Clinical Genomics*, 14 NATURE REV. GENETICS 415, 415 (2013) (stating that “[g]enomic technologies are reaching the point of being able to detect genetic variation in patients at high accuracy and reduced cost”).

<sup>2</sup> To be clear, “generating genetic data” means several things, some of which sound in laboratory services and some of which sound in the practice of medicine. Next generation sequencing (NGS) involves: identifying the nucleotide sequences in a person’s genome; processing that information to draw probabilistic inferences about ways the person’s genome differs from a human reference genome, with the aim of identifying the person’s genetic variants; and then attempting to interpret the clinical significance of those variants, i.e., how the person’s health may be affected by the variants that were found. Before NGS, it was a great challenge to characterize the nucleotide sequences and identify the person’s variants. NGS has made that easier. But the problem of interpreting what the variants mean is just as challenging now as it was in the days of single-gene testing technologies. *Id.*

standardized methods for generating and processing sequence data are in place, the way labs interpret genetic data remains in flux.<sup>3</sup> And, increasingly, how a given laboratory interprets genetic data has become more salient because physicians rely on those interpretations in their medical practices.<sup>4</sup> These changes in data interpretation have brought new medical and legal challenges.<sup>5</sup>

In the process of generating potentially clinically relevant findings, next generation sequencing also produces large amounts of data that currently lack clinical significance. In fact, sequencing reveals many never before seen genetic variations.<sup>6</sup> As such, labs lack sufficient knowledge to designate these variations as either pathogenic—disease-causing—or benign.<sup>7</sup> Consequently, labs classify them as variants of uncertain significance (VUSs).<sup>8</sup> VUSs are extremely common due to the large number of rare variants in the genome, insufficient information about the normal distribution of variants across populations, and the absence of biological functional data.<sup>9</sup> In fact, every patient who is sequenced currently has several VUSs.<sup>10</sup>

The understanding of genetic information evolves as scientists report new findings, additional population data become available, and labs develop more advanced computational tools.<sup>11</sup> With time and more data, uncertain variants

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<sup>3</sup> See Sue Richards et al., *Standards and Guidelines for the Interpretation of Sequence Variants: A Joint Consensus Recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology*, 17 GENETICS MED. 1, 2 (2015) (stating that “[i]n 2015, The American College of Medicine Genetics and Genomics (ACMG) and the Association for Molecular Pathology issued professional guidelines for the interpretation of sequence data”); see also Cristi Radford & Michele Gabree, *Variants of Uncertain Significance—Frequently Asked Questions*, THE ONCOLOGY NURSE (Sept. 9, 2019), <http://www.theoncologynurse.com/ton-issue-archive/2018/july-2018-vol-11-no-3/17516-variants-of-uncertain-significance>. These guidelines are used merely as a framework, recommending that sequence variants be classified into one of five categories along a gradient, ranging pathogenic to benign. *Id.* Along with this framework, labs use their own internal protocols and data; for example, different labs might weigh a piece of evidence differently in their determination of a variant’s classification, ultimately resulting in different classifications of the same variant. *Id.*

<sup>4</sup> Richards et al., *supra* note 3, at 9.

<sup>5</sup> Cf. Pengfei Liu et al., *Reanalysis of Clinical Exome Sequencing*, 380 NEW ENG. J. MED. 2478, 2479 (2019) (illustrating that not all physicians follow up with patients after results of their genetic reanalysis have been received).

<sup>6</sup> Richards et al., *supra* note 3, at 20.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> See *id.* (stating that discovering new variants occurs when a gene has never been associated with any patient phenotype or when the gene has been associated with a different phenotype from that under consideration).

<sup>10</sup> See *id.* (noting “all individuals are expected to have approximately one de novo variant in their exome or 100 in their genome”).

<sup>11</sup> See Yvonne Stevens et al., *Physicians’ Duty to Recontact and Update Genetic Advice*, 14 PERSONALIZED MED. 1, 2 (2017) (noting that “[s]ome DNA sequencing laboratories and services have taken it upon themselves to update previous variant classifications”).

should be reclassified as benign or pathogenic. In most cases, VUSs end up being benign and having no adverse clinical implications.<sup>12</sup> Rarely, variants previously classified as pathogenic may be found to be benign or vice versa.<sup>13</sup> Before a stable scientific consensus emerges, labs may reclassify the variant multiple times, moving it from pathogenic to non-pathogenic or the reverse.<sup>14</sup> As labs face the challenge of dealing with this data, which may—or may not—gain clinical significance, the potential for legal liability raises the stakes of accurate variant interpretation.

Consider this hypothetical. A patient visits her primary care physician (PCP) to discuss her family history of colon cancer. As a result of their discussions, her doctor orders a genetic test for hereditary cancers from a clinical laboratory. Following the doctor's orders, the lab sequences the patient's DNA and sends a report to her PCP. That report indicates that the patient has no known pathogenic genetic variants, but the lab also notes a number of VUSs. The PCP, relying on those findings, reports that there is nothing specifically actionable for the PCP or the patient. Three years later, the patient is diagnosed with ovarian cancer. She asks whether her previous genetic test indicated that she was at increased risk. Her doctor asks the lab to look back at her previous testing. The lab finds that, six months ago, a peer-reviewed study linked one of the patient's VUS to a risk of Lynch syndrome, which is associated with colon, uterine, and ovarian cancer. Had the patient known of this risk, she could have taken steps to screen for these cancers or had a hysterectomy and oophorectomy to reduce the risk of uterine and ovarian cancer. Yet no one communicated this information to the patient, and the patient dies of the disease.<sup>15</sup> Clinical genetics laboratories need to consider the scope of their long-term obligations to update test results in response to evolving knowledge. This Article contemplates the potential tort liability of those labs.

If the patient's family decides to sue the lab, which body of law will govern the claim? Is it medical malpractice with all of its accompanying doctrines?<sup>16</sup> Or is her family's claim more properly construed as ordinary

<sup>12</sup> See Thomas Salvin et al., *The Effects of Genomic Germline Variant Reclassification on Clinical Cancer Care*, 10 *ONCOTARGET* 417, 420 (2019) (noting that of the variants that underwent any reclassification, only 25/322 (7.8%) resulted in a change in actionability).

<sup>13</sup> See *id.* (stating that of the 36% were actionable downgrades—likely pathogenic or pathogenic reclassified to benign, likely benign, or VUS categories).

<sup>14</sup> See *id.* at 419 (noting that in February 2017, 1743 participants had 1816 variants analyzed and of these, 294 individuals (16.9%) had 315 variants (17.3%) reclassified).

<sup>15</sup> For a similar hypothetical, see Stevens et al., *supra* note 11, at 1.

<sup>16</sup> See, e.g., *Williams v. Quest Diagnostics, Inc.*, 353 F. Supp. 3d 432, 442 (D.S.C. 2018) (citing *Dawkins v. Union Hosp. Dist.*, 408 S.C. 171, 758 S.E.2d 501, 504–05 (2014) (explaining that differentiating between medical negligence and malpractice and ordinary negligence depends on facts of each case)). It is likely that the family would also bring an action against the PCP directly, though the focus of this Article is the action taken against laboratories.

negligence? The answer to these questions has serious consequences for plaintiffs, laboratories, and the attorneys who represent them.

The lawyers litigating cases against clinical laboratories will have to anticipate which body of substantive law the courts will apply.<sup>17</sup> All fifty states have adopted some variation of a medical malpractice statute. The term malpractice statute, as used here, is broadly defined to include: (1) statutes that directly bear on the conduct of malpractice suits in a state, such as statutes defining the tort standard of care, the statutes of repose/limitations, and medical malpractice reform statutes; and (2) medical practice acts and other general state laws relating to medical professional licensure and licensing and regulation of healthcare facilities, to the extent that these statutes help determine who falls within the scope of a state's malpractice doctrines. Typically, malpractice statutes apply only to healthcare providers.<sup>18</sup> Who constitutes a healthcare provider, however, isn't always immediately clear from the face of the statute.<sup>19</sup>

Medical malpractice laws have far-reaching implications. For example, malpractice legislation often caps damages.<sup>20</sup> In fact, thirty out of the fifty states have established damage caps,<sup>21</sup> ranging from \$250,000<sup>22</sup> to \$2,250,000.<sup>23</sup> Some limit compensatory damages, while others restrict noneconomic damages.<sup>24</sup> These caps might lessen plaintiffs' recoveries,

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<sup>17</sup> Patients, doctors, and laboratories may all be in different states. Some labs have physical facilities in multiple states but have headquarters or corporate offices in one state. Many civil procedure issues are implicated by genetic malpractice claims against clinical laboratories. These are beyond the scope of this Article and will be fully considered in a subsequent paper. Jessica L. Roberts et al., *Issues in the Legal Liability of Clinical Genetics Laboratories* (unpublished manuscript) (on file with author).

<sup>18</sup> See, e.g., ARK. CODE ANN. § 16-114-201 (West 2013) (illustrating that the statute for malpractice includes the term "medical care provider"); CAL. CIV. PROC. CODE ANN. § 3333.2(1), 425.13 (West 2016) ("[h]ealth care provider"); CONN. GEN. STAT. ANN. § 52-184c (West 2019) ("health care provider"); LA. STAT. ANN. § 40:1231.1 (2015) ("healthcare provider").

<sup>19</sup> See also *infra* notes 85, 88 and accompanying text (illustrating that the definition of healthcare provider varies from state to state, and that the definitions have room for ambiguity).

<sup>20</sup> *Malpractice Caps in All 50 States*, MILLER & ZOIS LLC (Feb. 2019), <https://www.millerandzois.com/malpractice-damage-caps.html> [hereinafter *Malpractice Caps*]; Cf. *Moore v. Mobile Infirmary Ass'n*, 592 So.2d 156, 172 (Ala. 1991) (finding that limiting noneconomic damages recoveries against physicians violated the state constitution and the U.S. Constitution).

<sup>21</sup> *Malpractice Caps*, *supra* note 20 (noting that caps have been declared unconstitutional in eight states).

<sup>22</sup> See MONT. CODE ANN. § 25-9-411 (West 2019) (where malpractice claims in Montana are capped at \$250,000).

<sup>23</sup> See NEB. REV. STAT. ANN. § 44-2825 (West 2019) (where malpractice claims in Nebraska are capped at \$2,250,000).

<sup>24</sup> See Catherine M. Sharkey, *Unintended Consequences of Medical Malpractice Damage Caps*, 80 N.Y.U. L. REV. 391, 396-97 (2005) (highlighting the variation of total compensatory, punitive and noneconomic damages in medical malpractice caps).

particularly for noneconomic damages.<sup>25</sup>

Additionally, malpractice statutes often include statutes of limitations shorter than those that apply to ordinary negligence claims. For example, Louisiana, Nevada, and North Carolina require malpractice actions to be brought no later than one year after the discovery of an actionable injury.<sup>26</sup> Moreover, statutes of repose, which further restrict the ability of plaintiffs to recover, may also apply in medical malpractice—but not general negligence—cases.<sup>27</sup> These provisions actually provide more robust protection to healthcare providers than statutes of limitations because they do not allow equitable tolling.<sup>28</sup> In malpractice cases involving genetics, statutes of repose have been important<sup>29</sup> because it may take a plaintiff several years to discover a genetic condition.<sup>30</sup> And while some courts have been sympathetic that genetics cases may raise unique issues, others have not.<sup>31</sup>

Malpractice statutes may also compel arbitration, modify expert witness standards, or shift the costs and burdens of litigation from the provider to the injured patient.<sup>32</sup> Requiring patients to arbitrate before they can sue could limit how many medical malpractice claims go to court.<sup>33</sup> Yet, even when cases are not sent to arbitration, the vast majority are settled rather than

<sup>25</sup> See *id.* at 399 (providing pain and suffering as an example of non-economic damages).

<sup>26</sup> LA. STAT. ANN. § 5628 (2019); NEV. REV. STAT. § 41A.097 (2019); N.C. GEN. STAT. § 1-15 (2019).

<sup>27</sup> See Gary E. Marchant et al., *Unjust Timing Limitations in Genetic Malpractice Cases*, 83 ALB. L. REV. (forthcoming 2019).

<sup>28</sup> See Gary E. Marchant & Rachel A. Lindor, *Genomic Malpractice: An Emerging Tide or Gentle Ripple?*, 71 FOOD & DRUG L. J. 1, 28 (2018) (providing examples of cases which were dismissed after plaintiff brought the action upon discovery but after the statute of repose tolled).

<sup>29</sup> See *id.* (summarizing the Michigan Court of Appeals' dismissal of a case where the physician failed to take action on a child's prolonged QT finding and the plaintiff family learned about the physician's failure after the child died four years later, but after the statute of repose tolled).

<sup>30</sup> See *id.* (providing two examples of cases dismissed because the statutes of repose tolled where the plaintiffs discovered the genetic condition four and five years after the negligent acts occurred); *id.* (providing two examples of cases dismissed because the statutes of repose tolled where the plaintiffs discovered the genetic condition four and five years after the negligent acts occurred); *id.* at 15 (noting that "[genetic] malpractice claims take approximately twice as long as other medical malpractice cases to resolve is likely due to the often-cryptic nature of genetic conditions which may not become clear for many years").

<sup>31</sup> Compare *Hauser v. Kaufman*, 972 N.E.2d 927, 938 (Ind. Ct. App. 2012) (stating "[w]e are, of course, fully cognizant that we are permitting a nearly four-decade old claim of malpractice to proceed at this time"), with *Kush v. Lloyd*, 616 So.2d 415, 420–21 (Fla. 1992) (holding that a family's action was barred by the statute of repose, although the birth that created the cause of action did not arise until after the statute of repose had expired).

<sup>32</sup> See Shirley Qual, *A Survey of Medical Malpractice Tort Reform*, 12 WILLIAM MITCHELL L. REV. 418, 429, 432, 436 (1986).

<sup>33</sup> Lauren K. Saunders, *The Quest for Balance: Public Policy & Due Process in Medical Malpractice Arbitration Agreements*, 23 HARV. J. ON LEGIS. 267, 268 (1986).

litigated.<sup>34</sup>

Finally, while ordinary negligence only requires the providers of goods or services to act reasonably, medical malpractice law generally requires healthcare providers to meet medical standards of care and to perform the associated legal duties.<sup>35</sup>

Taken together, all of these features of malpractice law share a common denominator: they can have a tremendous impact on the outcomes of claims construed as medical malpractice. Plaintiffs may try to escape these harsh consequences by framing their claims as general negligence. This strategy is sometimes successful and sometimes not.<sup>36</sup>

*Williams v. Quest Diagnostics, Inc.*

A current case playing out in the South Carolina courts, *Williams v. Quest Diagnostics*, demonstrates the increasing relevance of these issues.<sup>37</sup> As this case makes clear, the question of liability will—to some extent—turn on whether clinical laboratories are healthcare providers for purposes of medical malpractice statutes.<sup>38</sup> In *Williams*, a mother sued Athena Diagnostics on behalf of her deceased son for failing to correctly diagnose the pathogenicity of a genetic variant.<sup>39</sup> Christian Williams was born in the summer of 2005 and for four months seemed to be developing normally.<sup>40</sup> At the four-month mark, he began to suffer from severe seizures.<sup>41</sup> When treatments failed and his condition worsened, the family consented to genetic testing by Athena's laboratory to identify mutations in a specific gene—*SCN1A*.<sup>42</sup> The *SCN1A* gene encodes sodium channels, and defects in sodium channels in the brain's neurons can cause seizures.<sup>43</sup>

On June 30, 2007, Athena reported that Christian had a *SCN1A* variant, which the lab classified as a VUS.<sup>44</sup> Unbeknownst to Christian's parents, two publications, one released in 2006 and another in 2007—both of which

<sup>34</sup> See Theodore Eisenberg, *What Is the Settlement Rate and Why Should We Care?*, 6 J. EMPIRICAL LEGAL STUD. 111, 111 (2009) (noting that “[o]f major case categories, tort cases to have the highest settlement rates”).

<sup>35</sup> Yvette Brazier, *Medical Malpractice: What Does It Involve?*, MED. NEWS TODAY (Apr. 5, 2017), <https://www.medicalnewstoday.com/articles/248175.php>.

<sup>36</sup> See generally *Ho-Rath v. R.I. Hosp.*, 89 A.3d 806, 812 (R.I. 2014) (stating that “in the absence of clear statutory language to the contrary, the legislature did not intend for negligence actions against laboratories to fall under the ambit of medical malpractice”).

<sup>37</sup> *Id.* at 436–37.

<sup>38</sup> *Williams v. Quest Diagnostics, Inc.*, 353 F. Supp. 3d 432, 438 (D.S.C. 2018).

<sup>39</sup> *Id.* at 437, 442.

<sup>40</sup> *Id.* at 436.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> Compl. for Pet'r at 12, *Williams v. Quest Diagnostics, Inc.*, 353 F. Supp. 3d 432, 437 (D.S.C. 2018) (No. 2016-CP-40-01166) [hereinafter Complaint for Petitioner].

<sup>44</sup> *Williams*, 353 F. Supp. 3d at 436.



predated Christian's testing—identified Christian's variant in patients with Dravet Syndrome, a severe form of epileptic encephalopathy.<sup>45</sup> In fact, Athena's chief compliance laboratory director, who signed off on Christian's test results, was an author on one of those publications.<sup>46</sup>

Relying on the laboratory's report, however, Christian's doctors rejected a diagnosis of Dravet Syndrome.<sup>47</sup> He received additional doses of medications that tragically exacerbate seizures in patients with Dravet Syndrome.<sup>48</sup> In 2008, following a seizure, Christian died.<sup>49</sup>

Williams' clinical geneticist requested a copy of the 2007 report in 2014.<sup>50</sup> Athena then issued a revised 2015 report.<sup>51</sup> The updated report correctly identified Christian's variant as pathogenic.<sup>52</sup> In light of this new information, a pediatric neurologist concluded that had Christian's Dravet Syndrome been properly diagnosed and treated, he could have avoided the fatal seizure.<sup>53</sup> His mother then sued Athena for wrongful death.<sup>54</sup>

The *Williams* case was promptly removed to federal court.<sup>55</sup> Before considering any of the claims, the district court certified a question to the South Carolina Supreme Court.<sup>56</sup> The judge asked whether, under South Carolina state law, a clinical genetics laboratory is a licensed healthcare provider.<sup>57</sup> This issue was crucial to the outcome of the case. Classifying the lab as a healthcare provider meant that medical malpractice statutes would apply.<sup>58</sup> If the district court treated the claims as medical malpractice—as opposed to ordinary negligence—the statute of limitations could bar the

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<sup>45</sup> Complaint for Petitioner, *supra* note 43, at 6. Note that we do not mean to imply that a single study makes for a diagnosis. Rather the studies provided some evidence of pathogenicity, arguably making the VUS determination inaccurate, as evidenced by the lab's later reclassification in Williams' subsequent report. *See infra* note 52 and accompanying text. The issue here is not whether a variant was actually widely accepted by the medical literature and community as pathogenic, but rather that the lab had—using their specific internal guidelines—reclassified it as such. There are important threshold issues about when a variant is declared pathogenic, which are beyond the scope of this Article.

<sup>46</sup> Complaint for Petitioner, *supra* note 43, at 12–13.

<sup>47</sup> *Id.* at 15.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.* at 16.

<sup>50</sup> *Williams v. Quest Diagnostics, Inc.*, 353 F. Supp. 3d 432, 437 (D.S.C. 2018).

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *See* Complaint for Petitioner, *supra* note 43, at 16 (stating that the plaintiff, Williams, submitted an affidavit prepared in anticipation of litigation, signed by Dr. Max Wiznitzer, a pediatric neurologist board-certified by the American Board of Pediatrics and by the American Board of Psychiatry and Neurology).

<sup>54</sup> *Williams*, 353 F. Supp. 3d at 437.

<sup>55</sup> *Id.* at 436.

<sup>56</sup> *Id.* at 438.

<sup>57</sup> *Id.*

<sup>58</sup> *Id.* at 440.

case.<sup>59</sup> Given that Christian's treating physician requested the genetic testing for the purposes of diagnosis and treatment, the South Carolina Supreme Court determined that the clinical genetics laboratory is a healthcare provider for medical malpractice purposes four to one.<sup>60</sup>

How to classify clinical laboratories for purposes of medical malpractice is a matter of state law. Sometimes, the text of the medical malpractice statute explicitly defines healthcare provider.<sup>61</sup> Other times, as in *Williams*, courts make these determinations. Ultimately, whether a certain provider falls within the definition of healthcare provider differs from state to state. We therefore conducted a fifty-state survey to assess the current doctrinal landscape.

### *Survey Results*

Whether clinical laboratories are healthcare providers for medical malpractice purposes will often turn on the applicable statutes and how courts construe them. We surveyed the statutes and relevant judicial opinions in each state to determine whether a clinical laboratory providing genetic testing services would likely be categorized as a healthcare provider.

By way of quick overview, we found that twenty-five states have no clear statutory provisions or caselaw on this issue. Thus, half of states have no definitive answer to this important legal question. Six states expressly include laboratories or laboratory personnel in their statutory definition of healthcare provider. In the face of statutory ambiguity, courts in fifteen states have held that the definition of healthcare provider includes clinical laboratories. By contrast, courts in four states have concluded that labs are *not* healthcare providers. We detail our findings below.

LABS AS HEALTHCARE PROVIDERS	PERCENTAGE (#)	STATES
<b>Yes, by statute</b>	12% (6)	Colorado, Hawaii, Louisiana, Montana, Nevada, North Carolina
<b>Yes, according to caselaw</b>	30% (15)	Alabama, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Indiana, Maryland, Massachusetts, Michigan, New York, Ohio, South

<sup>59</sup> *Id.* at 443.

<sup>60</sup> *Williams v. Quest Diagnostics, Inc.*, 423 S.C. 547, 565 (2018).

<sup>61</sup> See e.g., S.C. CODE ANN. § 15-79-110 (West 2019) (defining "healthcare provider" as "a physician, surgeon, osteopath, nurse, oral surgeon, dentist, pharmacist, chiropractor, optometrist, podiatrist, or any similar category of licensed healthcare provider, including a healthcare practice, association, partnership, or other legal entity").

		Carolina, Texas
<b>No, according to caselaw</b>	8% (4)	Maine, Rhode Island, South Dakota, Virginia
<b>Maybe, not enough information</b>	50% (25)	Arizona, Alaska, Delaware, Idaho, Kentucky, Kansas, Iowa, Mississippi, Minnesota, Missouri, Nebraska, New Mexico, New Jersey, New Hampshire, North Dakota, Pennsylvania, Oregon, Oklahoma, Tennessee, Vermont, Utah, Wyoming, Wisconsin, West Virginia, Washington

### *Unresolved Status*

In twenty-five states (50%), it is unclear if clinical laboratories are health care providers for medical malpractice purposes. This ambiguity exists for two reasons. First, the medical malpractice statutes make no direct reference to clinical laboratories. Next, no available caselaw interprets the statute to apply—or to not apply—to labs.

Take Pennsylvania, for example. A search of the National Institutes of Health's Genetic Testing Registry reveals three genetic testing labs located and certified in Pennsylvania.<sup>62</sup> In relevant part, Pennsylvania's Health Care Services Malpractice Act reads:

Health care provider. A primary health care center . . . or a person, including a corporation, university or other educational institution licensed or approved by the Commonwealth to provide health care or professional medical services as a physician, a certified nurse midwife, a podiatrist, hospital, nursing home, birth center, and an officer, employee or agent of any of them acting in the course and scope of employment.<sup>63</sup>

Pennsylvania's statute does not reference clinical laboratories, nor does it mention genetic testing services.<sup>64</sup> Based on the statutory language, one could argue that a clinical laboratory that is licensed by the Commonwealth, certified under the federal Clinical Laboratory Improvement Amendments of

<sup>62</sup> See *Genetic Testing Registry*, NAT'L CTR. BIOTECHNOLOGY INFO, <https://www.ncbi.nlm.nih.gov/gtr/> (last accessed Nov. 9, 2019) (displaying a database which includes all clinical laboratories providing genetic testing services located and certified in each state, which can be filtered by search restrictions, such as whether the lab is certified under the Clinical Laboratory Improvement Amendments).

<sup>63</sup> 40 PA. STAT. ANN. § 1303.503 (West 2019).

<sup>64</sup> *Id.*

1999 (CLIA), and providing genetic testing services that aid medical diagnoses falls within the definition. The results of our survey indicated, however, that no court has decided that issue.

*Explicitly Included by Statute*

Six states (12%) include clinical laboratories or laboratory personnel in their statutory definitions of healthcare provider.<sup>65</sup> Colorado,<sup>66</sup> Hawaii,<sup>67</sup> Louisiana,<sup>68</sup> Montana,<sup>69</sup> Nevada,<sup>70</sup> and North Carolina.<sup>71</sup> Colorado's definition of healthcare institution includes "a laboratory certified under [CLIA] to perform high complexity testing."<sup>72</sup> A 2010 amendment to the Louisiana Medical Malpractice Act added licensed clinical laboratories to the definition of health care providers, explicitly noting that a healthcare provider "means a . . . licensed clinical laboratory scientist."<sup>73</sup> As an aside, the legislature also planned to increase medical malpractice damages caps.<sup>74</sup> Adding clinical lab personnel to the definition ensured that they would also be subject to the new caps.<sup>75</sup>

Likewise, Hawaii's law includes "clinical laboratory technologist[s] or technician[s]."<sup>76</sup> Montana's medical malpractice law governs actions brought for injury or death "against a . . . clinical laboratory bioanalyst, clinical laboratory technologist, . . . or licensed medical professional corporation."<sup>77</sup> The Nevada statute's healthcare provider definition expressly includes a "medical laboratory director or technician."<sup>78</sup> Lastly, North Carolina medical malpractice law covers any person conducting a "laboratory analysis."<sup>79</sup>

<sup>65</sup> COLO. REV. STAT. ANN. § 13-64-202 (West 2019); HAW. REV. STAT. § 657-7.3 (West 2019); LA. STAT. ANN. § 40:1231.1 (West 2019); LA. STAT. ANN. § 40:1231.1 (West 2019); MONT. CODE ANN. § 27-2-205 (West 2019); NEV. REV. STAT. ANN. § 41A.017 (West 2019); N.C. GEN. STAT. ANN. § 90-21.11 (West 2019).

<sup>66</sup> COLO. REV. STAT. ANN. § 13-64-202 (West 2019).

<sup>67</sup> HAW. REV. STAT. § 657-7.3 (West 2019).

<sup>68</sup> LA. STAT. ANN. § 40:1231.1 (West 2019).

<sup>69</sup> MONT. CODE ANN. § 27-2-205 (West 2019).

<sup>70</sup> NEV. REV. STAT. ANN. § 41A.017 (West 2019).

<sup>71</sup> N.C. GEN. STAT. ANN. § 90-21.11 (West 2019).

<sup>72</sup> COLO. REV. STAT. ANN. § 13-64-202 (West 2019).

<sup>73</sup> 2010 La. Sess. Law. Serv. 1 Act 568 (H.B. 264) (West).

<sup>74</sup> Rose Valazquez, *Raise \$500,000 Cap on Louisiana Medical Malpractice Damages? Not So Fast, Legislators Say*, NEW ORLEANS ADVOCATE (Apr. 14, 2017), [https://www.nola.com/news/politics/article\\_b5f69eff-7264-5011-be9e-90ffb67a99df.html](https://www.nola.com/news/politics/article_b5f69eff-7264-5011-be9e-90ffb67a99df.html).

<sup>75</sup> See FRANKLIN D. BEAHM ET AL., UPDATES AND HANDLING POTENTIAL PROBLEMS/DIFFICULTIES IN PROFESSIONAL MEDICAL NEGLIGENCE CASES 8 (2010).

<sup>76</sup> HAW. REV. STAT. § 657-7.3 (2019).

<sup>77</sup> MONT. CODE ANN. § 27-2-205 (West 2019).

<sup>78</sup> NEV. REV. STAT. ANN. § 41A.017 (West 2019).

<sup>79</sup> N.C. GEN. STAT. ANN. § 90-21.11 (West 2019).

STATE	STATUTE	DEFINITION	STATUTE OF LIMITATIONS	STATUTE OF REPOSE	MANDATORY ARBITRATION	DAMAGE CAPS
Colorado	COLO. REV. STAT. ANN. § 13-64-202 (West).	"a laboratory certified under [CLIA] to perform high complexity testing"	2 years	3 years	An arbitration agreement shall be a voluntary agreement between a patient and a healthcare provider	\$1,000,000 umbrella cap, \$350,000 cap on noneconomic damages
Hawaii	HAW. REV. STAT. § 657-7.3 (West).	"clinical laboratory technologist or technician"	2 years	6 years	Must be heard by a screening panel before trial or submit the case to arbitration	\$375,000 cap on pain and suffering damages (applicable to all tort actions)
Louisiana	LA. STAT. ANN. § 40:1231.1.	"means a . . . licensed clinical laboratory scientist"	1 year	3 years	Must be heard by a screening panel before trial	\$500,000 actual damages plus future medical expenses
Montana	MONT. CODE ANN. § 27-2-205.	"clinical laboratory bioanalyst, clinical laboratory technologist"	2 years if filed before July 1, 2019 3 years if filed on or after July 1, 2019	5 years	Must be heard by a screening panel before trial	\$250,000 cap on noneconomic damages
Nevada	NEV. REV. STAT. ANN. § 41A.017 (West).	"medical laboratory director or technician"	1 year	3 years	Parties shall attend settlement conference before trial	\$350,000 cap on noneconomic damages
North Carolina	N.C. GEN. STAT. ANN. § 90-21.11 (West).	"laboratory analysis"	1 year	3 years	Parties may agree to submit the dispute to arbitration before or after the action has been filed	\$569,247 cap on noneconomic damages

*Included, According to Caselaw*

In fifteen of the states (30%) where malpractice statutes do not explicitly address laboratories, courts have decided that clinical labs are healthcare providers. Of course, in all cases, whether a lab is a healthcare provider

depends on the facts. For example, two cases involved plaintiffs being misinformed of genetic risks.<sup>80</sup> Clinical laboratories, however, offer many kinds of services. Although the focus of this paper is on laboratories that perform genetic testing, the caselaw addresses laboratories that performed a diverse set of tests. Hence, if genetic testing was not at issue, one cannot say definitively that courts would rule similarly in a case involving genetic testing services. While we recognize that these cases may ultimately not be controlling, they would likely be an authority that a court would use for guidance in claims involving genetic testing.

Of the decisions finding labs to be healthcare providers under state malpractice law, most relied on the labs' providing services closely linked to a doctor's diagnosis.<sup>81</sup> *Williams* is a prime example. In reaching its decision, the South Carolina Supreme Court noted that a clinical laboratory performs genetic tests at the request of a treating physician<sup>82</sup> for the purpose of assisting the treating physician in making a diagnosis.<sup>83</sup> Diagnostic testing, the court noted, is a core function of hospitals, and hospitals are clearly included in the definition of licensed healthcare providers.<sup>84</sup> The South Carolina statute provides that "any similar category of licensed healthcare providers" is subject to liability under the law.<sup>85</sup> Given the similarity to hospitals, the court held that a genetic testing laboratory clearly fell within that catchall category.<sup>86</sup>

Likewise, the Alabama Supreme Court decided the issue based on the Alabama statute's definition of "other healthcare providers," which includes "[a]ny professional corporation or any person employed by physicians, dentists, or hospitals who are directly involved in the delivery of healthcare services."<sup>87</sup> The court emphasized that the physician asked the lab to analyze the patient's sample, and that the test was directly linked to the physician's

<sup>80</sup> *Johnson v. Superior Court*, 101 Cal. App. 4th 869, 879 (2002); *Pascarella v. Corning Clinical Labs., Inc.*, No. 325312, 1997 WL 155381 (Conn. Super. Ct. Mar. 25, 1997).

<sup>81</sup> See, e.g., *Anderson v. Ala. Reference Labs.*, 778 So. 2d 806 (Ala. 2000); *Johnson*, 101 Cal. App. at 879; *Baskette v. Atlanta Ctr. for Reproductive Med., LLC*, 285 Ga. App. 876, 648 S.E.2d 100 (2007); *Wood v. Schuen*, 760 N.E.2d 651, 653 (Ind. Ct. App. 2001); *Loudermilk v. Prof'l Lab. Serv.*, 75AP-219, 1975 WL 181821, at \*2 (Ohio Ct. App. Oct. 7, 1975), adhered to on denial of reconsideration, 75AP-219, 1975 WL 182033 (Ohio Ct. App. Dec. 18, 1975); *Palonis v. Jewel Food Stores, Inc.*, 383 F. Supp. 2d 1072 (N.D. Ill. 2005); *Annunziata v. Quest Diagnostics, Inc.*, 127 A.D.3d 630, 631, 8 N.Y.S.3d 168, 169 (N.Y. App. Div. 2015); *Williams v. Quest Diagnostics, Inc.*, 816 S.E.2d 564, 565 (S.C. 2018).

<sup>82</sup> *Williams*, 816 S.E.2d at 565.

<sup>83</sup> *Id.*

<sup>84</sup> *Id.* But note that all of *Athena's* tests were "send-outs," a point the court fails to consider at all in the analysis.

<sup>85</sup> *Id.* (quoting S.C. CODE ANN. § 38-79-410).

<sup>86</sup> *Id.*

<sup>87</sup> *Anderson v. Ala. Reference Labs.*, 778 So. 2d 806, 809–10 (Ala. 2000) (quoting ALA. CODE § 6-5-481(8) (1975)).

diagnosis and treatment.<sup>88</sup>

Court decisions in other states relied on similar factors. Some considered whether the actions of the laboratory had caused medical injury.<sup>89</sup> Others looked to how closely the laboratory's services were related to human health.<sup>90</sup> To some courts, the physician's involvement in directing the lab's services was important.<sup>91</sup> The physicians decided which tests and services were necessary.<sup>92</sup> Ultimately, the data reveal that—regardless of the variation among the statutes themselves—the relationship between the laboratory's services, medical decision-making, and the consequences of those choices were key to establishing liability.

STATE	STATUTE	CASE	FACTS	HOLDING
Alabama	Alabama Medical Liability Act of 1987, Code 1975, §§ 6–5–542(1), 6–5–481(8)	Anderson v. Ala. Reference Labs., 778 So. 2d 806 (Ala. 2000)	Action brought against medical reference laboratory for negligently, wantonly, or recklessly performing tuberculosis testing. Plaintiff claimed the lab committed “legal fraud” in reporting false test results, thereby causing severe emotional distress, economic losses, and loss of consortium.	Because the testing was directly linked to the doctor's diagnosis, the laboratory fell within definition of “other health care provider” of Alabama Medical Liability Act of 1987 (AMLA), such that patient's medical malpractice action was subject to the AMLA.
Arkansas	ARK. CODE ANN. § 16-114-201 (West)	Green v. Nat'l Health Labs. Inc., 316 Ark. 5, 7, 870 S.W.2d 707, 708 (1994)	Laboratory and physician are sued under the state's malpractice statute for issuing an erroneous positive test result for cancer.	The Supreme Court of Arkansas allows claims to proceed under malpractice statute, considering the actions at issue to fall under “medical injury” as defined by the law.
California	CAL. CIV. PROC. CODE ANN. § § 3333.2, 425.13 (West)	Johnson v. Superior Court, 101 Cal. App. 4th 869, 879, 124 Cal. Rptr. 2d 650, 658 (2002)	Medical malpractice action against sperm bank and bank's physicians, arising from hereditary kidney disease the child inherited from sperm donor (misinformed of genetic risk).	Cryobank is a healthcare provider as that term is used in the statute because it is a licensed clinical laboratory. The court found that the lab's services were “inextricably identified with the health of humans.” The lab's services, while not essential to human health, were related to human health, and as such, the lab was a healthcare provider under the statute. 101 Cal. App. 4th 869, 880, 124 Cal. Rptr. 2d 650, 659 (2002).

<sup>88</sup> *Id.* at 810.

<sup>89</sup> *See, e.g.,* Green v. Nat'l Health Labs., Inc., 870 S.W.2d 707, 709 (Ark. 1994) (stating laboratory caused “medical injury”); Pascarella v. Corning Clinical Labs., Inc., No. 325312, 1997 WL 155381, at \*2 (Conn. Super. Ct. Mar. 25, 1997) (noting that an HIV test was incorrectly reported as positive by a clinical laboratory).

<sup>90</sup> *See, e.g.,* Johnson v. Superior Court, 124 Cal. Rptr. 2d 650, 658 (Cal. Ct. App. 2002) (stating the lab's services were “inextricably identified with the health of humans”).

<sup>91</sup> Baskette, v. Atlanta Ctr. for Reprod. Med., LLC, 648 S.E.2d 100, 104 (Ga. Ct. App. 2007); Annunziata, v. Quest Diagnostics, Inc., 8 N.Y.S.3d 168, 168 (N.Y. App. Div. 2015).

<sup>92</sup> *See, e.g.,* Baskette, 648 S.E.2d at 104 (noting that tests are performed under supervision of physicians, who exercise of medical knowledge and judgment); Annunziata, 8 N.Y.S.3d at 168 (stating that the lab's services were provided at the direction of a physician).

<b>Connecticut</b>	CONN. GEN. STAT. ANN. § 52-184b (West)	Pascarella v. Coming Clinical Labs., Inc., 325312, 1997 WL 155381, at *2 (Conn. Super. Ct. Mar. 25, 1997)	Proceeding instituted against Coming Clinical Laboratories, Inc., a blood testing facility. Plaintiff asserted that Coming performed an analysis of his blood and concluded that he was HIV positive. Subsequent tests revealed the test results were in error. A key inquiry was whether a blood testing facility fell under the statute's definition of a healthcare provider.	The court found that, under the broad language of the statute, the blood testing facility could reasonably be characterized as a facility licensed by this state to provide professional health services. There were enough similarities between the blood testing facility and a pharmacy and pharmacists, previously held to be healthcare providers under the law, for the court to conclude the lab also fell within the statutory definition.
<b>Florida</b>	West's F.S.A. §§ 766	Nehme v. Smithkline Beecham Clinical Labs., Inc., 822 So. 2d 519, 520–21 (Fla. Dist. Ct. App. 2002), approved, 863 So. 2d 201 (Fla. 2003)	Action against clinical laboratory for medical malpractice and wrongful death, arising from misdiagnosis of pap smear, which indicated presence of malignancy.	Court assumes the lab is a medical provider. Actions for medical malpractice and wrongful death brought by personal representative of patient's estate against clinical laboratory were governed by four-year statute of repose for malpractice actions.
<b>Georgia</b>	GA. CODE ANN. § 9-3-70 (West)	Baskette v. Atlanta Ctr. for Reproductive Med., LLC, 285 Ga.App. 876, 648 S.E.2d 100 (2007)	Plaintiffs brought claim against lab for the loss of husband's sperm. The state law's terms stated that an "action for medical malpractice" included any claim for damages resulting from an injury to any person arising out of a medical service rendered by any person acting under the supervision and control of a lawfully authorized person.	The lab's services involved the exercise of professional medical knowledge and judgment. Claims against medical center, technologist, and lab director constituted claims for medical malpractice, rather than for ordinary negligence.  The center was a medical facility, technologist and director thawed and used patient's husband's sperm to fertilize patient's eggs, and they performed those tasks within the scope of their employment and under the supervision of physicians.
<b>Illinois</b>	735 ILL. COMP. STAT. ANN. 5/2-622	Palonis v. Jewel Food Stores, Inc., 383 F. Supp. 2d 1072 (N.D. Ill. 2005)	Employee, a truck driver who was terminated after he tested positive for cocaine, brought suit for negligence against laboratory that tested his urine sample.	In collecting, handling, and testing his urine samples for drugs and in reporting results to his employer, laboratory's alleged negligence did not arise from application of "healing art," but rather laboratory acted in context of employer-mandated drug test given for purposes of determining employee's eligibility to continue working, not for purpose of diagnosing or treating him. Had the tests been performed for that reason, however, malpractice would have been applicable.
<b>Indiana</b>	IND. CODE ANN. § 34-18-2-14 (West)	Wood v. Schuen, 760 N.E.2d 651, 653 (Ind. Ct. App. 2001)	Patient filed medical malpractice claim against director of cytopathology at medical laboratory that allegedly misread patient's tests and failed to diagnose cervical cancer.	Because there was no direct nexus between the director's actions and the alleged negligence upon which the claim was based, there was no liability in this case.



				The court noted, however, that persons whose lab results were misread by a lab are not without remedy. But the court emphasized the need for a "direct nexus between the director's actions and the alleged negligence upon which the claim of <i>medical malpractice</i> is based." 760 N.E.2d 651, 659 (Ind. Ct. App. 2001) (emphasis added).
<b>Maryland</b>	MD. CODE ANN., CTS. & JUD. PROC. § 3-2A-01 (West)	Young v. Medlatic Labs., 125 Md. App. 299, 725 A.2d 572 (1999)	Patient sued laboratory that had performed pathology tests on her tissue samples, alleging that laboratory was negligent in communicating results to patient's physician.	Claim proceeds as a medical malpractice claim and is not barred by statute of limitations but court doesn't analyze the statute.
<b>Massachusetts</b>	MASS. GEN. LAWS ANN. ch. 231, § 60B (West)	Morgan v. Lab. Corp. of Am., 65 Mass. App. Ct. 816, 844 N.E.2d 689, 19 A.L.R.6th 923 (2006)	Negligence claims against clinical laboratory that analyzed patient's post-surgery blood tests, alleging in part that laboratory failed to provide prompt notice to surgeon that laboratory's analysis of patient's blood sample had revealed life-threatening change in anticoagulation level of patient's blood.	In this case, an instruction on medical malpractice caps was in error, because the claims brought were ordinary negligence claims. The court held that the evidence was sufficient for the jury to find a clinical laboratory's common-law negligence in failing to promptly notify the doctor. Medical malpractice liability for the lab, however, may have been applicable under different facts.
<b>Michigan</b>	MICH. COMP. LAWS ANN. § 600.2912b (West)	Herrmann v. Pinkus Dermatopathology Labs., P.C., 198380, 1998 WL 2016556, at *1 (Mich. Ct. App. Mar. 20, 1998)	Plaintiffs alleged that defendant lab failed to indicate that the portion of a lesion remaining after a biopsy on decedent's shoulder was potentially dangerous and because of that he failed to demand an immediate, complete excision of that remaining portion.	Court analyzes the facts under the standards for a medical malpractice action.
<b>New York</b>	N.Y. C.P.L.R. 214-a (McKinney)	Anunziata v. Quest Diagnostics, Inc., 127 A.D.3d 630, 631, 8 N.Y.S.3d 168, 169 (N.Y. App. Div. 2015)	Complaint alleged that Quest, a laboratory, was negligent in misreading the tissue sample.	Laboratory services performed at the direction of a physician, are an integral part of the process of providing medical treatment. The court found that a claim stemming from the rendition of such services is a medical malpractice claim.
<b>Ohio</b>	OHIO REV. CODE ANN. § 2305.234 (West)	Loudermilk v. Prof'l Lab. Serv., 75AP-219, 1975 WL 181821, at *2 (Ohio Ct. App. Oct. 7, 1975), adhered to on denial of reconsideration, 75AP-219, 1975 WL 182033 (Ohio Ct. App. Dec. 18, 1975)	In an action brought against a clinical laboratory, the main issue for determination was whether an action for medical malpractice could lie against any person performing testing services for the plaintiff.	In order for a medical malpractice action to be appropriately brought, there must have been a professional medical service rendered or performed. Secondly, for such an action to properly lie, there must be a showing of the physician-patient relationship. The court determined that the services being performed by the lab were professional medical services and determined that a physician-patient relationship

				existed.
<b>South Carolina</b>	S.C. CODE ANN. §§ 15-79-110(4), 38-71-1920(7), 38-79-410	<i>Williams v. Quest Diagnostics, Inc.</i> , 423 S.C. 547, 816 S.E.2d 564 (2018)	Suit for wrongful death against federally licensed genetic testing laboratory and related entities, based on allegation that laboratory staff failed to properly determine, at treating physician's request, patient's medical condition.	A genetic testing laboratory that performs 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 falls within the statutory definition of "licensed health care providers." Testing was performed at the request of a treating physician for the purpose of diagnosis and treatment, which is a core function of hospitals in diagnosing and treating patients.
<b>Texas</b>	Texas Medical Liability Insurance Improvement Act (MLIIA), TEX. CIV. PRAC. & REM. CODE § 74.351(a) (Vernon 2005)	<i>Brown v. Villegas</i> , 202 S.W.3d 803, 804 (Tex. App.—San Antonio 2006, no pet.)	Patient brought healthcare liability claim against laboratory and laboratory technician, seeking damages arising out of lab's failure to recognize abnormal cells in patient's pap smear.	Laboratories are not presumptively excluded from the definition of "health care providers" under the statute. But because the record did not contain any evidence establishing that LabCorp was "duly licensed, certified, or registered or chartered by the State of Texas to provide health care," or that LabCorp was an independent contractor of the treating physician, the trial court's order applying malpractice principles was reversed.

*Excluded, According to Caselaw*

Finally, courts in four different jurisdictions (8%)—South Dakota, Rhode Island, Virginia, and Maine—have explicitly decided not to define clinical laboratories as healthcare providers.<sup>93</sup> In three of the four states, the states' highest court rendered the decision.<sup>94</sup> Although these cases held that clinical laboratories were not subject to medical malpractice claims, some left open the possibility that different facts might lead to different outcomes.<sup>95</sup>

The Virginia Supreme Court held that a clinical laboratory was not a healthcare provider in 1988.<sup>96</sup> The medical malpractice statute did not explicitly mention labs, and the court declined to construe it to include

<sup>93</sup> See *Dupuis v. Cancer Screening Servs.*, No. CIV. 96-169-P-C., 1997 WL 97110, at \*4 (D. Me. Feb. 13, 1997); *Ho-Rath v. R.I. Hosp.*, 89 A.3d 806, 812 (R.I. 2014); *Sander v. Geib*, 506 N.W.2d 107, 124 (S.D. 1993); *Richman v. Nat'l Health Labs.*, 367 S.E.2d 353, 357 (Va. 1988).

<sup>94</sup> *Ho-Rath*, 89 A.3d at 806; *Richman*, 367 S.E.2d at 353; *Sander*, 506 N.W.2d at 107.

<sup>95</sup> See, e.g., *Dupuis*, 1997 WL 97110, at \*4 (stating clinical laboratory did not have direct patient contact); *Ho-Rath*, 89 A.3d 806 at 812 (noting that laboratories having no direct patient contact and provide only testing services which are not included in statute).

<sup>96</sup> *Richman*, 367 S.E.2d at 357.

them.<sup>97</sup> Further, the court held that the lab—licensed by the federal government and not the Commonwealth—was both excluded from the statutory list of healthcare providers and not acting as the doctor’s agent.<sup>98</sup> A 1992 lower court decision relied on that case, noting that “[r]ules of liberal construction cannot properly be applied to rewrite a statute in order to alter what it actually says.”<sup>99</sup>

South Dakota Supreme Court used a slightly different line of reasoning in 1993, when deciding whether the lab was a “practitioner of the healing arts,” within the meaning of the state’s medical malpractice statute.<sup>100</sup> Because previous caselaw—as well as the plain text of the statute—required a “practitioner” to be a natural person, the court held that the clinical lab did not fall within the statute’s ambit.<sup>101</sup>

A federal district court, applying Maine state law, came to a similar conclusion in 1997.<sup>102</sup> Despite the fact that courts had construed the state’s medical malpractice statute liberally, the court found that the statute did not cover the clinical laboratory.<sup>103</sup> The defendant laboratory had no direct contact with patients.<sup>104</sup> The court concluded that evaluating tissue samples and reporting results did not constitute “medical services.”<sup>105</sup> The court, therefore, found that the medical malpractice statute did not apply.<sup>106</sup>

In 2014, the Rhode Island Supreme Court arrived at the same conclusion.<sup>107</sup> The court held that, because the lab had no direct patient contact and provided only testing services, the lab’s actions did not fall under the medical malpractice statute.<sup>108</sup>

STATE	STATUTE	CASE	FACTS	HOLDING
Maine	ME. REV. STAT. tit. 24, § 2502	Dupuis v. Cancer Screening Servs.,	Patient brought a claim against a clinical	The defendant laboratory had no direct contact with patients; its

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* (noting that the text of the Commonwealth’s statute indicated that covered institutions had to be licensed by the Commonwealth and that the lab was inspected by the Commonwealth and licensed by the federal government).

<sup>99</sup> *Nevitt v. Va. Heart Surgery Assocs., P.C.*, No. 109236, 1992 WL 884702, at \*1 (Va. Cir. May 28, 1992) (citing *Richman*, 367 S.E.2d at 357).

<sup>100</sup> *Sander*, 506 N.W.2d at 124.

<sup>101</sup> *Id.*

<sup>102</sup> *Dupuis v. Cancer Screening Servs.*, No. CIV. 96-169-P-C., 1997 WL 97110, at \*4 (D. Me. Feb. 13, 1997).

<sup>103</sup> *Id.* (“Rules of liberal construction cannot properly be applied to rewrite a statute in order to alter what it actually says.”).

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

<sup>107</sup> *Ho-Rath v. R.I. Hosp.*, 89 A.3d 806, 812 (R.I. 2014).

<sup>108</sup> *Id.* at 810, 812.

		1997 U.S. Dist. LEXIS 2456 *12 (D.Me. Feb. 13, 1997)	laboratory for medical malpractice, claiming the laboratory had negligently performed cancer screening tests.	<p>evaluation of tissue samples and reporting results were not “medical services,” and the court, therefore, found that the medical malpractice statute did not apply.</p> <p>The lower court noted, however, that the reach of the Act has been interpreted liberally with regard to claims brought against healthcare providers.</p>
<b>Rhode Island</b>	5 R.I. GEN. LAWS ANN. §5-37-1 (West)	Ho-Rath v. R.I. Hosp., 89 A.3d 806 (R.I. 2014)	Parents brought action against numerous defendants alleging negligence for injuries sustained by their minor daughter, who was born with alpha thalassemia, a genetic blood disorder.	<p>Laboratories, having no direct patient contact and providing only testing services, did not fall under the medical malpractice statute.</p> <p>The court was of the opinion that, in the absence of clear statutory language to the contrary, the legislature did not intend for negligence actions against laboratories to fall under the ambit of medical malpractice.</p>
<b>South Dakota</b>	S.D. CODIFIED LAWS § 21-3-11	Sander v. Geib, Elston, Frost Prof'l Ass'n, 506 N.W.2d 107, 124 (S.D. 1993)	Patient brought medical malpractice action against clinical laboratory for alleged negligence in reading of her pap smear slides. At issue was whether Clinical Lab is a “practitioner of the healing arts” within the meaning of the state’s medical malpractice statute.	<p>The court concluded that the language of the statute and previous caselaw plainly required a “practitioner” to be a natural person. The court held the term “other practitioner of the healing arts” not to include entities such as Clinical Lab, a medical corporation.</p> <p>On occasion, the court had found individuals to be “practitioner[s] of the healing arts” even though they were not licensed under the Medical Practice Act. Unlike a corporation, however, those individuals were capable of becoming licensed under the Medical Practice Act.</p>
<b>Virginia</b>	Virginia Medical Malpractice Act, VA. CODE ANN. § 8.01-581.1 (West)	Nevitt v. Va. Heart Surgery Assocs., P.C., 38 Va. Cir. 505 (1992)	The court considered the holding of a previous case, <i>Richman v. National Health Laboratories</i> , 235 Va. 353 (1988), finding that an unlicensed lab did not fall within the ambit of the statute.	<p>“There is nothing about the nature of hospitals and nursing homes which suggests that clinical laboratories, though not mentioned, should nevertheless be included in the statute. Rules of liberal construction cannot properly be applied to rewrite a statute in order to alter what it actually says.” 38 Va. Cir. 505, 505 (1992).</p>

## CONCLUSION

Genetic testing, given its rapid growth, will likely generate a good deal of future litigation. Whether clinical genetics labs are healthcare providers is a significant threshold inquiry. States have answered this important question differently, and the answer a state provides may vary depending on the facts of the particular case. The cases from our study are the starting point for any practitioner's argument for—or against—treating a clinical genetics laboratory as a healthcare provider under state medical malpractice law.

How states decide this issue will impact the outcomes of lawsuits against clinical laboratories. If the labs are healthcare providers, they will be subject to a given state's medical malpractice law, including statutes of limitations, statutes of repose, damages caps, and procedural idiosyncrasies. Moreover, in lieu of establishing ordinary negligence, plaintiffs will have to assert that the laboratories breached the applicable standard of care. Perhaps our most significant finding was that half of states have yet to tackle this issue directly. Our other key finding was that, where labs have been subjected to malpractice law, the relationship between the laboratory's services and ordering physician was key to establishing liability. Because of the growing importance of this question, we encourage state legislatures to weigh in to provide clarity, in one way or another. In the meantime, healthcare attorneys must keep careful watch as the law on this issue continues to develop.

