UNJUST TIMING LIMITATIONS IN GENETIC MALPRACTICE CASES[†]

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As genomic data are increasingly being collected and applied in clinical care, physicians, laboratories, and other health care providers are more frequently being sued for alleged medical malpractice or negligence.[1] Because the genetic underpinnings of an existing or future health condition may not be immediately apparent, such cases sometimes raise unique timing issues involving the applicable statute of limitations, statute of repose, or statutory notification requirements.[2] Although these timing limitations on when a lawsuit can be brought have important policy rationales and justifications, such as helping to protect providers from open-ended liability,[3] their application to genetic liability cases may sometimes result in fundamental unfairness and unjust results because of the unavoidable delayed discovery of the potential negligence in detecting or addressing the genetic contribution of a patient's condition.[4]

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[1] Gary E. Marchant & Rachel A. Lindor, *Genomic Malpractice: An Emerging Tide or Gentle Ripple?*, 73 FOOD DRUG L.J. 1, 2 (2018).

[2] *Id.* at 26.

[3] *See infra* notes 19–22 and accompanying text.

[4] *See* Marchant & Lindor, *supra* note 1, at 26; *infra* notes 25–26 and accompanying text.

The timing dilemmas presented in genetic malpractice cases are illustrated by a closely-watched pending case in South Carolina—*Williams v. Quest Diagnostics, Inc.*[5] In that case, a test laboratory failed to recognize the clinical significance of a mutation carried by a child, classifying it as a variant of unknown significance.[6] As a result, the child was not given the appropriate treatment and tragically passed away.[7] The substantive issue in the case is when the laboratory should have recognized the pathogenic nature of the mutation and communicated that information to the child's treating physician.[8] However, the case may be decided on a procedural timing issue, depending in part on whether the lawsuit against the laboratory is considered a medical malpractice case or a general negligence case.[9] The South Carolina District Court certified a question to the South Carolina Supreme Court to determine whether "a federally licensed genetic testing laboratory" is considered a "licensed health care provider" under South Carolina law, and the South Carolina Supreme Court answered affirmatively, meaning that the six-year statute of repose for medical malpractice may apply.[10]

The defendants have now moved to dismiss the case since the case was brought more than eight years after the laboratory's allegedly negligent act.[11] However, the plaintiff's mother did not discover, and had no reasonable means to discover, until long after the statute of repose had run that the laboratory allegedly should have known of the pathogenic nature of the child's mutation at the time of testing.[12] Although this case is still pending as of the time of this writing, if the court were to dismiss the plaintiff's claim as untimely, such an outcome would be an example of a manifestly unjust result in a genetic malpractice case in which a family had no possible way to determine the nature of the genetic condition and the alleged malpractice until well after the time for filing a lawsuit had expired.

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[5] Williams v. Quest Diagnostics, Inc., 353 F. Supp. 3d 432, 440, 443 (D. S.C. 2018); *see* Turna Ray, *Mother's Negligence Suit Against Quest's Athena Could Broadly Impact Genetic Testing Labs*, GENOMEWEB (Mar. 14, 2016), https://www.genomeweb.com/molecular-diagnostics/mothers-negligence-suit-against-quests-athena-could-broadly-impact-genetic [https://perma.cc/3TVH-Y539].

[6] *Williams*, 353 F. Supp. 3d at 436–37.

[7] *Id.* at 437.

[8] *See id.* at 437, 441, 443, 445.

[9] *See id.* at 438, 440, 443.

[10] *Id.* at 436, 440; Williams v. Quest Diagnostics, Inc., 816 S.E.2d 564, 564, 566 (S.C. 2018).

[11] *Williams*, 353 F. Supp. 3d at 436, 443.

[12] *Id.* at 444–45.

While similar problems occasionally pop up in other types of medical malpractice cases,[13] they are likely to be much more common in genetic malpractice cases because the provider error often remains hidden for years or even decades.[14] This then creates a growing tension between the injured plaintiff's right to seek legal recourse in a case, where they have allegedly been injured, against the providers' interest in preventing open-ended liability and the litigation of old cases where the evidence may be stale. This Article addresses this tension and the potential unfairness that may result in genetic malpractice cases due to statutory timing constraints. In Part I, we provide background on the types, purposes, requirements, and prevalence of such timing limitations. In Part II, we provide some additional examples of unfair and unjust outcomes in genetic malpractice cases from applying such timing limits. Finally, in Part III, we offer some potential solutions that recognizes the legitimate need of health care providers to not face open-ended liability while also protecting injured patients from being blocked from seeking a legal remedy when they could not have possibly discovered their potential legal claim before the applicable timing limitation had expired. This problem raises the broader issue of what should lawmakers do when a legal regime that was created for an earlier era and different technology is now challenged by new technology that may not fit or align well with that historical legal regime.

I. BACKGROUND ON LITIGATING TIMING LIMITATIONS

In torts and other types of litigation, certain state statutes limit the time within which a plaintiff can bring a claim, which are generically called statutory limitations (SLs).[15] These statutory limitations can be in two main categories: statutes of limitation (SoLs) and statutes of repose (SoRs).[16] As elaborated below, SoLs generally run from the time that the plaintiff did or should have discovered that they had a cause of action, whereas SoRs are more harsh, and run from the time that the tortious act occurred, regardless of whether or when the plaintiff discovered the tortious nature of the act.[17] A third type of timing limitation in tort lawsuits

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[13] *See, e.g.*, Jewson v. Mayo Clinic, 691 F.2d 405, 407, 409, 411 (8th Cir. 1982).

[14] *See* Marchant & Lindor, *supra* note 1, at 10, 26.

[15] *See* Reynolds v. Porter, 760 P.2d 816, 819–20 (Okla. 1988).

[16] *Id.*

[17] *See id.* For further elaboration on the SoL and SoR, see *infra* notes 27–37 and

are statutes that require a plaintiff to provide timely notification of their intent to sue, which often apply only to defendants that are public institutions.[18]

These SLs impose bright-line rules to bar claims brought after the times specified.[19] Courts emphasize that the purpose of such SLs involves justice and process concerns, including that evidence deteriorates over time, defendants are entitled to peace of mind at some point, insurers and defendants need a degree of certainty in order to estimate future costs, and societal expectations and standards change over time.[20] For example, the U.S. Supreme Court stated back in 1944 that statutory limitation periods are

> designed to promote justice by preventing surprises through the revival of claims that have been allowed to slumber until evidence has been lost, memories have faded, and witnesses have disappeared. The theory is that even if one has a just claim it is unjust not to put the adversary on notice to defend within the period of limitation and that the right to be free of stale claims in time comes to prevail over the right to prosecute them.[21]

In the genetic context, these practical arguments for timing limitations will have particular salience. There is a strong argument that providers need to be protected from open-ended liability, as gene sequencing and testing will generate many "variants of unknown significance" at the time of the testing, but which may have clinical significance later on.[22] Given the well-known hindsight bias of jurors and the liability system,[23] there will be a tendency and temptation to

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accompanying text.

[18] *See, e.g.*, N.Y. GEN. MUN. LAW § 50-e (McKinney 2019); UTAH CODE ANN. § 63G-7-401 (LexisNexis 2019).

[19] 1 DAN B. DOBBS ET AL., THE LAW OF TORTS § 241, at 871 (2d ed. 2011).

[20] *Id.* § 241, at 872; *see also* Methodist Healthcare Sys. of San Antonio v. Rankin, 307 S.W.3d 283, 287 (Tex. 2010) ("One practical upside of curbing open-ended exposure is to prevent defendants from answering claims where evidence may prove elusive due to unavailable witnesses (perhaps deceased), faded memories, lost or destroyed records, and institutions that no longer exist.").

[21] Order of R.R. Tels. v. Ry. Express Agency, 321 U.S. 342, 348-49 (1944).

[22] *See* Adrian Thorogood et al., *Public Variant Databases: Liability?*, 19 GENETICS MED. 838, 839 (2017).

[23] *See e.g.*, Hal R. Arkes, *The Consequences of the Hindsight Bias in Medical Decision Making*, 22 CURRENT DIRECTIONS PSYCHOL. SCI. 356, 356 (2013); Matt Groeb, *Does Bifurcation Eliminate the Problem: A Closer Look at Hindsight Bias in the Courtroom*, 23 JURY EXPERT 17, 17–18 (2011); Marchant & Lindor, *supra* note 1, at 9–10; Philip G. Peters, Jr., *Hindsight Bias and Tort Liability: Avoiding Premature Conclusions*, 31 ARIZ. ST. L.J. 1277, 1281–82 (1999).

second-guess the provider's initial judgment and attribute greater knowledge than is fair retrospectively the longer the window of liability remains open.[24]

On the other hand, as discussed further below, the unique timing issues and nature of genetic malpractice cases may result in some plaintiffs not discovering the negligence that harmed them until after the timing statute has expired.[25] Thus, although the purpose and meaning of SLs may seem simple on first impression, their application raises many complex and difficult issues in balancing the interests of the parties. Judge Richard Posner cautioned, "Though rarely the subject of sustained scholarly attention, the law concerning statutes of limitations fairly bristles with subtle, intricate, often misunderstood issues."[26]

Typically, in negligence claims,[27] the statutory clock does not start until the defendant commits a negligent act *and* that act caused legally cognizable harm.[28] Many states have added a third triggering requirement, which is when the plaintiff reasonably should have discovered the negligent act.[29] This two- or three-prong requirement is typical for *statutes of limitation*.[30] *Statutes of repose*, on the other hand, provide an alternative to the two- or three-prong requirement of statutes of limitations and require only that a negligent act occurred to trigger the statutory clock.[31] Although almost all legal actions have an SoL (extreme criminal charges such as murder being an exception), SoRs are imposed by state legislatures much more selectively.[32] In addition, unlike an SoL, an SoR generally cannot be

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[24] *See* Arkes, *supra* note 23, at 358.

[25] *See infra* notes 160–169 and accompanying text.

[26] Wolin v. Smith Barney, Inc., 83 F.3d 847, 849 (7th Cir. 1996).

[27] Negligence claims are a subset of tort claims where a defendant allegedly fails to exercise reasonable care. *See* B. Sonny Bal, *An Introduction to Medical Malpractice in the United States*, 467 CLINICAL ORTHOPAEDICS RELATED RES. 339, 340 (Nov. 26, 2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2628513/pdf/11999_2008_Article_636.pdf [https://perma.cc/TAT9-AU63]. Most medical malpractice lawsuits involve a negligence claim. *See, e.g.*, *id.* at 342.

[28] 1 DOBBS ET AL., *supra* note 19, § 242, at 876. These two requirements do not apply to all torts. *Id.*

[29] *Id.* § 243, at 878 & n.6.

[30] *Id.* § 243, at 878–79.

[31] *Id.* § 244, at 884. The act of diagnosing and communicating the diagnosis to the patient is considered the legally cognizable "act," not the means of coming to the diagnosis by viewing records or lab tests, which might occur on a different day than the communication with the patient. *See, e.g.*, Green v. Nat'l Health Lab., 870 S.W.2d 707, 709 (Ark. 1994).

[32] *See* Cara O'Neill, *Civil Statutes of Limitations*, NOLO (Mar. 6, 2019), https://www.nolo.com/legal-encyclopedia/statute-of-limitations-state-laws-chart-29941.html [https://perma.cc/VG3A-PH82]; *Criminal Statutes of Limitations: Time Limits for State Charges*, LAWINFO, https://resources.lawinfo.com/criminal-defense/criminal-statute-limitations-time-limits.html [https://perma.cc/B2LN-7PU6]; *see, e.g.*, *New York Legislature Considers Enacting Statute of*

tolled.[33] A Tennessee court succinctly explained the difference between an SoL and SoR as follows:

> A statute of limitations governs the time within which suit may be brought once a cause of action accrued. A statute of repose limits the time within which an action may be brought, "but it is entirely unrelated to the accrual of a cause of action and can, in fact, bar a cause of action before it has accrued."[34]

In order to understand the differential purposes of SoLs and SoRs, it is helpful to consider the history of SoRs, the more recent of the two SLs. SoRs were mostly enacted as part of the tort reform legislation in the 1970s and 80s and were created to protect certain groups such as product manufacturers, government entities, architects and builders, and health care professionals from long liability "tails" that were seen as excessive.[35] The SoRs were intended "to eliminate uncertainties under the related statute of limitations and to create a final deadline for filing suit that is not subject to any exceptions."[36] SoRs pertaining to health care providers' typically begin to run at the moment of "the doctor's last act or the completion of treatment," even if the harm from that last act does not become evident until later.[37]

Because health care providers are subject to primarily negligence and medical malpractice claims, SLs in negligence and medical malpractice statutes are relevant here. Medical malpractice claims are a subset of negligence claims, but courts do not have standardized rules across jurisdictions for determining whether a case with a

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Repose Legislation, GOLDBERG SEGALA (Mar. 15, 2019), https://www.goldbergsegalla.com/news-and-knowledge/news/new-york-legislature-considers-enacting-statute-of-repose-legislation [https://perma.cc/ZK4T-BKDL].

[33] CTS Corp. v. Waldburger, 573 U.S. 1, 9 (2014) (quoting Lozano v. Montoya Alvarez, 572 U.S. 1, 10 (2014)).

[34] Jones v. Methodist Healthcare, 83 S.W.3d 739, 743 (Tenn. Ct. App. 2001) (quoting Cronin v. Howe, 906 S.W.2d 910, 913 (Tenn. 1995)) (citing Cheswold Volunteer Fire Co. v. Lambertson Constr. Co., 489 A.2d 413, 421 (Del. 1985)).

[35] 1 DOBBS ET AL., *supra* note 19, § 244, at 885; *see, e.g.*, Branch v. Willis-Knighton Med. Ctr., 636 So. 2d 211, 212–217 (La. 1994) (discussing a medical malpractice tort reform statute). To date, the greatest number of SoRs involve construction and products liability. *See* Aaron Larson, *What Is a Statute of Repose*, EXPERTLAW (May 8, 2018), https://www.expertlaw.com/library/civil-litigation/what-statue-of-repose [https://perma.cc/K7PT-EWA6]. The groups protected by SORs starting in the 1970s and 80s lobbied for the statutes that instituted shorter statutory clocks vis-à-vis 1-prong "act" triggers. *See* 1 DOBBS ET AL., *supra* note 19, § 244, at 885.

[36] Methodist Healthcare Sys. of San Antonio v. Rankin, 307 S.W.3d 283, 286 (Tex. 2010).

[37] 1 DOBBS ET AL., *supra* note 19, § 244, at 885; *see, e.g.*, ALA. CODE § 6-5-482(a) (2019); FLA. STAT. § 95.11(4)(b) (2019); MICH. COMP. LAWS § 600.5838a(2) (2019); MO. REV STAT. § 516.105 (2018).

health care professional defendant is one of typical negligence or medical malpractice;[38] and this impacts SL determinations because negligence and medical malpractice SLs can be different within the same jurisdiction.[39] For example, Minnesota has a medical malpractice SoL of four years[40] and a negligence SoL of six years.[41] Additionally, SoRs apply much more selectively, and in many states will apply to a medical malpractice action but not a general negligence claim.[42]

If the SL is written to require an alleged wrongful act and some knowledge of the defendant's alleged contribution to the harm (in other words, written as an SoL), then the court has to determine based on statutory language and case law precedent if the triggering event is the manifestation of an injury *or* the discovery of the defendant's role in causing the injury.[43] If, on the other hand, the statute is written to require only an alleged act, as is the case of an SoR, this distinction is moot. Specifically, SoRs are upheld even when the injury becomes perceptible after the SoR time has run,[44] whereas SoL decisions often revolve around determination of when the injury occurred[45] and/or when the plaintiff knew or with reasonable diligence should have known of the injury, its cause, and the defendant's possible error.[46] Figure 1 provides a conceptual timeline depicting a hypothetical medical practitioner's act, a cognizable injury, and patient's discovery with arrows indicating what is conceptually categorized as an SoR or SoL. As will be seen in later case examples, the SoR often does not extend to the patient's discovery of the tort, especially in cases like genomic malpractice, where the tort and injury may not be immediately apparent.[47]

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[38] *See, e.g.*, Williams v. Quest Diagnostics, Inc., 353 F. Supp. 3d 432, 440, 441–42 (D. S.C. 2018) (citing Dawkins v. Union Hosp. Dist., 758 S.E.2d 501, 504–05 (S.C. 2014)); Scott v. Uljanov, 541 N.E.2d 398, 398–99 (N.Y. 1989) (quoting Bleiler v. Bodnar, 479 N.E.2d 230, 234 (N.Y. 1985)).

[39] *See Scott*, 541 N.E.2d at 399.

[40] MINN. STAT. § 541.076(b) (2019).

[41] *Id.* § 541.05 subdiv. 1(5).

[42] *See, e.g.*, Piedmont Hosp., Inc. v. D. M., 779 S.E.2d 36, 39 (Ga. Ct. App.2015).

[43] *See* 1 DOBBS ET AL., *supra* note 19, § 244, at 878-84.

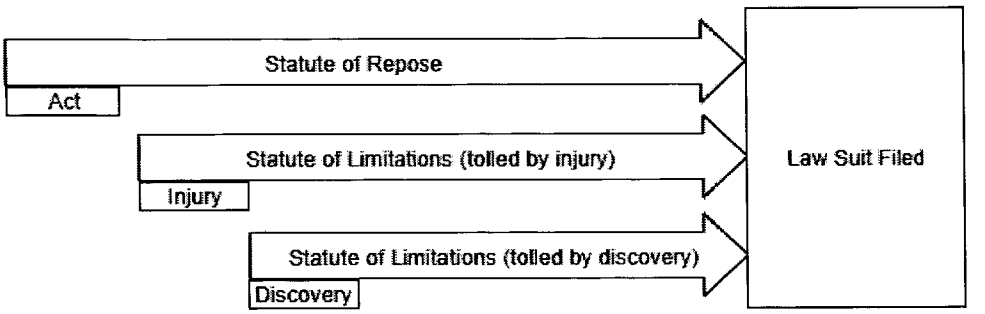
[44] *See, e.g.*, Blazevska v. Raytheon Aircraft Co., 522 F.3d 948, 950–52 (9th Cir. 2008) (holding that an eighteen-year statute of repose of the General Aviation Revitalization Act of 1994 bars products liability claims by survivors of passengers killed in airplane crash).

[45] *See, e.g.*, Rotella v. Wood, 528 U.S. 549, 553, 555 (2000).

[46] 54 C.J.S. *Limitations of Actions* § 250 (2019).

[47] *See infra* Part II.

Figure 1: Conceptual Model of SoR and SoL



The following sections describe cases involving defendant health care professionals and plaintiffs who suffered a harm but whose genetic malpractice claims were barred by various SLs, explaining how genetic conditions pose a particularly acute problem to traditional medical malpractice SLs.

II. EXAMPLES OF UNJUST OUTCOMES IN GENOMIC MALPRACTICE CASES

Genetic conditions will often present SoL and SoR issues because the discovery of the genetic risk may not occur until several years after a physician commits the allegedly negligent act, by which time the traditional SoL, SoR, or statutory notification requirement may have run. A recent analysis of over 200 genetic malpractice cases found that "the mean time between filing of a case and the final decision was 6.75 years,"[48] whereas other medical malpractice cases take a mean of just over 3.5 years from conduct to resolution.[49] Thus, genetic malpractice cases take, on average, almost twice as long to resolve as other medical malpractice cases. Presumably, the actual litigation of a genetic malpractice case does not take significantly longer than any other malpractice case, it is just that genetic malpractice cases are discovered and filed later after the time of medical error than in other medical malpractice cases.[50] This is because the negligent act regarding a genetic test is often not immediately manifest but may remain latent for years or even

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[48] Marchant & Lindor, *supra* note 1, at 15.

[49] *See* Seth A. Seabury et al., *On Average, Physicians Spend Nearly 11 Percent of Their 40-Year Careers with an Open, Unresolved Malpractice Claim*, 32 HEALTH AFF. 111, 113 (2013).

[50] *See* Marchant & Lindor, *supra* note 1, at 26.

decades before being discovered.[51] Thus, the traditional application of litigation timing requirements in a medical malpractice case involving genetics could result in manifestly unjust results.

SoRs result in particularly harsh results.[52] For example, consider a case decided by the Florida Supreme Court.[53] In this case, a family had their first child who was affected by multiple disabilities, and the parents then were tested for genetic abnormalities that might affect future children.[54] Even though the child did have a genetic abnormality (trisomy of part of chromosome 10), as revealed by chromosomal testing, that result was never communicated to the family.[55] The failure of the physician to communicate the genetic testing results to the family was the allegedly negligent act.[56] However, the harm caused by that negligent act did not arise until five years later when the couple had a second child with the same genetic condition, and the physician's error in failing to communicate the genetic results five years earlier was discovered.[57] It is important to note that, although the negligent act occurred five years later, the tort was not completed, and no lawsuit could have been filed, until the second child was born, as the harm caused by the negligence was the birth of the second affected child (damages are an essential precondition for filing a tort claim).[58] Although the parents filed their lawsuit two years after their second child was born, the Florida Supreme Court held that the lawsuit was barred by Florida's four-year statute of repose for medical malpractice actions.[59] In other words, the statute of repose had run before the tort was even complete.[60] The parents' right to sue had expired before a lawsuit could possibly have been filed, which is arguably a manifestly unjust outcome.

Another statute of repose case involved alleged negligence in failing to diagnose Long QT syndrome, a genetic condition that increases the risk of sudden death.[61] The physician defendant

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[51] *See id.* at 26–27.

[52] *See* Kush v. Lloyd, 616 So. 2d 415, 421–22 (Fla. 1992) (per curiam) (citing Melendez v. Dreis & Krump Mfg. Co., 515 So. 2d 735, 735–36 (Fla. 1987)).

[53] *Kush*, 616 So. 2d 415.

[54] *See id.* at 417.

[55] *See id.*

[56] *See id.*

[57] *See id.*

[58] *See* 3 DOBBS ET AL., *supra* note 19, § 479, at 2.

[59] *See Kush*, 616 So. 2d at 417, 421–22, 424 (citing Melendez v. Dreis & Krump Mfg. Co., 515 So. 2d 735, 735–36 (Fla. 1987)).

[60] *See id.* at 421.

[61] Burton v. Macha, 846 N.W.2d 419, 420–21 (Mich. Ct. App. 2014).

admitted Connor Burton into the hospital on June 21, 2005, for a tonsillectomy and adenoidectomy.[62] An EKG readout at the hospital reported "prolonged QT", and although the defendant reviewed and initialed the EKG report, he took no other action on this information.[63] Almost four years later, on April 17, 2009, Connor passed away suddenly, and his autopsy failed to detect any signs of injury or illness.[64] A few months later, on September 11, 2009, genetic testing revealed a mutation "strongly associated with an arrhythmia-causing syndrome, such as Type 3 Long QT Syndrome."[65] A month later, on October 13, 2009, Connor's death certificate was amended to reflect "[s]udden cardiac death due to or as a consequence of Prolonged QT Syndrome due to or as a consequence of Mutation SCN5A Thr 370 Type 3 Met (of years duration)."[66] Connor's family brought a medical malpractice lawsuit on October 13, 2011, alleging that the defendants were negligent in "failing to diagnose Connor with prolonged QT syndrome and failing to refer him for appropriate treatment."[67] The Court of Appeals of Michigan held that although the three-year statute of limitations did not start to run until the death certificate was amended based on the genetic testing in the fall of 2009, the six-year statute of repose started to run on the date of the negligent act (June 21, 2005), and therefore the lawsuit was precluded by the statute of repose.[68]

This case has a harsh outcome, although it is not as egregious as the previous one because the harm (Connor's sudden death) occurred before the statute of repose had completely run.[69] Yet, by the time the death certificate was revised, giving the family the first clue that a potentially negligent act had contributed to Connor's death, the family was left with only about twenty months to discover the negligence and file a lawsuit before the statute of repose had run.[70] Additionally, even though the lawsuit was filed well within the three-year statute of limitations, a claim just needs to exceed one of the applicable SLs to be dismissed.[71]

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[62] *See id.* at 420.
[63] *See id.* at 420–21.
[64] *See id.* at 420.
[65] *Id.*
[66] *Id.* at 420–21.
[67] *Id.* at 421.
[68] *See id.* at 420–23.
[69] *See id.* at 420–21, 423.
[70] *See id.* at 420–23.
[71] *See id.* at 421–22.

In another genetic SoR case, the Superior Court of Pennsylvania in 2017 upheld a trial court's finding for the defendant medical practitioner, awarding judgment based on an expired SoR.[72] In this case, a son donated a lobe of his liver to his mother, who was diagnosed with a genetic disorder, Alpha-1 Antitrypsin Deficiency (AATD), after testing in the same year as the donation purportedly demonstrated that the son did not have AATD.[73] Eleven years later, in 2014, when his mother was experiencing more liver issues, the family discovered the son's positive AATD test result from 2003.[74] A lawsuit was filed in 2015.[75] The SoR at issue in this case detailed a general rule for the SoR and an exception:

> § 1303.513. Statute of repose
> (a) General rule.--Except as provided in subsection (b) or (c), no cause of action asserting a medical professional liability claim may be commenced after seven years from the date of the alleged tort or breach of contract.
> (b) Injuries caused by foreign object.--If the injury is or was caused by a foreign object unintentionally left in the individual's body, the limitation in subsection (a) shall not apply.[76]

However, the state supreme court's previous precedent explained that "the injury need not have occurred, much less have been discovered."[77] Thus, because judicial gloss did not leave room to argue that "alleged tort" must include a cognizable, known injury, patients argued that (1) the SoR violated equal protection and due process in the Pennsylvania and U.S. Constitutions, and (2) the SoR violated the open courts provision of the Pennsylvania Constitution.[78] The state appellate court disagreed with the arguments, reasoning that (1) there is no fundamental human interest at stake in obtaining damages in civil claims and the foreign object exception is different

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[72] *See* Yanakos v. UPMC, No. 1331 WDA 2016, 2017 WL 3168991, at *7 (Pa. Super. Ct. July 26, 2017) (citing Swift v. Milner, 538 A.2d 28, 31 (Pa. Super. Ct. 1988); Booher v. Olczak, 797 A.2d 342, 345 (Pa. Super. Ct. 2002)), *cert. granted in part, denied in part*, 183 A.3d 346 (Pa. 2018) (per curiam), *and rev'd*, No. 10 WAP 2018, 2019 WL 5608534 (Pa. Oct. 31, 2019).

[73] *See Yanakos*, 2017 WL 3168991, at *1.

[74] *See id.*

[75] *Id.* at *2.

[76] *Id.* at *3; *accord* 40 PA. CONS. STAT. § 1303.513 (2019), *invalidated by* Yanakos v. UPMC No. 10 WAP 2018, 2019 WL 5608534 (Pa. Oct. 31, 2019).

[77] *Yanakos*, 2017 WL 3168991, at *3 (quoting Abrams v. Pneumo Abex Corp., 981 A.2d 198, 211 (Pa. 2009)).

[78] *Yanakos*, 2017 WL 3168991, at *2.

from the instant case because durability of evidence is not as strong as having evidence of wrongdoing nestled in one's body and (2) state Supreme Court precedent rejects the open courts argument to SoRs.[79]

On March 28, 2018, the Pennsylvania Supreme Court granted certiorari in this case to hear the specific question: "Does the [Medical Care Availability and Reduction of Error Act] MCARE Statute of Repose violate the Open Courts guarantees of the Pennsylvania Constitution, Article I, § 11, where it arbitrarily and capriciously deprives some patients of any access to courts, but permits actions by similarly situated patients?"[80] The Pennsylvania Supreme Court answered this question affirmatively on October 31, 2019, and struck down the MCARE statute of repose,[81] an outcome that will likely have an important impact on the role of SoRs in denying plaintiffs a viable litigation option in similar SoR cases.

SoLs can also produce harsh results in genetic malpractice cases, especially in states with very short statutes of limitation for medical malpractice actions.[82] An example is provided by a case in which a pregnant mother knew she was a carrier for the sickle cell trait and had the father of her fetus genetically tested in order to prevent conceiving a child with sickle cell disease.[83] On January 16, 1985, the hospital misread the test results and incorrectly reported that father was not a carrier, and the mother gave birth to a child on August 30, 1985.[84] The child was diagnosed with sickle cell disease, and the mother brought suit against the hospital.[85] She was first required to provide notice to the hospital, which she did on November 27, 1985, and then filed a lawsuit on September 11, 1986.[86] A lower court held that the statute of limitations was tolled by the "continuous treatment doctrine," under which the statute of limitations does not start to run until the end of the patient's treatment, which the lower court determined to be the date of the child's birth.[87] The lawsuit was brought within eighteen months of

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[79] *See id.* at *5–7 (first quoting Abdul-Akbar v. McKelvie, 239 F.3d 307, 317 (3d Cir. 2001); and then quoting Krason v. Valley Crest Nursing Home, 755 F.2d 46, 52 (3d Cir. 1985)) (citing Freezer Storage, Inc. v. Armstrong Cork Co., 382 A.2d 715, 720 (Pa. 1978)).

[80] Yanakos v. UPMC, 183 A.3d 346, 346–47 (Pa. 2018) (per curiam).

[81] *Yanakos*, 2019 WL 5608534, at *1.

[82] *See* Marchant & Lindor, *supra* note 1, at 26–29.

[83] Jorge v. N.Y.C. Health & Hosp. Corp., 590 N.E.2d 239, 239 (N.Y. 1992).

[84] *Id.* at 239–40.

[85] *Id.* at 240.

[86] Jorge v. N.Y.C. Health & Hosp. Corp., 563 N.Y.S.2d 411, 412 (App. Div. 1991), *rev'd*, 590 N.E.2d 239 (N.Y. 1992).

[87] *See Jorge*, 590 N.E.2d at 240 (citing Nykorchuck v. Henriques, 577 N.E.2d 1026, 1027 (N.Y. 1991)); *Jorge*, 563 N.Y.S.2d at 413.

the child's birth, when the mother first had the opportunity to discover the hospital's negligence, and therefore the lower court held that the suit was brought within the applicable SoL.[88] The New York Court of Appeals, in contrast, held that the statute of limitations started to run on the date that the father's erroneous genetic results were reported since that genetic test "was simply not committed in relation to the ongoing obstetric care that plaintiff received."[89] Thus, the eighteen-month statute of limitations ran throughout the remainder of the pregnancy, during which the mother had no way of knowing the hospital had made its mistake. Consequently, by the time the negligence was discovered and the lawsuit was filed, the eighteen-month statute of limitations had run, and the lawsuit was dismissed as time-barred.[90]

Another type of timing limitation is a requirement to provide advance notice of a pending lawsuit against a public entity, such as a city or a public university hospital.[91] This type of timing requirement, which is typically very short, can also produce unjust results in a genetic malpractice case.[92] In one such example involving a statutory notice requirement, a five-year-old girl died while being treated by a doctor employed by a public university clinic, and an autopsy and further research indicated that the patient had an undisclosed genetic heart condition.[93] Once the genetic risk factor was discovered after the girl's death, the mother promptly brought a lawsuit alleging the doctor was negligent in not diagnosing the girl's genetic heart ailment.[94] The case was dismissed because the plaintiff failed to comply with the notice requirement for a public entity, which requires that a medical malpractice plaintiff provide notice of the claim within ninety days of the negligent act.[95] In this case, the mother had no way to discover the negligent act until over ninety days after the negligent act occurred, but the court dismissed the claim nonetheless, even while acknowledging that the genetic nature of disease was not known during the ninety day notice period.[96]

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[88] *See Jorge*, 563 N.Y.S.2d at 412–14.

[89] *Jorge*, 590 N.E.2d at 240 (citing *Nykorchuck*, 577 N.E.2d at 1027).

[90] *Jorge*, 590 N.E.2d at 240 (citing *Nykorchuck*, 577 N.E.2d at 1027).

[91] *See* Marchant & Lindor, *supra* note 1, at 29.

[92] *See id.*

[93] *See* Hood v. Ramagopal, No. A-1480-13T4, 2015 WL 5008979, at *1–2 (N.J. Super. Ct. App. Div. Aug. 18, 2015).

[94] *See id.*

[95] *See id.* at *4, *6.

[96] *See id.* at *2, *6.

III. SOLUTIONS

The specific examples presented in the previous section portend a much greater forward-looking problem for the medical malpractice system. As genetics becomes an increasingly important part of clinical medicine,[97] and consequently as more cases of genomic malpractice are brought to the courts,[98] the problem of unjust application of SLs in such cases will surely proliferate. This is due to both the increased frequency of such cases,[99] and the inherent nature of genetic malpractice cases where a provider's error may remain "silent" and undetectable for years or even decades.[100] These genomic malpractice cases typically involve the failure to accurately obtain and apply information about future health risks, and so the harm and indication of error usually does not become apparent until those future genetic-related risks manifest.[101] By that time, under current legal doctrine, the SoL or SoR may well have expired.

How can legal systems respond when legal doctrine established to control technology in one era now become obsolete or result in unjust outcomes when applied to new technologies not anticipated when the original doctrine was established? One option would be to just accept some unjust applications—the world is not perfect, and if the legal doctrine is serving a useful purpose in most contexts (which is the case with SLs), then maybe some unjust applications are inevitable.[102] This strategy of complacency and non-action is becoming increasingly untenable in the era of clinical genomics, when more and more unjust results like the ones described in the previous section are expected occur.

A second strategy would be to throw out the old rules altogether and go without rules in that subject area.[103] SLs do serve important functions in protecting providers and the court system from stale cases and open-ended liability,[104] so eliminating SLs altogether is also an untenable solution. A third strategy would be to adopt *sui generis* SL rules just for genomic malpractice cases.[105] But

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[97] *See* Marchant & Lindor, *supra* note 1, at 1–2.

[98] *See id.* at 16.

[99] *Id.*

[100] *Id.*

[101] *See id.* at 15, 18–19, 26.

[102] *See* Methodist Healthcare Sys. of San Antonio v. Rankin, 307 S.W.3d 283, 292 (Tex. 2010) (citing S.V. v. R.V., 933 S.W.2d 1, 23 (Tex. 1996)).

[103] *See* 1 DOBBS ET AL., *supra* note 19, § 241, at 875.

[104] *See supra* notes 19–24 and accompanying text.

[105] Lyria Bennet Moses, *Sui Generis Rules*, *in* 7 THE GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL OVERSIGHT: THE PACING PROBLEM 77–78, 81 (Gary E.

technology-specific *sui generis* rules have many problems, including definitional issues, unfairness, and over-inclusivity and under-inclusivity.[106] Moreover, since SLs are adopted on a state-by-state basis by state legislatures,[107] it would be impractical to expect new laws to be adopted specifically for genetic malpractice cases in every state any time in the foreseeable future.

Since doing nothing, eliminating the existing SL rules, or adopting *sui generis* SLs for genomic malpractice are all untenable or infeasible, the remaining option would be to try to modify the application of SLs to avoid the harsh and unjust impacts in genomic malpractice cases.[108] There is a long history of courts, and to a lesser extent legislatures, modifying the application of SLs in other contexts where they were producing unfair or unjust outcomes.[109] Historically, courts have interpreted state timing statutes to instill a degree of flexibility by making findings of law that control (1) the starting time for the statutory clock, (2) time-outs (or "tolling"), and (3) selecting which statute applies to the case.[110] For example, courts in most states adopted a "discovery rule" under which the applicable statute of limitations would only start running once the plaintiff did or should have discovered the tortious act, rather than the traditional rule, which started the statute of limitations when the tortious act occurred.[111] Some precedents of judicial flexibility and creativity in applying statutory timing limitations and the lessons they may provide for genetic malpractice cases are provided in Section III.A. To address the unfair and unjust application of timing provisions in genetic malpractice suits, several other policy fixes are possible, which are addressed in Section III.B, below.

A. Past Precedents for Adjusting Litigation Timing Provisions to Avoid Injustice

Timing limitations such as SoL and SoR have resulted in unreasonable or unjust outcomes in other litigation contexts,[112] and

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Marchant et al. eds., 2011).

[106] *Id.* at 83–84, 86, 88.

[107] *See* 1 DOBBS ET AL., *supra* note 19, § 241, at 872.

[108] *See id.* § 241, at 875; Marchant & Lindor, *supra* note 1, at 26–27.

[109] *See* 1 DOBBS ET AL., *supra* note 19, § 241, at 875–76; Marchant & Lindor, *supra* note 1, at 26–27.

[110] 1 DOBBS ET AL., *supra* note 19, § 241, at 875.

[111] 2 J.D. LEE & BARRY A. LINDAHL, MODERN TORT LAW: LIABILITY AND LITIGATION, § 25.83, at 370–71 (rev. ed. 1994).

[112] *See, e.g.*, Am. Pipe & Const. Co. v. Utah, 414 U.S. 538, 540–44 (1974); Burnett v. N.Y. Cent. R.R. Co., 380 U.S. 424, 424–25 (1965).

in some cases, courts or legislatures have intervened to prevent such unfair results.[113] In one such example, a litigant brought a lawsuit in state court, but the court dismissed the case for improper venue.[114] The plaintiff then properly filed the same lawsuit in the federal court, but the district court and appellate court held that the action was now time barred because the SoL had expired.[115] The Supreme Court reversed, holding that although the SoL had technically run, the policy behind timing limitations is outweighed "where the interests of justice require vindication of the plaintiff's right."[116]

Another context that required judicial flexibility was when a harmed party was within a putative class in a prospective class action, but then the class was not certified for one reason or another.[117] By the time a court decides not to certify the class, it may be too late under the SoL for prospective class members to file individual lawsuits. The U.S. Supreme Court held that in at least some such circumstances the SoL for individual lawsuits by putative class members is tolled during the pendency of the class certification process.[118] The Court stated that tolling the SoL in such circumstances was within the power of the courts since it was consistent with "the policies of ensuring essential fairness to defendants and of barring a plaintiff who 'has slept on his rights.'"[119] Such a judicial modification to the application of the SoL "is in no way inconsistent with the functional operation of a statute of limitations."[120]

Another judicial innovation to address injustices created by rigid application of the statute of limitations is the "two disease" rule.[121] For example, plaintiffs exposed to hazardous substances, such as asbestos, face a dilemma due to the typical lag between exposure and a diagnosis of mesothelioma.[122] The initial symptom of a disease process, however, is a condition known as asbestosis, which is usually not life threatening, and in many cases followed by a much more

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[113] *See, e.g.*, *Am. Pipe & Const. Co.*, 414 U.S. at 555; *Burnett*, 380 U.S. at 430, 434–35.

[114] *Burnett*, 380 U.S. at 424–25.

[115] *Id.* at 425 (first citing Burnett v. N.Y. Cent. R.R. Co., 230 F. Supp. 767, 767–68 (S.D. Ohio 1963); and then citing Burnett v. N.Y. Cent. R.R. Co., 332 F.2d 529, 531 (6th Cir. 1964)).

[116] *Burnett*, 380 U.S. at 428, 434–36.

[117] *See Am. Pipe & Const. Co.*, 414 U.S. at 542–43.

[118] *Id.* at 560–61.

[119] *Id.* at 554 (quoting *Burnett*, 380 U.S. at 428).

[120] *Am. Pipe & Const. Co.*, 414 U.S. at 554.

[121] *See* Daley v. A.W. Chesterton, Inc., 37 A.3d 1175, 1177 (Pa. 2012).

[122] *See* James A. Henderson, Jr. & Aaron D. Twerski, *Asbestos Litigation Gone Mad: Exposure-Based Recovery for Increased Risk, Mental Distress, and Medical Monitoring*, 53 S.C. L. REV. 815, 820 & n.18 (2002).

lethal mesothelioma several years or decades later.[123] If an exposed person suffering from asbestosis brings a lawsuit at the onset of initial symptoms, she would be barred by *res judicata* from bringing a second lawsuit years later if and when she developed mesothelioma.[124] But if she waited to file a lawsuit until she developed a more serious condition, such as mesothelioma, the defendant would argue that the statute of limitations started to run when the plaintiff first experienced asbestosis, and thus were barred from bringing a subsequent suit.[125] Some states such as Virginia still apply that harsh rule.[126] But courts in other states used their equitable authority to adopt a "two disease" rule, in which each disease has its own statute of limitations, even though they result from the same tortious act.[127]

In more recent years, the courts have used the term "equitable tolling" to refer to a court's inherent authority to toll a statute of limitations when justice so requires.[128] The Supreme Court has generally become more strict over time in applying the equitable tolling doctrine, now limiting its application to situations in which the litigant establishes two elements: "(1) that he has been pursuing his rights diligently, and (2) that some extraordinary circumstance stood in his way and prevented timely filing."[129] In addition, the Supreme Court has expressly held that equitable tolling applies only to statutes of limitation and not statutes of repose.[130]

A similar but distinct doctrine is the "accrual suspension doctrine," which holds that a cause of action does not accrue when the "defendant has concealed its acts with the result that plaintiff was unaware of their existence or it must show that its injury was 'inherently unknowable' at the accrual date."[131] The accrual suspension doctrine is "well settled" in case law and "distinct from

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[123] *See id.* at 817 n.2, 820 n.18.

[124] *Res Judicata*, BLACK'S LAW DICTIONARY (11th ed. 2019); Henderson & Twerski, *supra* note 122, at 819–20.

[125] *See* Pustejovsky v. Rapid-Am. Corp., 35 S.W.3d 643, 646 (Tex. 2000); Henderson & Twerski, *supra* note 122, at 820.

[126] *See* Kiser v. A.W. Chesterton Co., 736 S.E.2d 910, 913 (Va. 2013).

[127] Wilson v. Johns-Manville Sales Corp., 684 F.2d 111, 112, 120–21 (D.C. Cir. 1982).

[128] *See* Holland v. Florida, 560 U.S. 631, 649 (2010) (quoting Pace v. DiGuglielmo, 544 U.S. 408, 418 (2005)); Honda v. Clark, 386 U.S. 484, 500 (1967).

[129] Menominee Indian Tribe of Wis. v. United States, 136 S. Ct. 750, 755 (2016) (quoting *Holland*, 560 U.S. at 649 (2010)).

[130] Cal. Pub. Emps.' Ret. Sys. v. ANZ Sec., Inc., 137 S. Ct. 2042, 2045 (2017) ("[T]he Court repeatedly has stated that statutes of repose are not subject to equitable tolling.").

[131] Japanese War Notes Claimants Ass'n v. United States, 373 F.2d 356, 358–59 (Ct. Cl. 1967) (quoting Urie v. Thompson, 337 U.S. 163, 169 (1949)).

the question whether equitable tolling is available."[132] This doctrine has traditionally been applied in contractual claims cases against the United States Government involving the interpretation of the term "accrual" in 28 U.S.C. § 2501,[133] but the same equitable doctrine could possibly be applied in other contexts, especially when the statute of limitations used the term "accrual."

The treatment of SLs by courts seems inconsistent—sometimes they are applied flexibly and adjusted by equitable factors, while other times they are applied rigidly as jurisdictional requirements with no flexibility.[134] Justice Breyer recently tried to reconcile this disparate treatment as follows:

> Most statutes of limitations seek primarily to protect defendants against stale or unduly delayed claims. . . . Such statutes also typically permit courts to toll the limitations period in light of special equitable considerations.
>
> Some statutes of limitations, however, seek not so much to protect a defendant's case-specific interest in timeliness as to achieve a broader system-related goal, such as facilitating the administration of claims, limiting the scope of a governmental waiver of sovereign immunity, or promoting judicial efficiency. The Court has often read the time limits of these statutes as more absolute. . . . As convenient shorthand, the Court has sometimes referred to the time limits in such statutes as "jurisdictional."[135]

Medical malpractice actions are primarily intended to protect health care providers from stale claims and uncertainty,[136] rather than serving some governmental purpose as in the examples cited by Justice Breyer requiring a more absolute approach,[137] and thus should be open to equitable discretion by courts to prevent unjust results.

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[132] Martinez v. United States, 333 F.3d 1295, 1319 (Fed. Cir. 2003).

[133] *See* 28 U.S.C. § 2501 (2012); *Martinez*, 333 F.3d at 1318–19; Kinsey v. United States, 852 F.2d 556, 557 (Fed. Cir. 1988) (quoting Oceanic S.S. Co. v. United States, 165 Ct. Cl. 217, 225 (1964)).

[134] *See* John R. Sand & Gravel Co. v. United States, 552 U.S. 130, 133–34 (2008).

[135] *Id.* at 132–34 (internal citations omitted).

[136] *See* Ruther v. Kaiser, 983 N.E.2d 291, 298 (Ohio 2012); *cf. John R. Sand & Gravel Co.*, 552 U.S. at 133 ("Most statutes of limitations seek primarily to protect defendants against stale or unduly delayed claims.").

[137] *See John R. Sand & Gravel Co.*, 552 U.S. at 133–34.

Another strategy for challenging unreasonable applications of statutes of limitations or statutes of repose is to argue that such application violates the applicable state constitution,[138] which often contain provisions assuring a citizen's right to litigate valid legal claims.[139] For example, the New Hampshire Supreme Court held that a statute of repose that denied a plaintiff a remedy for an injury from a defective machine tool that occurred after the statute of repose had run was unconstitutional (the lower court had held that the statute of repose had started to run when the defective tool was sold by the defendant).[140] The court cited approvingly this colorful passage from a dissenting opinion in another case:

> Except in topsy-turvy land, you can't die before you are conceived, or be divorced before ever you marry, or harvest a crop never planted, or burn down a house never built, or miss a train running on a non-existent railroad. For substantially similar reasons, it has always heretofore been accepted, as a sort of logical "axiom," that a statute of limitations does not begin to run against a cause of action before that cause of action exists, i.e., before a judicial remedy is available to a plaintiff.[141]

This "logical axiom" arguably applies to all cases in which there was no cognizable harm until after the SL expired, but not all states have this logical axiom codified in precedent.

There have, however, been other medical malpractice cases where the statute of repose expired before the plaintiffs had any reason to know of the negligent act, and the court did not find the statute unconstitutional.[142] For example, the Ohio Supreme Court upheld that state's four-year statute of repose for medical malpractice cases against a constitutional challenge in 2012.[143] The defendant physician and hospital in that case had allegedly failed to act on abnormal liver enzyme tests for a patient who was diagnosed with liver lesions and hepatitis C some ten years later.[144] The Ohio Supreme Court overturned the lower court decision that held the

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[138] *See* Heath v. Sears, Roebuck & Co., 464 A.2d 288, 291–92 (N.H. 1983).

[139] *See id.* at 294.

[140] *Id.* at 292, 296.

[141] *Id.* at 295–96 (quoting Dincher v. Marlin Firearms Co., 198 F.2d 821, 823 (2d Cir.1952) (Frank, J., dissenting)).

[142] *See, e.g.*, Ruther v. Kaiser, 983 N.E.2d 291, 300 (Ohio 2012).

[143] *See id.* at 293.

[144] *Id.* at 293.

statute of repose unconstitutional because it extinguished the plaintiff's legal claim before such a claim was cognizant.[145] The higher court held that the legislature was within its power to establish "a period beyond which medical claims may not be brought even if the injury giving rise to the claim does not accrue because it is undiscovered until after the period has ended."[146] The state supreme court found that the legislature's decision had a rational basis that the courts were required to defer to:

> Forcing medical providers to defend against medical claims that occurred 10, 20, or 50 years before presents a host of litigation concerns, including the risk that evidence is unavailable through the death or unknown whereabouts of witnesses, the possibility that pertinent documents were not retained, the likelihood that evidence would be untrustworthy due to faded memories, the potential that technology may have changed to create a different and more stringent standard of care not applicable to the earlier time, the risk that the medical providers' financial circumstances may have changed—i.e., that practitioners have retired and no longer carry liability insurance, the possibility that a practitioner's insurer has become insolvent, and the risk that the institutional medical provider may have closed.[147]

The Supreme Court of Wisconsin reached a similar decision in a case involving a child who was born with a congenital condition that later caused blindness, but which was not discovered until after her tenth birthday.[148] A lawsuit was then filed against the doctor who had treated her as a newborn, but the supreme court held that the claim was barred by the state's five-year statute of repose for medical malpractice actions.[149] Recognizing the "harsh" implications of its decision,[150] the supreme court nevertheless held that "the legislature may sever a person's claim by a statute of limitations or a statute of repose when the person has had no possibility of discovering the injury-when the person has been blameless in every respect. These

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[145] *Id.* at 292, 293–94 (citing and quoting Ruther v. Kaiser, No. CA2010-07-066, 2011 WL 1346836, at *1, *6 (Ohio Ct. App. Apr. 11, 2011)).

[146] *Ruther*, 983 N.E.2d 291 at 296, 300.

[147] *Id.* at 296.

[148] *See* Aicher v. Wis. Patients Comp. Fund, 613 N.W.2d 849, 853–55 (Wis. 2000).

[149] *Id.* at 854–55, 873.

[150] *Id.* at 873.

decisions represent judicial deference to the stated policy of the legislature."[151]

Thus, a constitutional challenge to a timing limitation that prevents a plaintiff from bringing a valid case before they even had reason to know they had a claim will succeed in some but not all situations. The Supreme Court of Pennsylvania recently held a statute of repose unconstitutional in a genomic malpractice case.[152] In situations where a judicial solution is not available on either equitable or constitutional grounds, the legislature would be the last resort for a remedy to abolish or modify an unfair statutory timing limitation that prevents plaintiffs from bringing valid claims.[153] For example, Illinois originally had a two-year statute of limitations and a twelve-year statute of repose for personal injury actions from childhood sexual abuse, but in 1994, eliminated the twelve-year statute of repose, apparently, in response to a series of discovered childhood sexual abuse cases, which would have been time-barred by the statute of repose notwithstanding the due diligence of the plaintiffs.[154] Another example is that in some states, such as Mississippi and Massachusetts, the state legislature, rather than the courts, enacted a discovery rule for starting the clock on the statute of limitations when the plaintiff discovers the tort, rather than when the tort occurs, in at least some tort cases.[155]

Perhaps the most pertinent example is the recent legislative activity in the State of New York to pass "Lavern's Law," a bill that redefines the state's statute of limitations for medical malpractice claims by cancer patients by extending the initiation time from when the medical mistake is made (often involving a physician failing to make an earlier cancer diagnosis) forward in time to when the cancer is discovered.[156] The bill was named after a cancer patient named Lavern Wilkinson who died from cancer and was denied the right to pursue a medical malpractice case due to the existing SoL.[157] The case attracted much attention, particularly in the *Daily News*, and

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[151] *Id.* at 864.

[152] Yanakos v. UPMC, No. 10 WAP 2018, 2019 WL 5608534, at *11 (Pa. Oct. 31, 2019).

[153] *See Aicher*, 613 N.W.2d at 865 (citing Tomczak v. Bailey, 578 N.W.2d 166, 170–71 (Wis. 1998)).

[154] Doe v. Boy Scouts of Am., 66 N.E.3d 433, 454 (Ill. App. Ct. 2016) (citing Doe v. Diocese of Dall., 917 N.E.2d 475, 484 (Ill. 2009)).

[155] MASS. GEN. LAWS ch. 260, § 4C (2019); MISS. CODE ANN. § 15-1-36 (2019); 1 DOBBS ET AL., *supra* note 19, § 243, at 877–78.

[156] *See* Editorial, *Reset the Clock for Malpractice Suits*, N.Y. TIMES (Aug. 18, 2017), https://www.nytimes.com/2017/08/18/opinion/new-york-laverns-law-malpractice.html [https://perma.cc/E686-ED36].

[157] *See id.*

resulted in reform legislation that passed both houses of the New York legislature and was signed into law by the Governor on January 31, 2018.[158] The changes to the SoL in the new bill only apply to cancer patients,[159] but this bill sets a precedent that similar changes could be made for genetic malpractice cases.

B. Solutions for Unjust Timing Limitations in Genetic Malpractice Cases

From the examples discussed above involving non-genomic contexts, there are several possible approaches to avoid the unjust application of statutes of limitation, statutes of repose, or statutory notification requirements in genetic malpractice cases. Courts can use their discretion and creativity by applying doctrines such as equitable tolling to avoid unfair and unjust application of statutory time limitations in genetic malpractice cases. In at least two cases, the court used such discretion in a genetic malpractice case. The first case involved a physician who failed to report a positive PKU test of a newborn girl, who was then disabled throughout her life but was never diagnosed with PKU.[160] Decades later, she gave birth to a son who had microcephaly, and it was then discovered that high levels of phenylalanine in the mother's blood due to her PKU caused the son's severe impairment.[161] Although decades had passed since the negligent act had occurred, the Indiana Appellate Court held that the statute of limitations did not start to run until the mother discovered her PKU status, and hence, the physician's negligence, several decades later.[162] The court of appeals noted,

> We are, of course, fully cognizant that we are permitting a nearly four-decade old claim of malpractice to proceed at this time. Nonetheless, it is not unheard of in our jurisprudence to permit lawsuits based upon decades-old acts of negligence

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[158] *See* Heidi Evans, *Hospital's Mistake Leaves Single Brooklyn Mom with 6 Months to Live*, DAILY NEWS (Jan. 6, 2013, 2:00 AM), https://www.nydailynews.com/life-style/health/hospital-mistake-leaves-single-mom-6-months-live-article-1.1233989 [https://perma.cc/F4WT-578C]; Michael T. Hensley & Lauren Fenton-Valdivia, *New York's Lavern's Law Expands the Discovery Rule Such that the Statute of Limitations Runs from the Cancer Diagnosis*, BRESSLER, AMERY & ROSS, P.C. (Feb. 15, 2018), https://www.bressler.com/new-yorks-laverns-law-expands-the-discovery-rule-such-that-the-statute-of-limitations-runs-from-the-cancer-diagnosis [https://perma.cc/S235-VY7X]; Editorial, *Reset the Clock for Malpractice Suits*, *supra* note 156.

[159] Hensley & Fenton-Valdivia, *supra* note 158.

[160] Houser v. Kaufman, 972 N.E.2d 927, 930–31 (Ind. Ct. App. 2012).

[161] *Id.* at 931–32.

[162] *Id.* at 937–38.

> to proceed, under very limited circumstances. . . . Stacy has been forced to suffer needlessly from a debilitating, but treatable, illness for almost forty years. Given the highly unique facts here, and given the designated evidence of diligence by Stacy and her parents with respect to her PKU diagnosis (or lack thereof for the first thirty-three years of her life), we conclude that allowing this case to proceed does not contravene public policy and is consistent with the Act's goals of maintaining sufficient medical treatment and controlling malpractice insurance costs by, in part, encouraging the prompt presentation of claims.[163]

A second example is a New York case in which a couple used in vitro fertilization (IVF) with an egg donor to give birth to twin sons.[164] The IVF clinic purported to have genetically screened the egg donor, but one of the conceived children was determined to have fragile X syndrome many months after the child was born.[165] The New York statute of limitations for a medical malpractice action required a lawsuit to be filed within 2.5 years of "the act, omission or failure" that was the subject of the lawsuit.[166] The defendant argued, and the plain reading of the statute would suggest, that the act of failing to adequately test the egg donor occurred before the IVF procedure, in which case the statute of limitations would have expired by the time the lawsuit was filed.[167] The New York court, however, used creativity and held that the statute started to run when the child was born, explaining that in a "claim for wrongful birth, 'the parents' legally cognizable injury is the increased financial obligation' of raising an impaired child" and "[w]hether this legally cognizable injury will befall potential parents as the result of the gestation of an impaired fetus cannot be known until the pregnancy ends. Only if there is a live birth will the injury be suffered."[168] The case was therefore ruled to be timely and allowed to proceed, a decision that was upheld on appeal.[169]

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[163] *Id.* at 938 (citing Van Dusen v. Stotts, 712 N.E.2d 491, 496 (Ind. 1999)).

[164] B.F. v. Reprod. Med. Assocs. of N.Y., 22 N.Y.S.3d 190, 192 (App. Div. 2015), *aff'd*, 92 N.E.3d 766 (N.Y. 2017).

[165] *Id.*

[166] *Id.* at 193 (quoting N.Y. C.P.L.R. 214-a (McKinney 2019)).

[167] *See B.F.*, 22 N.Y.S.3d at 193–94.

[168] *Id.* at 194–95 (quoting Foote v. Albany Med. Ctr. Hosp., 944 N.E.2d 1111, 1113 (N.Y. 2011)).

[169] B.F. v. Reprod. Med. Assocs. of N.Y., 92 N.E.3d 766, 773 (N.Y. 2017).

Judges and attorneys in other genetic malpractice cases in which the statute of limitations would unfairly bar a plaintiff from bringing a genetic malpractice lawsuit could similarly invoke their equitable powers and creativity to extend the time for bringing the case. Unfortunately, such a strategy will likely not work for statutes of repose. As the U.S. Supreme Court has explained, "Statutes of repose, on the other hand, generally may not be tolled, even in cases of extraordinary circumstances beyond a plaintiff's control."[170]

However, a recent genetic malpractice case in North Carolina demonstrated another creative way that a court was able to circumvent the unjust results of a statute of repose.[171] In that case, a pregnant wife engaged the defendant for prenatal care, which included genetic testing for cystic fibrosis carrier status.[172] Although the genetic test results found the woman was a cystic fibrosis carrier, which normally would have led to testing of the husband and then fetus, the physician erroneously wrote in the medical record and communicated to the couple that the wife had tested negative for cystic fibrosis carrier status.[173] The couple had a healthy child, but several years later she got pregnant again.[174] Because the wife's medical records showed that she did not carry a cystic fibrosis mutation, she was not genetically tested again.[175] Unfortunately, she gave birth to a child who was subsequently diagnosed with cystic fibrosis, over five years after the original mistake was made in misdiagnosing the wife.[176] The parents soon thereafter filed a medical malpractice lawsuit, but the defendants argued, and the trial court held, that the suit must be dismissed because it was barred by the state's four-year statute of repose for medical malpractice.[177] The Court of Appeals overturned this decision, however, by determining that same health care facility provided care for the couple during both pregnancies, and thus under the "continuing course of treatment" doctrine had continued to provide care and perpetuate the original error through the second pregnancy.[178] The four-year statute of repose therefore did not start to run until the final pre-conception

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[170] CTS Corp. v. Waldburger, 573 U.S. 1, 9 (2014).

[171] *See* Glover v. Charlotte-Mecklenburg Hosp. Auth., No. COA 17-1398, 2018 WL 4440582, at *7 (N.C. Ct. App. Sept. 18, 2018).

[172] *Id.* at *1.

[173] *Id.*

[174] *Id.* at *1–2.

[175] *Id.* at *2.

[176] *See id.*

[177] *Id.* at *3.

[178] *Id.* at *7.

appointment in the second pregnancy so that the lawsuit was timely.[179] In reaching this decision, the North Carolina Court of Appeals was clearly troubled by the equities of the situation:

> Plaintiffs did not know, nor should they have known, of the malpractice that had occurred—that of incorrect information regarding Ms. Glover being a cystic fibrosis carrier—until the birth of their son, J.G. It would be senseless to expect Plaintiffs would presciently know of the misinformation, before a problem arose, and would leave no recourse for Plaintiffs. As they moved forward with family planning decisions, such unknown abnormalities could have arisen many years later. No matter the number of years, the information would have been new to Plaintiffs. For the above reasons, we find the "continuing course of treatment" doctrine squarely applies.[180]

In cases where judicial discretion under the equitable tolling or other doctrines are unavailable to prevent unjust application of timing limitations, state constitutional arguments may provide an alternative argument for not applying the statute of limitations, statute of repose, or statutory notice requirement where it will unfairly deprive a plaintiff from bringing a case to vindicate their rights.[181] As described previously, some but not all state courts have held statutes of limitation or repose unconstitutional as applied to limit a plaintiff's right to bring a timely claim because the statute had run before the plaintiff knew the cause of the injury.[182] This type of constitutional claim may be most often invoked against statutes of repose because they are not subject to the equitable tolling or adjustment that the courts have often applied to statutes of limitation.

In at least one case, a court has upheld a constitutional challenge to a statute of limitations that had run before the plaintiffs would have had time to realize they had a viable genetic malpractice claim.[183] In that case, a couple who had already had one child with Duchenne's muscular dystrophy got pregnant again and sought

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[179] *Id.* at *8.

[180] *Id.* at *7.

[181] *See, e.g.*, Heath v. Sears, Roebuck & Co., 464 A.2d 288, 296 (N.H. 1983).

[182] *See, e.g., id.*; Nelson v. Krusen, 678 S.W.2d 918, 923 (Tex. 1984); Susan C. Randall, Comment, *Due Process Challenges to Statutes of Repose*, 40 SW. L.J. 997, 1001 n.18 (1986).

[183] *Nelson*, 678 S.W.2d at 923.

genetic testing to determine whether the mother was a carrier.[184] The genetics expert they consulted conducted genetic testing of the mother and reported that she did not carry the condition.[185] Three years after the second child was born, he was diagnosed with Duchenne's muscular dystrophy.[186] The parents filed a medical malpractice lawsuit, but it was dismissed on the grounds that the two-year statute of limitations had started to run at the time of the negligent genetic advice and had, therefore, expired.[187] The Texas Supreme Court reversed this decision, holding that applying the two-year statute of limitations to prevent the parents from bringing a suit after they first learned of the mistake after the correct genetic diagnosis of their child violated the open courts provision of the state constitution "by cutting off a cause of action before the party knows, or reasonably should know, that he is injured."[188] The state supreme court described such an unfair outcome as "shocking" and "absurd."[189]

If neither an equitable or constitutional court challenge to an unjust SoL or SoR is available, the final option is legislative relief.[190] It may be difficult to persuade state legislators to take up this issue when only a handful cases have presented problems to date. However, if genomic malpractice cases become more prevalent, and more plaintiffs are unfairly denied an opportunity to pursue their claims on the merits due to the unique timing issues in many genetic malpractice cases, it is possible that a legislative remedy could eventually be feasible.[191] A high-profile case that stirs public outrage at the unfairness and injustice of the outcome, as has recently occurred in New York with Lavern's Law,[192] would likely be necessary to get sufficient political traction and support. At a minimum, given that statutes of repose only exist in some but not all states in the medical context, legislatures should be wary of adopting new statutes of repose that would apply to genomic malpractice cases.

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[184] *Id.* at 919–20.

[185] *Id.* at 920.

[186] *Id.*

[187] *Id.* at 919.

[188] *Id.* at 919, 922–23.

[189] *Id.* at 923 (quoting Hays v. Hall, 488 S.W.2d 412, 414 (Tex. 1972); Gaddis v. Smith, 417 S.W.2d 577, 681 (Tex. 1967)).

[190] *See, e.g.*, Editorial, *Reset the Clock for Malpractice Suits*, *supra* note 156.

[191] *See supra* notes 154–155 and accompanying text.

[192] *See supra* notes 156–158 and accompanying text.

CONCLUSION

Genetic malpractice cases present unique timing issues because they often involve negligent acts that do not result in manifested clinical outcomes until several years or even a generation or two later. As a result, the fair resolution of such cases will often be in tension with statutory timing limits such as statutes of limitations and statutes of repose. There have already been several cases where plaintiffs allegedly harmed by a provider's negligent act relating to genetic information were denied an opportunity to prosecute their case because they did not discover the tort until after the timing limit had expired. Judges and attorneys should be aware that there may be judicial tools available to counter unfair and unjust applications of statutory timing limits. In particular, the courts can use equitable tolling or other equitable patterns to ensure fair application of the statute of limitations by providing the plaintiff a reasonable opportunity and time to file a lawsuit after the time in which they did or reasonably should have discovered the existence of their legal claim. Statutes of repose present a greater challenge, since they are generally not subject to equitable modifications, and therefore a constitutional challenge is the most promising approach. If a judicial solution is not available, then legislative modifications of the statutory timing limitation may be the only recourse for plaintiffs denied a fair opportunity to litigate their genetic malpractice claim.