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# **GENOMIC MALPRACTICE: AN EMERGING TIDE OR GENTLE RIPPLE?**

**GARY E. MARCHANT AND RACHEL A. LINDOR\***

## **ABSTRACT**

Genomics is becoming a prevalent part of medical practice as we move into an era of personalized or precision medicine. Yet most physicians have had no formal training in genetics, and there are concerns about whether the health infrastructure is prepared for the clinical implementation of genomic medicine. Given this situation, medical malpractice litigation, which we refer to in the genomics context as genomic malpractice, would seem to be a major threat to health care providers. This paper identifies ten “red flags” signaling potential liability risk for health care providers relating to genomic medicine. Additionally, this paper provides the first ever comprehensive empirical study of genomic malpractice litigation in the United States. Over the past 40 years of such litigation, the frequency of such cases has risen modestly, but still remains at a fairly low level with 12 or fewer reported cases being closed per year. A total of 202 reported cases were identified and analyzed. Even more perplexing, the cases that have been litigated demonstrate a relatively high rate of success for plaintiffs; moreover, the average payout in such cases is an order of magnitude higher than traditional medical malpractice cases. The study concludes by assessing the reasons behind the relatively low rate of litigation, which is attributed primarily to the slower than expected uptake of genomic medicine by health care providers and the reluctance of plaintiffs’ lawyers to take such complex and scientifically-intense cases. However, given the 10 red flags discussed in the paper and the herd behavior of plaintiffs’ attorneys, there is no basis for complacency going forward as genomics continues to infuse more and more areas of the practice of medicine.

## **INTRODUCTION**

The age of widespread medical genomics has arrived, powered by innovations in DNA sequencing and gene discovery. Although clinical implementation of genomics is lagging behind the rapid development of genomic science, it now seems to be gathering momentum and becoming an important element of many areas of medical practice. The U.S. government’s “Precision Medicine Initiative” to accelerate the

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implementation and use of personalized medicine will further spur the growth of genomic science and genomic medicine.<sup>1</sup>

The rapid growth in genomic science and genomic medicine may also be triggering a third wave of genomic innovation, genomic liability, which is lagging even further behind genomic science and genomic medicine but is now gaining momentum. Over the past decade, experts have repeatedly warned about a potential tsunami of medical malpractice lawsuits for negligent performance of genetic testing.<sup>2</sup> This third wave of genomics involves liability risks for health care providers who fail to properly apply new developments in genomic science and medicine. We refer to this malpractice liability against physicians and other health care professionals for negligent implementation of genomic medicine as “genomic malpractice.”<sup>3</sup>

Medical malpractice liability is a double-edged sword affecting both safety and effectiveness in the practice of medicine. On one hand, the threat of malpractice liability can cause health care providers to exercise greater care and to be more diligent in adopting the best practices and technologies available for health care delivery. On the other hand, liability can cause uncertainty and unfairness for health care professionals and can lead to maladaptive responses such as defensive medicine and prohibitive malpractice insurance premiums.<sup>4</sup> Genomic malpractice invokes both the good and bad dimensions of medical malpractice and will present new challenges for all participants in the medical malpractice system, including providers, patients, judges, attorneys and malpractice insurers. Notwithstanding the potential importance of liability in influencing the future direction and uptake of genomic medicine, relatively little is known about, and very little empirical research has been conducted on, the liability risks associated with the clinical implementation of genomic medicine.<sup>5</sup>

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<sup>1</sup> Francis S. Collins & Harold Varmus, *A New Initiative on Precision Medicine*, 372 *NEW ENG. J. MED.* 793 (2015).

<sup>2</sup> Amy Lynn Sorrel, *Judging Genetic Risks: Physicians Often Caught Between What Patients Want and What Science Offers*, *AM. MED. NEWS* (Nov. 10, 2008), *Amednews.com* [<https://perma.cc/E5AJ-WRXH>] (rapidly evolving world of personalized medicine “portends a world of potential legal liability for physicians, experts say”); John Carroll, *Genetic Testing: Counselors Desperately Needed*, 6(2) *BIOTECHNOLOGY HEALTHCARE*, 14, 21 (2009) (given rapid increase in genetic testing, “[t]hese are very dangerous times for practicing physicians”); Mark A. Rothstein, *Liability Issues in Pharmacogenetics*, 66 *LA. L. REV.* 117, 123 (2005) (“[C]oncerns about liability may prove to be a key factor that drives the adoption of pharmacogenomics tests and medications.”).

<sup>3</sup> The term “genetic malpractice” has previously been used in the literature. *See, e.g.*, Carolyn Lee Brown, Editorial Note, *Genetic Malpractice: Avoiding Liability*, 54 *U. CIN. L. REV.* 857, 858 n.2 (1986); M.J. Howlett, Denise Avard & B.M. Knoppers, *Physicians and Genetic Malpractice*, 21 *MED. & L.* 661, 667 (2002). As the science and medicine has expanded from genetics (characterization and testing of single genes) to genomics (studying multiple genes and gene products), the new term “genomic malpractice” is now an appropriate descriptor.

<sup>4</sup> *See, e.g.*, David M. Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 *JAMA* 2609, 2609–10 (2005); Daniel Kessler & Mark McClellan, *Do Doctors Practice Defensive Medicine?*, 111 *QUART. J. ECON.* 353 (1996).

<sup>5</sup> Legal scholars have discussed the potential importance of genetic and genomic malpractice but to date have necessarily based such analyses mostly on predictions and specific examples rather than systemic empirical evidence. *See, e.g.*, Gary E. Marchant & Rachel A. Lindor, *Commentary, Personalized Medicine and Genetic Malpractice*, 15 *GENETICS MED.* 921, 922 (2013); Gary E. Marchant, Rachel A. Lindor & Doug E. Campos-Outcalt, *Physician Liability: The Next Big Thing for Personalized Medicine?*, 8 *PERSONALIZED MED.* 457, 465 (2011); Barbara J. Evans, *Finding a Liability-Free Space in which Personalized Medicine*

In this Article, we examine the underlying factors and empirical trends of genomic malpractice litigation. The focus here is primarily on physicians, testing laboratories and other health providers, although pharmaceutical manufacturers,<sup>6</sup> test developers,<sup>7</sup> pharmacists,<sup>8</sup> and researchers<sup>9</sup> also face potential liability risks relating to genomic medicine. Part I describes the rise of genomic science and genomic medicine, now subsumed under the name of Precision Medicine, and the factors that may impede the uptake of such technologies by physicians and other health care providers, thereby opening the door to potential malpractice claims. Part II summarizes the doctrinal and technological drivers of medical malpractice litigation, and why genomic medicine may create significant malpractice opportunities and concerns. Part III provides an empirical analysis of reported genomic malpractice cases through the end of 2016, identifying temporal trends and the types of claims and defenses asserted in such lawsuits. Finally, Part IV provides some observations and conclusions about the results of the empirical analysis and their implications for the future of genomic medicine and genomic malpractice litigation.

## I. THE RISE OF GENOMIC SCIENCE AND PRECISION MEDICINE

The completion of the sequencing of the first human genome in 2003 as the primary endeavor of the Human Genome Project (HGP) was the starting gun for the new era of genomic medicine.<sup>10</sup> Medical researchers and practitioners had identified and applied tests for a number of rare genetic disorders for several decades before the HGP was completed in 2003, but the new sequence data and associated tools made available by the HGP sparked the rapid increase in the number of clinically available genetic tests that are available to physicians and health care providers.<sup>11</sup>

The practice of medicine in the United States is on the verge of a profound paradigm shift from the “one size fits all” approach of the past to the new model of precision medicine (sometimes also called personalized or individualized medicine) in which a

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*Can Bloom*, 82. CLINICAL PHARMACOLOGY & THERAPEUTICS 461 (2007); Gary E. Marchant, Robert R. Milligan & Brian Wilhelmi, *Legal Pressures and Incentives for Personalized Medicine*, 3 PERSONALIZED MED. 391 (2006); Lori B. Andrews, *Torts and the Double Helix: Malpractice Liability for Failure to Warn of Genetic Risks*, 29 HOUS. L. REV. 149 (1992); Note, *Father and Mother Know Best: Defining the Liability of Physicians for Inadequate Genetic Counseling*, 87 YALE L. J. 1488 (1978); Alexander Morgan Capron, *Tort Liability in Genetic Counseling*, 79 COLUM. L. REV. 618 (1979).

<sup>6</sup> Mollie Roth, *Personalized Medicine: Using Effective Partnering For Managing the Risk of Legal Liability*, 4 PERSONALIZED MED. 329, 331 (2007).

<sup>7</sup> Pilar N. Ossorio, *Product Liability for Predictive Genetic Tests*, 41 JURIMETRICS 239 (2001).

<sup>8</sup> Aniwaa Owusu-Obeng et al., *Emerging Roles for Pharmacists in Clinical Implementation of Pharmacogenomics*, 34 PHARMACOTHERAPY 1102 (2014).

<sup>9</sup> See, e.g., Amy L. McGuire et al., *Can I Be Sued for That? Liability Risk and the Disclosure of Clinically Significant Genetic Research Findings*, 24 GENOME RES. 719 (2014); Ellen Wright Clayton & Amy L. McGuire, *The Legal Risks of Returning Results of Genomics Research*, 14 GENETICS MED. 473 (2012).

<sup>10</sup> Eric D. Green et al., *Charting a Course for Genomic Medicine from Base Pairs to Bedside*, 470 NATURE 204, 204–05 (2011).

<sup>11</sup> See *Genetic Test Registry*, NAT'L CTR. BIOTECHNOLOGY INFO., <https://www.ncbi.nlm.nih.gov/gtr> [<https://perma.cc/EQU2-VCJV>] (last visited Oct. 21, 2017) (number of genetic tests has grown from 1,038 in 2012 to 52,349 in 2017).

new generation of molecular diagnostics will be used to predict health risks, diagnose disease subcategories, and target treatments based on the individual patient's unique genetic and molecular profile.<sup>12</sup> As NIH Director Francis Collins recently noted, “[t]he power of the molecular approach to health and disease has steadily gained momentum over the past several decades and is now poised to catalyze a revolution in medicine.”<sup>13</sup> Notwithstanding the enormous potential and excitement about the dawning era of precision medicine, its implementation and clinical uptake has been slower and more complex than many experts originally anticipated.<sup>14</sup>

A number of factors may explain the slower than expected uptake of genomic medicine in clinical care. Randomized control studies showing the clinical utility of genetic testing are lacking for many applications.<sup>15</sup> Most physicians have not yet received formal training in genomics, making them reluctant to utilize new genetic tools even when they acknowledge they should.<sup>16</sup> The lack of adequate clinical decision support systems to assist many physicians in incorporating genetic testing into treatment and prescription decisions is another obstacle to wider uptake of genetic testing.<sup>17</sup> Clinical guidelines are also lacking to guide physicians in most applications of genetic testing.<sup>18</sup>

Notwithstanding these limitations, genetic science has steadily pushed forward, especially with the advent of high-throughput genomics technologies and the steadily declining costs of genetic testing,<sup>19</sup> and there are now many potential clinical applications of genetic tests that are at various levels of clinical implementation.<sup>20</sup> Chromosomal disorders were one of the first genetic conditions tested for, as they can often be observed visually after staining cells and observing the chromosomes under a microscope (known as cytogenetic analysis). The most well-known chromosomal disorder is Down syndrome, which occurs in individuals born with three copies of chromosome 21. There are only a few other examples where an affected individual will survive with an abnormal number of chromosomes.<sup>21</sup> In addition to variations in

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<sup>12</sup> Margaret A. Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, 363 NEW ENG. J. MED. 301 (2010).

<sup>13</sup> Francis C. Collins, *Opportunities for Research and NIH*, 327 SCIENCE 36, 36 (2010).

<sup>14</sup> Pedro J. Caraballo et al., *Multidisciplinary Model to Implement Pharmacogenomics at the Point of Care*, 19 GENETICS MED. 421, 421 (2017); Megan C. Roberts et al., *The Current State of Implementation Science in Genomic Medicine: Opportunities for Improvement*, 19 GENETICS MED. 858, 858 (2017).

<sup>15</sup> U. Amstutz & B.C. Carleton, *Pharmacogenetic Testing: Time for Clinical Practice Guidelines*, 89 CLINICAL PHARMACOLOGY & THERAPEUTICS 924, 926 (2011).

<sup>16</sup> See *infra* notes 39–41 and accompanying text.

<sup>17</sup> Caraballo et al., *supra* note 15, at 422 (notwithstanding useful advances in incorporating genomic information into electronic health records (EHRs) and clinical decision support (CDS) systems, “current EHRs and CDS tools alone are not likely to be able to handle the influx of genomic data expected in the near future. Therefore, additional infrastructure in combination with a comprehensive strategy involving all aspects of PGx medicine, from the laboratory to data migration and clinical participation to multidisciplinary governance, will be required.”).

<sup>18</sup> Amstutz & Carleton, *supra* note 16, at 926.

<sup>19</sup> Caraballo et al., *supra* note 15, at 421. “High-throughput” genomic technologies include techniques such as multi-gene panels and whole genome sequencing which now permit a large amount of genetic data to be collected relatively quickly and cheaply using new automated technologies.

<sup>20</sup> See generally Green, *supra* note 11, at 204–06.

<sup>21</sup> Humans normally have 22 pairs of autosomes and one pair of sex chromosomes. Many fetuses have a different number of chromosomes, a condition known as aneuploidy, but rarely survive to birth. In addition

the number of chromosomes, cytogenetic tests can also detect aberrations of relatively large segments of a chromosome resulting from chromosomal breaks, including deletions, insertions and exchanges (translocations). One of the most recent applications of chromosomal analysis is the advent of non-invasive prenatal diagnosis (NIPD) to test for an abnormal number of chromosomes in fetal DNA collected from the mother's blood.<sup>22</sup>

Another well-established type of genetic testing is for so-called Mendelian genetic diseases, which are genetic diseases determined by a variant in a single gene. Some Mendelian diseases are caused by one copy of a dominant gene variant (e.g., Huntington disease) that is passed on from just one parent, but most are caused by two copies of a recessive gene variant (e.g., cystic fibrosis, Tay-Sachs, sickle cell disease) and cause disease only when the variant is passed on by both parents. In addition to testing patients who have the disease as a result of two copies of a gene variant, it is also possible to test individuals to see if they have one copy of the mutation, known as a carrier, which could affect their reproductive risks.

A fast growing and more controversial type of genetic testing is predisposition testing. This type of genetic testing tests an individual for gene variants which make him or her more likely to develop a specific disease in the future, although the predisposition variant is usually neither necessary nor sufficient to cause the disease. Thus, predisposition testing identifies probabilities of susceptibility, which are prone to misunderstanding and confusion by both patients and providers, and thus a rich potential source of miscommunications that may give rise to genomic malpractice lawsuits. Perhaps the best-known examples of predisposition genes are the BRCA1 and BRCA2 gene variants, which both increase the risk of, and reduce the survival from, breast and ovarian cancer in women.<sup>23</sup>

One of the newest types of genetic testing is pharmacogenomic testing, which uses genetics to tailor health care interventions to the profile of the individual patient.<sup>24</sup> For example, a subset of pharmacogenomics called pharmacogenetics, advocated for well over a decade, involves testing for inherited genetic variations affecting drug metabolism that can be used to predict individualized responses to medications and to prevent adverse drug reactions through individualized dosing regimens or avoidance of certain medications.<sup>25</sup> FDA's website lists over 230 drug-gene combinations for which some kind of warning is provided on the drug label.<sup>26</sup> Another type of pharmacogenomics test involves testing diseased cells for gene expression or

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to Down syndrome (trisomy 21), individuals with three copies (trisomy) of chromosome 18 and 13 occasionally survive to birth. Individuals with an abnormal number of sex chromosomes (XO, XXY, XYY) can also survive and have characteristic syndromes.

<sup>22</sup> Henry T. Greely, *Get Ready for the Flood of Fetal Gene Screening*, 469 *NATURE* 289 (2011).

<sup>23</sup> Virginia A. Moyer, *Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer in Women: U.S. Preventive Services Task Force Recommendation Statement*, 160 *ANNALS INTERNAL MED.* 271 (2014); Marjanka K. Schmidt et al., *Breast Cancer Survival of BRCA1/BRCA2 Mutation Carriers in a Hospital-Based Cohort of Young Women*, 109 *J. NAT'L CANCER INST.*, 329 (2017).

<sup>24</sup> Mary V. Relling & William E. Evans, *Pharmacogenomics in the Clinic*, 526 *NATURE* 343, 344-45 (2015); Amstutz & Carleton, *supra* note 16, at 924.

<sup>25</sup> Carabello et al., *supra* note 15, at 424 (discussing implementation of genetic testing for 18 specific drug-gene interactions at one leading health care clinic).

<sup>26</sup> *Table of Pharmacogenomic Biomarkers in Drug Labeling*, FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm> [<https://perma.cc/9VAT-M2EU>] (last visited Oct. 20, 2017).

mutational changes that can be used for prognosis or targeting individualized treatments.<sup>27</sup>

The newest, and ultimately most powerful, type of genetic testing is whole genome sequencing (WGS) or whole exome sequencing (WES).<sup>28</sup> WGS attempts to sequence an individual's entire genome, whereas WES only seeks to sequence the approximately two percent of the genome that codes for proteins.<sup>29</sup> As the cost of WGS and WES continue to drop, now approaching \$1000 per genome, this type of testing will increasingly become the primary form of genetic testing.<sup>30</sup>

There are many obstacles potentially affecting the implementation of personalized medicine. Less than 4000 genetic and genomic health care specialists have been certified in total since 1982, and many of these are now likely retired or no longer practicing.<sup>31</sup> And as of 2014, there were only 2400 genetic counselors in the United States.<sup>32</sup> Given the rapidly growing need for genetic testing in the context of cancer care, prenatal testing, newborn testing, and other areas, most genetic advice to patients comes from providers without genetic expertise, no doubt slowing the uptake of this technology.<sup>33</sup> Specific impediments include scientific complexity and uncertainties, the need for validation of biomarkers, commercial unavailability of relevant diagnostic tests, economic costs and turnaround times associated with genetic testing, lack of reimbursement for diagnostic testing, regulatory approval barriers, structural problems in the existing health care delivery system, lack of physician training and motivation, inadequate business models, and intellectual property issues.<sup>34</sup> Liability is one factor which could be enormously influential in the uptake and future direction of genomic medicine, although it has received little attention to date.

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<sup>27</sup> Relling & Evans, *supra* note 25, at 345–46.

<sup>28</sup> Noralane M. Lindor, Stephen N. Thibodeau & Wylie Burke, *Whole-Genome Sequencing in Healthy People*, 92 *MAYO CLINIC PROC.* 159 (2017).

<sup>29</sup> *Id.* at 163.

<sup>30</sup> *Id.* at 160; Jason L. Vassy et al., *The Impact of Whole-Genome Sequencing on the Primary Care and Outcomes of Healthy Adult Patients: A Pilot Randomized Trial*, 167 *ANNALS INTERNAL MED.* 159, 159 (2017).

<sup>31</sup> AMERICAN BOARD OF MEDICAL GENETICS AND GENOMICS, NUMBER OF ABMGG CERTIFIED SPECIALISTS IN MEDICAL GENETICS AND GENOMICS, (2016), <http://www.abmgg.org/pdf/Modified%20Statistics%20for%20all%20years%20end%20date%202015%20with%20footnotes.pdf>.

<sup>32</sup> BUREAU OF LABOR STATISTICS, U.S. DEPARTMENT OF LABOR, OCCUPATIONAL OUTLOOK HANDBOOK: GENETIC COUNSELORS, (Dec. 17, 2015), <https://www.bls.gov/ooh/healthcare/genetic-counselors.htm> [<https://perma.cc/ZL4A-KE2N>].

<sup>33</sup> See Susanne B. Haga, Wylie Burke & Robert Agans, *Primary-care Physicians' Access to Genetic Specialists: An Impediment to the Routine Use of Genomic Medicine?*, 15 *GENETICS IN MED.* 513, 513 (2013).

<sup>34</sup> *Realizing the Potential of Pharmacogenomics: Opportunities and Challenges*, SEC'Y'S ADVISORY COMM. ON GENETICS, HEALTH & SOCIETY (SACGHS), (May 2008), <https://osp.od.nih.gov/sacghsdocs/realizing-the-potential-of-pharmacogenomics-opportunities-and-challenges/> [<https://perma.cc/D8EW-9C7D>]; Relling & Evans, *supra* note 25, at 347–48; K.R. Crews et al., *Pharmacogenomics and Individualized Medicine: Translating Science Into Practice*, 92 *CLINICAL PHARMACOLOGY & THERAPEUTICS* 467, 470–72 (2012); J. Cohen, A. Wilson & K. Manzolillo, *Clinical and Economic Challenges Facing Pharmacogenomics*, 13 *PHARMACOGENOMICS J.* 378, 382–87 (2012).

## II. SCENARIOS AND DRIVERS OF GENOMIC MALPRACTICE

The rise of clinical use of genomics and precision medicine may present new liability risks to health care providers. This section explores some possible scenarios in which medical malpractice claims could arise from the use, failure to use, or misuse of genomic information by health care providers. Then some potential drivers of genomic malpractice litigation are examined.

### A. Liability Scenarios

There are a number of potential scenarios by which the increased availability and utility of genomic information could lead to malpractice liability. For example, patients who suffer a serious adverse effect from a pharmaceutical for which they carry a genetic susceptibility or a patient whose treatment was adversely affected by the failure to use new genetic diagnostic techniques in a timely manner, may bring a lawsuit against their physician. Once such lawsuits are successful, the dynamics of litigation generally are such that news of the successful litigation will spread quickly among the legal community, and the number of such cases brought by trial attorneys will quickly skyrocket. This pattern has repeated itself for a wide variety of medical liability targets, including Bendectin, tobacco, silicone breast implants, fen-phen, and Vioxx. If such a dynamic were to be unleashed in the context of genomic medicine, the impacts would be enormous. Even a relatively low number of lawsuits would have pervasive effects on how genomic medicine is delivered and implemented, since the economic and psychological consequences of liability for any individual at-risk provider could be substantial.

There is considerable uncertainty about the prospects of a lawsuit brought by patients or other injured persons alleging that their injury was caused or exacerbated by the use or failure to employ genomic medicine. For example, in some genetic testing contexts, there may be considerable uncertainty about who is the potentially liable party, such as when a patient was allegedly harmed by an adverse drug side-effect related to a susceptible genotype for which an erroneous genetic test was conducted. The injured plaintiff could conceivably sue the physician who prescribed the drug, the genetic specialist who ordered and reviewed the patient's genetic tests, the genetic counselor who may have counseled the patient, the nurse who may have administered the drug while the patient was in a hospital, the hospital or clinic in which the genetic services were offered (or not offered), the drug manufacturer who produced the drug, the manufacturer who developed the diagnostic test, the testing lab that conducted the test, the insurer which may not have been willing to pay for a more appropriate genetic test, or the pharmacist that dispensed the drug. As will be discussed below, most of these entities have been sued for malpractice or negligence in some genetic medicine cases, but it is physicians who are most at risk of lawsuits.

One potential litigation hotspot for physicians is their decision on whether to recommend genetic testing. A physician with little or no genetics training may not know that genetic testing is recommended in certain situations, such as an asymptomatic female patient with two first-degree relatives with breast or ovarian cancer, in which case genetic testing for the BRCA genes may be indicated.<sup>35</sup> The

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<sup>35</sup> *Final Recommendation Statement BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing*, U.S. PREVENTIVE SERV. TASK FORCE, (Dec. 2013), <https://www.uspreventive>

physician may also fail to recognize that the symptoms of their patient may have a genetic origin that could be revealed by a genetic test, and the delayed diagnosis results in irreversible harm to the patient or reproductive decisions by the affected child's parents that produces another child with the same condition. Or the physician may prescribe a drug without recommending a prior genetic test that may be indicated on the FDA label for the drug to warn susceptible patients. In addition to such examples of likely malpractice, a patient may also bring a lawsuit for lack of informed consent when a physician failed to adequately explain their genetic testing options.

Alternatively, the physician may know about the availability of a genetic test and make a judgment to not recommend it in a particular scenario that may be second-guessed by a patient who then has a bad outcome. Some tests with high uncertainty about benefits and risks that is characteristic for a rapidly developing technology like genomics may put physicians in a damned if they do, damned if they don't situation. For example, consider a genetic test such as the Oncotype Dx test that evaluates the risk of recurrence for a breast cancer tumor based on gene expression.<sup>36</sup> If a physician recommends the test and then suggests no chemotherapy is necessary based on a low recurrence score from the test, a rare patient in such situation whose cancer did happen to recur may bring a lawsuit saying it was not the standard of care to rely on such an "experimental" test. Alternatively, if the physician decides against recommending the test, and the physician and patient settle on a moderate course of treatment that fails to stop a rapidly growing and metastasizing tumor, the patient may sue alleging the physician failed to meet the standard of care by not recommending a test that may have indicated a more aggressive treatment. This is different from more established medical tests, which are already accepted as part of medical practice and generally yield results that dictate clearer follow-up actions, therefore creating less difficulty for providers who order these tests.

Another potential pitfall for physicians is in communicating the genetic test results, given the inherent ambiguity in many genetic test results and the relative lack of knowledge by many health care providers.<sup>37</sup> The physician may fail to deliver the test result altogether as a result of some type of paperwork error or mix-up. Because many genetic tests are mailed to outside laboratories and have varying turn-around times, they create a higher risk for providers to submit the tests incorrectly or to forget to follow up on the results. Physicians may also misinterpret the technical report returned by the testing laboratory and subsequently give the wrong advice to the patient. Unlike most laboratory tests that have results that are familiar to providers from their medical training and are easily interpretable, genomic test results are more complex and providers without special training may not be able to interpret them appropriately.

### *B. Liability Red Flags*

There are a number of red flags that indicate that genomic malpractice risks could quickly become a major issue for most health care providers. While many of these indicators of liability risk are common to other new medical technologies, many of them have particular salience for genomic malpractice given the rapid pace of the

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servicestaskforce.org/Page/Document/RecommendationStatementFinal/brca-related-cancer-risk-assessment-genetic-counseling-and-genetic-testing [https://perma.cc/VWZ8-BDX7].

<sup>36</sup> ONCOTYPEIQ, <http://www.oncotypeiq.com/en-US>. [https://perma.cc/YXE9-C4H2].

<sup>37</sup> See *infra* notes 39–41, 52–55 and accompanying text.

development and deployment of genetic technologies and the potential relevance of genetics to almost all disease conditions and treatment decisions. Thus, ten factors that suggest a growing potential for genomic malpractice suits and risk include:

### 1. *Unfamiliarity and Lack of Training*

The clinical application of genomics is new to most health care contexts and providers, thereby increasing the risk of error that can lead to liability. Most physicians practicing today have not had any significant training in medical genomics as medical schools have only started adding genetics to their curriculum in the past few years.<sup>38</sup> As a result, most physicians practicing in the United States lack the knowledge and training to order and understand genetic testing in treating their patients.<sup>39</sup> Unlike most new technologies and practice guidelines, which affect only certain subspecialties of providers, advances in genomics potentially affect every medical specialty, thereby significantly increasing the overall liability risk in comparison. This lack of experience and training will become even more significant as we move into the increased complexity created by whole genome sequencing.<sup>40</sup>

### 2. *Rapidly Changing Technology and Standards*

The unfamiliarity of health care providers with genomic science and genomic medicine is exacerbated by the rapidly changing knowledge and technologies in genomics. The history of medical malpractice shows that new technologies are a primary driver of medical malpractice liability, as summarized by William Sage:

Although technology is generally seen as a boon to safety, no other factor historically has surpassed it as a stimulus for litigation. Gains in clinical competence redefine success upward and make delay actionable.<sup>41</sup>

The lack of guidance and standards further exacerbates physicians' discomfort with new genomic technologies.<sup>42</sup>

### 3. *Hindsight Bias*

Hindsight bias is another factor that is likely to have particular salience in genomic malpractice cases. Hindsight bias is a problem that affects all medical malpractice cases, as the facts of the case and blameworthiness of the physician may look very

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<sup>38</sup> Laurie A. Demmer & Darrel J. Waggoner, *Professional Medical Education and Genomics*, 15 ANN. REV. GENOMICS & HUMAN GENETICS 507, 509 (2014).

<sup>39</sup> *Id.* at 508; E.J. Stanek et al., *Adoption of Pharmacogenomic Testing by US Physicians: Results of a Nationwide Survey*, 91 CLINICAL PHARMACOLOGICAL & THERAPEUTICS 450 (2012); Katherine A. Johansen Taber & Barry D. Dickinson, *Pharmacogenomic Knowledge Gaps and Educational Resource Needs Among Physicians In Selected Specialties*, 7 PHARMACOGENOMICS & PERSONALIZED MED. 145, 145 (2014).

<sup>40</sup> Kurt D. Christensen et al., *Are Physicians Prepared for Whole Genome Sequencing? A Qualitative Analysis*, 89 CLINICAL GENETICS 228, 232–33 (2016).

<sup>41</sup> William M. Sage, *Medical Liability and Patient Safety*, 22 HEALTH AFFAIRS 26, 28 (2003) (footnotes omitted). *See also* Kenneth De Ville, *Medical Malpractice in Twentieth Century United States*, 14 INT'L J. TECH ASSESS. HEALTH CARE 197, 200 (1998) (“Dramatic and genuine medical advances are invariably followed by heightened, and frequently excessive professional and lay expectations . . . [I]mproved procedures more often than not require greater learning, skill, and care. Consequently, technological advancement carries with it greater opportunity for error or accident.”).

<sup>42</sup> *See* Christensen et al., *supra* note 41, at 232.

different to juries evaluating the physician's actions after harm has resulted than the matter will have looked to the physician at the time he or she made her decision.<sup>43</sup> Tort doctrine holds that the reasonableness of a party's actions should be evaluated at the time and under the conditions the defendant's actions and decisions occurred, thus eliminating hindsight bias. However, hindsight bias still affects jury judgment, and is likely to be particularly strong in genomic malpractice cases where at the time of the alleged malpractice the physician may not have suspected a genetic factor was important, but which looks so different after the genetic explanation has been revealed. Moreover, the standard of care will have often changed in the several years that generally separate these lawsuits from the time of the alleged malpractice

#### 4. *The More You Can Do, The More That Can Go Wrong*

As the potential applications and capabilities of a technology or activity expand, so does the potential that something could go wrong and result in liability. An example is kidney dialysis machines – before such technology existed, patients with chronic kidney disease just died and there was no liability.<sup>44</sup> But “with the advent of dialysis, there are many compliance opportunities and when someone forgets to test a solution or check a shunt and harm results, there is a negligence claim that could not have existed before dialysis technology was introduced.”<sup>45</sup> In the same way, the greatly expanded potential uses of genomics in clinical care, including expansive new technologies such as whole genome sequencing and non-invasive prenatal diagnosis, present a massive increase in opportunities both to understand the patients' health status but also to make mistakes or oversights.<sup>46</sup>

#### 5. *Differential Uptake*

The standard of care in medical malpractice is traditionally based on local custom. Thus, if no local physicians are using a new technology such as genomic medicine, the standard of care will generally not require the application of such technology. That has been a consistently strong medical malpractice defense in the past when few physicians sought or used genomic information. But today, a growing number of providers at university hospitals and tech-savvy clinics are applying the latest in genomic technologies and data for everything from cancer diagnostics and prognostics, to pharmacogenomics testing, to fetal genetic risks, creating a growing gap between the early adopters and the laggards.<sup>47</sup> This gap creates a growing liability risk to providers that lag behind their colleagues in adopting genomic medicine. In addition, the majority of jurisdictions have now shifted to a national rather than local

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<sup>43</sup> See Hal R. Arkes, *The Consequences of the Hindsight Bias in Medical Decision Making*, 22 CURR. DIRECT. PSYCH. SCI. 356, 358 (2013).

<sup>44</sup> Mark F. Grady, *Why Are People Negligent? Technology, Nondurable Precautions, and the Medical Malpractice Explosion*, 82 NW. L. REV. 293, 312 (1988).

<sup>45</sup> *Id.*

<sup>46</sup> See Christensen et al., *supra* note 41, at 232–33.

<sup>47</sup> See Stanek et al., *supra* note 40, at 451 (early adopters of pharmacogenomics testing tended to practice in urban settings, were at an intermediate stage in their careers, and tended to practice oncology or a surgical specialty). For example, leading academic hospitals at places like the Mayo Clinic and Vanderbilt University have very sophisticated and advanced genomic medicine services. See Carabello et al., *supra* note 15, at 427.

standard of care,<sup>48</sup> and in addition many jurisdictions are also moving away from a custom-based standard of care to a reasonableness standard, where the fact that other physicians are also not doing something deemed reasonable will no longer be a defense.<sup>49</sup> This factor may have an especially strong effect in the arena of genomic practice, in which providers are limited primarily by knowledge of when and how to offer and interpret various genetic tests, compared to expensive technologies such as MRIs or CT scanners, with which providers may be limited in their ability to apply these technologies based on their lack of access to the machines. Local custom is more likely to protect providers who do not have access to expensive technologies, as this is often beyond the providers' control, and less likely to protect those who lack the knowledge of providers practicing in other locales, as this is fully within providers' control. The trend towards a national standard of care also opens up the scope of possible expert witnesses to support a plaintiffs' case, as the locality rule may discourage specialists in the same geographical area from testifying against their colleagues in the same location and specialty.<sup>50</sup>

### 6. *Expert Disagreement and Uncertainty*

When the best practice of medicine is clear and unambiguous, there are not many malpractice claims, because providers know what is expected of them, and any suits that are brought are quickly settled since the standards are clear. But in a rapidly developing and contested area such as precision medicine, there is much expert disagreement about the appropriate standard of care and whether certain genetic tests and knowledge should be applied to clinical decision-making.<sup>51</sup> Significant disagreement/uncertainty exists about which genetic tests are clinically appropriate in varied and important clinical contexts such as pre-prescription genetic testing for warfarin (Coumadin<sup>®</sup>) or clopidogrel (Plavix<sup>®</sup>),<sup>52</sup> or the use of breast cancer recurrence/gene expression assays.<sup>53</sup> Such expert disagreements could fuel litigation where there is discordant evidence to support both parties' position that a physician should or should not have recommended genetic testing of a patient.<sup>54</sup>

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<sup>48</sup> See, e.g., *King v. Williams*, 279 S.E.2d 618, 620 (S.C. 1981) (discarding "locality rule" for national standard of care); Michelle Huckaby Lewis, John K. Gohagen & Daniel Merenstein, *The Locality Rule and the Physician's Dilemma*, 297 JAMA 2633, 2634 (2007) (majority of states have abandoned locality rule in favor of a national standard of care).

<sup>49</sup> See Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 172 (2000).

<sup>50</sup> Alex Stein, *Toward a Theory of Medical Malpractice*, 97 IOWA L. REV. 1201, 1210–12 (2012).

<sup>51</sup> Relling & Evans, *supra* note 25, at 344 ("There is a substantial difference of opinion as to precisely which outcomes constitute clinical utility."); Amy L. McGuire, Laurence B. McCullough & James P. Evans, *The Indispensable Role of Professional Judgment in Genomic Medicine*, 309 JAMA 1465, 1465 (2013) ("[R]ecommendations will be based nuanced, tentative, and based on highly imperfect data.").

<sup>52</sup> Gary E. Marchant, Kathryn Scheckel & Doug Campos-Outcalt, *Contrasting Medical and Legal Standards of Evidence: A Precision Case Study*, 44 J. LAW, MED. & ETHICS 194, 195 (2016).

<sup>53</sup> Amalia M. Issa, Vivek S. Chaudhari & Gary E. Marchant, *The Value of Multigene Predictors of Clinical Outcome in Breast Cancer: An Analysis of the Evidence*, 15 EXPERT REV. MOLECULAR DIAGNOSTICS 277, 283 (2015).

<sup>54</sup> See James F. Blumstein, *Medical Malpractice Standard-Setting: Developing Malpractice "Safe Harbors" as a New Role for QIOs?*, 59 VAND. L. REV. 1017, 1029 (2006) (describing effect of clinical uncertainty on malpractice risks and decisions).

### 7. *Novel Legal Claims*

Another potential accelerator of genomic malpractice claims is the potential availability of novel legal claims that may surprise and jeopardize health care providers. For many years, wrongful life and wrongful birth claims have been put forward in genomic malpractice cases, with mixed results. In a wrongful birth case, the parents bring a claim for the damages associated with raising a child with a serious disease that the parents would not have chosen to bring into the world if the provider had not failed to warn them that the child may be affected by that disease. In a wrongful life case, the case is brought on behalf of the affected child, alleging that he or she was injured by being brought into existence as a result of the physician's negligence, again by the provider's failure to notify the parents of the child's probability of being affected by the disease. There had been a few wrongful birth or wrongful life cases prior to genetic-based claims, such as for fetuses affected by rubella vaccine. But the genetics cases raised a unique issue in that the physician's negligence did not cause the fetus's condition, which was present from natural causes at the moment of fertilization, but rather prevented the parents from having the opportunity to abort the affected child. Courts struggled with this issue, but in the 1980s courts in a number of states recognized wrongful birth cases, with only a few recognizing wrongful life claims. Other non-traditional and unique tort claims are possible with genomics, including a potential duty of a physician to notify a patient's relatives of their potential genetic risk,<sup>55</sup> a possible duty to disclose incidental findings discovered in genetic testing,<sup>56</sup> and a possible duty to update genetic advice.<sup>57</sup>

### 8. *Hungry Plaintiffs' Bar*

In recent years, many state legislatures have adopted legislation that restricts medical malpractice liability, through damage caps, constraints on expert witnesses, and other measures.<sup>58</sup> This has left many medical malpractice plaintiffs' attorneys who may have had a successful track record in such types of litigation in the past with less promising prospects with traditional malpractice cases.<sup>59</sup> The plaintiffs' bar may therefore be receptive to a potential new category of medical malpractice cases, where a significant number of serious injuries and deaths may be occurring and many physicians may lack the required expertise to apply this new technology appropriately.

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<sup>55</sup> Kenneth Offitt et al., The "Duty to Warn" a Patient's Family Members About Heredity Disease Risks, 292 JAMA 1469, 1469 (2004).

<sup>56</sup> Ellen Wright Clayton et al., Managing Incidental Genomic Findings: Legal Obligations of Clinicians, 15 GENETICS IN MED. 624, 624–29 (2013); McGuire et al. *supra* note 10, at 720; Barbara J. Evans, Minimizing Liability Risks Under the ACMG Recommendations for Reporting Incidental Findings in Clinical Exome and Genome Sequencing, 15 GENETIC MED. 915, 916 (2013); Clayton & McGuire, *supra* note 10, at 475.

<sup>57</sup> Yvonne A. Stevens, Grant D. Senner & Gary E. Marchant, *Physician's Duty to Recontact and Update Genetic Advice*, 14 PERSONALIZED MED. 367, 367 (2017); Mark A. Rothstein & Gil Siegal, *Health Information Technology and Physicians' Duty to Notify Patients of New Medical Development*, 12 HOUS. J. HEALTH L. POL'Y 93, 93–136 (2012); Clayton et al., *supra* note 57, at 628.

<sup>58</sup> See Allen Kachalia & Michelle M. Mello, *New Directions in Medical Liability Reform*, 364 NEW ENGL. J. MED. 1564, 1565 (2011).

<sup>59</sup> See Myungho Paik, Bernard Black & David A. Hyman, *The Receding Tide of Medical Malpractice Litigation: Part 1 – National Trends*, 10 J. EMPIRICAL LEGAL STUD. 612, 635 (2013) ("[F]or the past two decades, the tide [of medical malpractice litigation] has steadily receded.").

Indeed, there are already plaintiffs' law firms advertising their proficiency in bringing genetic malpractice claims.<sup>60</sup>

### 9. FDA Warnings

FDA drug labels, sometimes referred to as package inserts, are increasingly recommending genetic testing before prescribing a pharmaceutical.<sup>61</sup> While not conclusive as to the standard of care, such labels are often introduced in medical malpractice litigation as evidence of the standard of care, and although the courts have been inconsistent on what weight if any to give such evidence, they have sometimes been treated as *prima facie* evidence of due care by courts.<sup>62</sup> Many physicians are routinely ignoring FDA-approved warnings and recommendations for genetic testing on pharmaceutical labels, largely because of a lack of familiarity with and availability of genetic tests, leading to potential liability exposure if a patient has an adverse effect that could have been prevented by the recommended genetic testing. For example, even though FDA revised the label for warfarin to provide recommendations on genetic testing patients before prescribing warfarin, few physicians currently recommend such testing before prescribing this drug.<sup>63</sup>

### 10. Ample Supply of Adverse Outcomes

There is a large number of genetically affected patients who have a colorable claim that their condition could have been prevented, treated, or minimized by timely genetic testing that was not offered by their physicians. For example, professional guidelines recommend that expecting parents be tested to see if they are cystic fibrosis carriers, and so every baby born with cystic fibrosis whose parents were not offered genetic carrier testing is a potential lawsuit. Many women who have relatives with breast or ovarian cancer are not told about BRCA genetic testing, and many of these at-risk women go on to develop breast or ovarian cancer themselves that may have been detected earlier or prevented through genetic testing and prophylactic surgery. One recent study found that only 20.2 percent of women who meet the criteria for BRCA genetic testing were advised by their physician to undergo the genetic test, and some 1.2 to 1.3 million women in the United States who meet the criteria for testing have not been tested.<sup>64</sup> Finally, side effects from prescription drugs are one of the leading causes of death in the United States, causing over 100,000 deaths and 2 million

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<sup>60</sup> See, e.g., *Genetic Misdiagnosis*, Gorvitz & Borten. P.C., [http://www.gbmedlaw.com/new\\_page\\_14.htm](http://www.gbmedlaw.com/new_page_14.htm). [<https://perma.cc/Z39W-67EQ>].

<sup>61</sup> See *supra* note 27 and accompanying text.

<sup>62</sup> See, e.g., *Thompson v. Carter*, 518 So. 2d 609, 613 (Miss. 1988) (FDA-approved package insert "is prima facie proof of a proper method of use"); *Ohligschlager v. Proctor Community Hosp.*, 303 N.E.2d 392, 392 (Ill. 1973) ("[A] doctor's deviation from such recommendations [in drug label] is prima facie evidence of negligence."); *Richardson v. Miller*, 44 S.W.3d 1, 16 (Tenn. Ct. App. 2000) ("[M]ajority of jurisdictions have determined that a prescription drug's labeling . . . is admissible to prove the standard of care, but only if the plaintiff also introduces other expert testimony regarding the standard of care."). *But see Arnold v. Lee*, 720 N.W.2d 194, 194 (Iowa Ct. App. 2006) (package insert not admissible as evidence of standard of care).

<sup>63</sup> Marchant, Scheckel & Campos-Outcalt, *supra* note 53, at 199 ("Most physicians who prescribe warfarin today do not use genotyping to calibrate starting dose.").

<sup>64</sup> Christopher P. Childers et al., National Estimates of Genetic Testing in Women With a History of Breast or Ovarian Cancer, *J. CLINICAL ONCOLOGY*, Aug. 18, 2017, at 6.

hospitalizations each year,<sup>65</sup> many of which are due to genetic variants in drug metabolism that could have been detected and utilized for safer treatment using pharmacogenetic testing.

Taken together, these ten “red flags” suggest a potential rising tide of genomic malpractice litigation as genomics assumes an ever greater role in clinical care in the United States. Of course, there are other factors that may dampen liability, such as the lack of knowledge and experience by plaintiffs’ attorneys about genomics, and the difficulty in identifying capable and willing expert witnesses that can testify about the standard of genomic care. But overall, these qualitative factors suggest that the legal system may be predisposed to a major surge, if not a tidal wave, of genomic malpractice litigation and liability. However, any such trend will require a more quantitative empirical analysis, which is presented in the following section.

### III. EMPIRICAL STUDY OF GENOMIC MALPRACTICE

To date, reports of genomic malpractice cases are anecdotal. Such cases exist, but there has been no attempt to quantify, identify trends in, or classify such litigation. Traditional databases used to track medical malpractice litigation generally do not differentiate cases involving genetic testing or genetic information, so they cannot provide any insight in genomic malpractice cases specifically. To address this gap, we undertook an empirical analysis of reported genomic malpractice cases in the United States that had been decided by at least one court decision through the end of 2016, the results of which are reported here.

#### A. Methodology

Identifying all cases involving genomic malpractice would be a daunting challenge, since most such cases settle (often confidentially) or result in jury verdicts that are not appealed, and thus do not generally result in a reported judicial decision. We did not attempt to identify every genomic malpractice case filed, but rather focused primarily on reported judicial decisions available on Westlaw. This provided us with a consistent set of search criteria to discern if there was any trend across time in such cases, as well as to categorize cases by the legal claims brought and the type of medical error allegedly involved. In addition, focusing primarily on cases with judicial opinions allowed us to study any noteworthy holdings or dicta illuminating how courts are responding to any new issues presented by genomics in the medical malpractice context.

Our methodology focused on Westlaw searches in the allstates and allfeds databases for reported U.S. court decisions involving the term “genetic” or “genomic” with “malpractice” and/or “liability.” This was combined with searches of the Westlaw Verdicts & Settlements databases using the search term “genetics” and “genomics,” as well as some additional cases captured by Google search alerts with the search terms “genetic” with “malpractice” or “liability.” Only court decisions dated by December 31, 2016 were included.

This methodology has inherent limitations. First, it will miss many cases that are settled without any court decision and may also miss some jury verdicts that are not

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<sup>65</sup> Jason Lazarou, et al., *Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies*, 279 JAMA 1200, 1204 (1998).

reports in the Verdicts & Settlements database.<sup>66</sup> Second, not all genomic malpractice cases are equally likely to result in an appellate decision that is more likely to be captured by our search methodology. Cases involving significant doctrinal changes are more likely to result in appellate decisions. Thus, for example in the 1970s and 1980s, many state supreme courts or appellate courts were called upon to decide whether their state recognized wrongful birth and wrongful life claims. If a case with a similar malpractice fact pattern arose subsequent to that decision, it would likely not have reached the state appellate or supreme court, since the central doctrinal issue had already been resolved. This will have the effect of biasing the analysis towards greater recognition of earlier cases.

### B. Trends

The central hypothesis of this study is that the prevalence of genomic malpractice lawsuits is increasing as a result of the growing use of clinical genomics and the litigation red flags summarized in the previous section. Figure 1 shows the temporal trends in the 202 reported cases included in this study by year and type of genomic application. Two key points are evident from Figure 1. First, there has not been a major explosion in genomic malpractice cases, at least to date. In no year has the number of reported cases exceeded 12 per year. While the number of reported cases identified using this study methodology may only be a subset of actual lawsuits filed, the results of this empirical analysis show that genomic malpractice has yet to hit critical mass and become a major category of litigation.

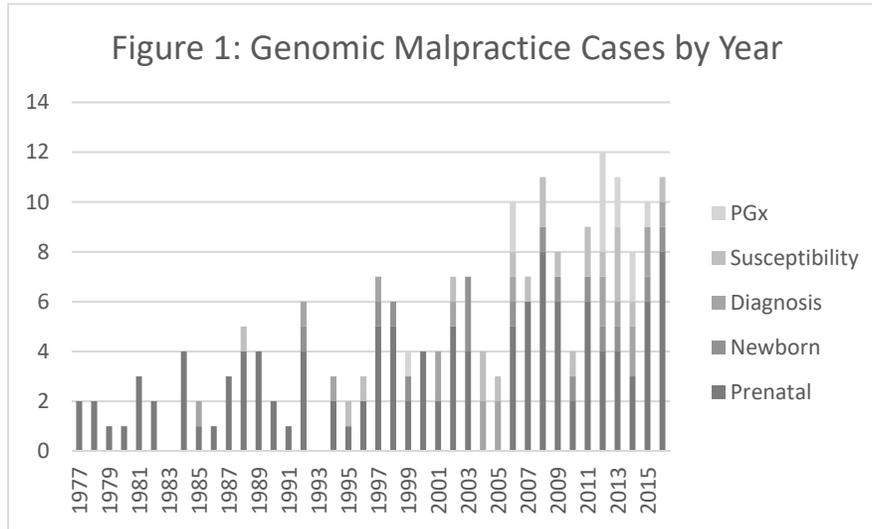
Of course, there is a lag between the filing of litigation and the reporting of final decisions. In the cases included in this study, the mean time between filing of a case and the final decision was 6.75 years (with a median of 6 years). Thirty-two of the 173 cases in this study in which sufficient data were available to calculate the length of time involved took 10 years or more from the conduct at issue to the resolution of the malpractice claim. In contrast, other medical malpractice cases take a mean of just over 3.5 years (43 months) from conduct to resolution.<sup>67</sup> This finding that genomic 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. Among other implications, this long period required to resolve such cases will increase the lag period in reporting cases, so many claims that may have occurred in the past few years may still not be reported. Since

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<sup>66</sup> Many interesting genomic malpractice cases were identified in news stories that never produced a decision or an accessible resolution. These cases presumably settled shortly after being filed, and no records of the case outcome can be found on Westlaw or in online case dockets. *See, e.g.*, Kyla Asbury, *Putnam Woman Sues Cabell Huntington Hospital, Physician for Breast Cancer Recurrence*, W. VA. Record (Dec. 10, 2012), <https://wvrecord.com/stories/510604056-putnam-woman-sues-cabell-huntington-hospital-physician-for-breast-cancer-recurrence> [<https://perma.cc/N3XL-R4NY>] (Woman with breast cancer recurrence sues doctor and clinic for failing to recommend BRCA genetic testing after first diagnosis of breast cancer); Mark Johnson, *Parents Sue Over Screening Delay for Newborn Son*, MILWAUKEE J. SENTINEL, Mar. 21, 2015 (parents sued clinic and doctor for brain damage to newborn son allegedly caused by delay in sending newborn screening genetic sample to laboratory). There are also pleadings of genomic malpractice cases available on Westlaw with no outcome available on Westlaw or other sites. *See, e.g.*, Complaint, *Cotton v. Esoterix Genetics Lab.*, No. 13-L-412, 2013 WL 4858952, at \*2 (Ill. Cir. Ct., Aug. 7, 2013) (parents sued genetic testing laboratory for false negative diagnosis of DiGeorge syndrome from prenatal genetic test).

<sup>67</sup> 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 AFFAIRS 111, 114 (2013).

the uptake of genomic medicine has only recently started to accelerate, and the evolution of new standards of care lag even further behind, it may be too early to see how much the shift to genomic medicine increases the rate of genomic malpractice litigation.



The second observation from Figure 1 is that although there has not been a major increase in genomic malpractice litigation, there has been a clear upward trend. The only years in which eight or more decisions were reported were nine of the past twelve years, in the period from 1977 through 2005, there were never more than seven cases reported.

This modest increase in genomic malpractice litigation over time reflects the increased role and diversity of genomic applications in clinical care. This is shown by the increased diversity of the types of genomic malpractice cases decided. As discussed further in the next section, almost all genomic malpractice cases prior to the past dozen years involved prenatal genetic testing, but the cases in other contexts of genomic testing have grown in frequency in recent years.

### C. Outcomes of Cases

There are 202 cases in the database.<sup>68</sup> Of these, the plaintiffs won 32 final verdicts, and the defendant(s) won final judgments in 75 cases. In another 41 cases, there was a reported settlement. In 48 other cases, the plaintiffs won the issues in the reported case, but no final verdict or settlement was reported. Presumably after winning the last reported decision in the case, the matter settled favorably for the plaintiff. Similarly, the defendant won an interim ruling in five cases, and presumably obtained a relatively favorable settlement. One case reached an interim decision that did not necessarily favor the defense or plaintiff. If the final judgments and interim decisions are combined, the plaintiffs succeeded in 80 cases, and the defendants also won in 80 cases. In other words, the plaintiffs won approximately 50 percent of the published

<sup>68</sup> The table listing the names, citations and various aspects of each case is available at <http://conferences.asucollegeoflaw.com/personalizedmedicine/genetics-liability-project/>.

decisions. If the reported settlements are combined with the plaintiffs' known and probable victories, the plaintiffs received a payout in 121 of the 202 cases (approximately 60 percent). In contrast, other medical malpractice areas have a payout to the plaintiff in only five to 22 percent of claims depending on the area of practice.<sup>69</sup> Another study found that only half of all medical malpractice claims go to litigation, of which half are dismissed by the judge, and almost 80 percent (79.6 percent) of cases going to verdict are decided in favor of the defendant.<sup>70</sup> Thus, the rate of success for a plaintiff in genomic malpractice litigation appears to be significantly higher than other types of medical malpractice litigation.

The known payments are summarized in Table 1.<sup>71</sup> Both the judgments in litigated cases and the settlement averages are significantly higher than the averages for other medical malpractice litigation. For example, one calculation of the average medical malpractice payout across specialties for medical malpractice cases with an indemnity payment was a mean of \$274,887 and a median of \$111,749.<sup>72</sup> Another comprehensive empirical study of medical malpractice payouts found that claims resolved by courts had a mean value of \$592,283 (\$324,450 median) while claims that were settled had a mean value of \$317,447 (\$185,00 median).<sup>73</sup> The average genomic malpractice payment reported in this study is more than an order of magnitude higher, with a mean of \$5,300,000 and a median of \$2,000,000.<sup>74</sup> Another study reported that in cases where the plaintiff won a jury verdict in a medical malpractice case, the median recovery was \$440,000.<sup>75</sup> Again, in the genomic malpractice cases reported in this study, the mean recovery in such cases was again almost an order of magnitude higher, at 3.0 million.

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<sup>69</sup> Anupam B. Jenba et al., *Malpractice Risk According to Physician Specialty*, 365 *NEW ENG. J. MED.* 629, 634 (2011). In cases that go to trial, plaintiffs win 27 percent of all medical malpractice cases. Although, only about 7 percent of all medical malpractice cases go to trial and receive a jury verdict. Neil Vidmar *Juries and Medical Malpractice Claims: Empirical Facts versus Myths*, 467 *CLINICAL ORTHOPAEDICS & RELATED RES.* 367, 368 (2009).

<sup>70</sup> Anupam B. Jena et al., *Outcomes of Medical Malpractice Litigation Against U.S. Physicians*, 172 *ARCHIVES OF INTERNAL MED.* 892, 893 (2012).

<sup>71</sup> One plaintiff's verdict amount was not reported, so only 31 of the 32 plaintiffs' verdicts are included in Table 1. In six of the cases known to have settled, the amount was not reported, so 35 of the 41 cases with known settlements are reported in Table 1.

<sup>72</sup> Jenba, *supra* note 70, at 633.

<sup>73</sup> Jessica B. Rubin & Tara F. Bishop, *Characteristics of Paid Malpractice Claims Settled In and Out of Court in the USA: A Retrospective Analysis*, *BMJ OPEN*, May 3, 2013, at 4.

<sup>74</sup> The actual difference between genomic malpractice and medical malpractice payouts may not be quite as large as indicated, because the statistics reported for all medical malpractice litigation included all claims filed (authors had access to large national malpractice insurer database), whereas the genomic malpractice numbers are from reported cases only. Thus, the genomic malpractice statistics likely exclude a lot of early settled claims, which may have on average lower payouts. However, these early settled claims may also include some real "whopper" cases where the defendant was clearly liable for a large compensation, so it is not clear how much this methodological variation affects the comparison.

<sup>75</sup> Vidmar, *supra* note 70, at 368.

Table 1: Plaintiffs Payouts (in \$Million)

	N	Mean	Median
Plaintiff Verdicts	31	9.1	3.0
Settlements	35	2.4	1.7
Plaintiffs Verdicts and Settlements	66	5.3	2.0

#### D. Types of Genetic Cases

There are a number of different applications of genetic testing that can give rise to a genomic malpractice lawsuit. The five categories of genetic testing that have been the subject of malpractice litigation to date are (i) prenatal genetic testing, (ii) newborn genetic testing, (iii) genetic testing for disease diagnosis, (iv) susceptibility genetic testing, and (v) pharmacogenomics testing. The number of cases in each of these five categories is shown in Table 2.

Table 2: Genomic Malpractice Cases by Type of Genetic Testing

Type of Genetic Testing	Number of Cases
Prenatal	125
Newborn	16
Diagnosis	22
Susceptibility	21
Pharmacogenomic	13

As Table 2 shows, the majority of genomic malpractice cases to date have involved prenatal genetic testing. As shown in Figure 1, almost all the cases decided (except for two) between 1977 and 1992 were prenatal cases. The other categories of cases have mostly occurred in the last decade or so, likely tracking the increasing diversity and complexity of genetic testing in clinical care in recent years.

#### E. Types of Errors

Each of the cases in the study was categorized by the type of error the defendant allegedly committed. The categories of error are:

##### 1. Diagnose

Failure to diagnose a genetic disorder in time to prevent an adverse outcome. Examples include failure to diagnose PKU in an infant before brain damage occurred due to build-up of toxic metabolites, or failure to diagnose Marfan syndrome in a patient who was dying from an aortic dissection (a common cause of death in Marfan patients), or failure to diagnose hemochromatosis in time to offer treatments that can prevent eventual organ failure.

##### 2. Interpret

Failure to appropriately interpret the results of genetic tests and explain the results fully to patients and their families. Examples include failure to interpret a genetic test result showing a “truncating mutation” as the presence of a heritable disorder (e.g.,

Angelman syndrome), or failure to interpret the results of a quad screen in pregnancy appropriately to recognize that it reflected a higher risk of Down syndrome in the fetus.

### 3. *Offer*

Failure to offer genetic screening despite indications that it was warranted. Examples include failure to recognize a high risk of genetic disorder related to maternal age (e.g. Down syndrome), a strong family history of disease (e.g., breast and ovarian cancer), high risk ethnicities (e.g. Asian couple not offered testing for blood dyscrasias, Ashkenazi Jewish couple not offered testing for CF), or presence of genetic disorder in parents themselves (e.g. Neurofibromatosis in parent not recognized, subsequent case for failure to offer prenatal genetic screening for the disorder).

### 4. *Return*

Failure to return test results to patients. This is the category that includes all the very clear mistakes: tests were run but results never made it back to the patients, either because the lab didn't return them, the doctors didn't follow-up, or the wrong results were returned.

### 5. *Treat*

Failure to properly treat a patient with a genetic disease. Examples include a doctor who failed to recommend a prognostic genetic test to help determine whether a woman with breast cancer should undergo chemotherapy, and a physician who prescribed a drug to a patient with a known genetic disorder that prevented proper metabolism of that drug.

The number of cases in each category are shown in Table 3. There are fewer cases in the treat error category, illustrating that genomic medicine is primarily at the diagnosis stage rather than treatment. Of the other categories, the three biggest categories of diagnose, interpret and offer are all knowledge-based errors, and are each larger than the return category, which is primarily ministerial errors in administering and returning genetic test results.

Table 3: Genetic Malpractice Cases by Type of Error

Error Category	# of Cases
Diagnose	57
Interpret	43
Offer	59
Return	36
Treat	8

This emphasis on knowledge-type errors by physicians is confirmed by a categorization of each case as an alleged judgment error or a ministerial error. The number of judgment-based cases was 120, whereas 82 were ministerial errors. This statistic, in combination with the type of error analysis, confirms that many physicians lack adequate training in genetics and are making frequent errors in professional judgment relating to genetics.

### F. Novel Claims

Genetic malpractice lawsuits have already begun to spawn novel legal claims, often in part to get around legislative restrictions on medical malpractice actions or the unique causation and damages issues presented by genetic malpractice cases.

#### 1. Wrongful Birth/Wrongful Life

One of the first innovations in genomic malpractice was the recognition of wrongful birth, and in a much smaller number of states, wrongful life causes of action.<sup>76</sup> In these cases, which courts in most states first addressed in the 1980s and 1990s, the health care professional being sued did not “cause” a child’s genetic disease, as that condition existed at the time of fertilization. Rather, the claim is that the health care provider’s negligence resulted in the parents not being informed about the risks of such a genetic condition in time to do something about it, whether it be to avoid creating a child or aborting the fetus if it already exists. This puts the parents in the awkward situation of arguing they (and in the case of wrongful life cases their child) would be better off if their child was never born, even while loving and caring for that same child.

Given this novelty, some courts rejected wrongful birth (as well as wrongful life) claims as a non-traditional tort. The Georgia Supreme Court, for example, held: “Simply put, ‘wrongful birth’ does not fit within the parameters of traditional tort law.”<sup>77</sup> As noted by a Minnesota Supreme Court Justice: “A tort of wrongful birth is not an accepted part of existing common law but would be something new.”<sup>78</sup>

Parents bringing wrongful birth cases must argue that, but for the physician’s negligence, they would have aborted their fetus, who in most cases is now their child. When parents indicate they would not have aborted their fetus, their wrongful birth claim is rejected.<sup>79</sup> For example, in one case the court stated that the defendants had “conducted scorched earth discovery,” including depositions of multiple family members and friends, for any shred of evidence that the parents “had an intention other than to terminate the pregnancy” if the fetus had a chromosomal abnormality.<sup>80</sup> In the words of the court, “[t]he defense has gone so far as to seek public records of all of [the mother’s] work email (denied by the Court) and, then, served subpoenas on each of [the couple’s] friends and family members for production of all ‘letters, emails, text

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<sup>76</sup> See, e.g., *Becker v. Schwartz*, 386 N.E.2d 807 (N.Y. 1978) (recognizing wrongful birth claim in New York); *Berman v. Allan*, 404 A.2d 8 (N.J. 1979) (recognizing wrongful birth claims in New Jersey); *Moores v. Lucas*, 405 So.2d 1022 (Fla. Dist. Ct. App. 1981) (recognizing wrongful birth but not wrongful life cause of action in Florida); *Naccash v. Burger*, 290 S.E.2d 825 (Va. 1982) (recognizing wrongful birth claim in Virginia); *Turpin v. Sortini*, 643 P.2d 954 (Cal. 1982) (recognizing wrongful life claim in California). *But see* *Azzolino v. Dingfelder*, 337 S.E.2d 528 (N.C. 1985) (recognizing neither wrongful life nor wrongful birth claims in North Carolina).

<sup>77</sup> *Atlanta Obstetrics & Gynecology Grp. v. Abelson*, 398 S.E.2d 557, 563 (Ga. 1990).

<sup>78</sup> *Hickman v. Group Health Plan*, 396 N.W.2d 10, 15 (Minn. 1986) (Simonette, J., concurring).

<sup>79</sup> Verdict and Settlement Summary, *Volker-Ruiz v. Garvin*, No. NWC 02527, 1988 WL 1099048 (Cal. Super. 1988) (jury verdict for physician after evidence that mother stated she would never abort her fetus); Verdict and Settlement Summary, *Sanchez v. Lacanlale*, No. BC154567, 1998 WL 1054785 (Cal. Super. 1998) (jury verdict for doctors who argued that plaintiff would not have aborted her fetus even if doctors had informed her that the fetus had Down syndrome).

<sup>80</sup> Trial Motion, Memorandum and Affidavit, *Wuth v. Lab Corp.*, No. 102432892, 2013 WL 7210884, at \*3, (Wash. Super., Aug. 9, 2013).

messages, and social media posts, relating in any way to your communications with [the couple]’ regarding a broad array of subjects.”<sup>81</sup>

In another case a mother had a dominant genetic condition called “incontinentia pigmenti” which involved a significant risk of having a baby with major neurological problems.<sup>82</sup> Her physician failed to diagnose the genetic condition of the mother and she produced a baby carrying the same genetic condition who had serious neurological problems. The jury held in favor of the physician based on evidence that the mother subsequently had another pregnancy, which undercut her argument she would not have proceeded with the original pregnancy if her physician had diagnosed her genetic condition (which could not be detected in utero at the time).

In a New Jersey case,<sup>83</sup> the mother and father who brought a wrongful birth case both declined to say in their separate depositions that they would have aborted the affected fetus if they had been given the opportunity.<sup>84</sup> Although the father subsequently stated in a declaration that he would have aborted the fetus,<sup>85</sup> the District Court denied the parents the right to recovery for their child’s extraordinary medical expenses given their failure to clearly demonstrate they would have aborted their fetus but for the testing laboratory false positive result.<sup>86</sup>

In an Illinois case, the physician was indisputably negligent in misreading an alpha-fetoprotein test, and the mother gave birth to a baby with Down syndrome.<sup>87</sup> The parents brought a wrongful birth case, but the physician argued that the mother had told him in his office that if the fetus had a genetic condition, she would not abort the fetus.<sup>88</sup> The plaintiff denied this conversation occurred, and both she and her husband strenuously argued that they would have aborted their fetus if they had known it had Down syndrome.<sup>89</sup> The jury found for the defendant, which was upheld on appeal.<sup>90</sup> Although it eventually settled for \$6.6 million, in another case the defendant argued that the parents were members of the Coptic Christian church which has strong beliefs against abortion, and therefore it is unlikely the mother would have gone forward with an abortion even if she had been timely informed of the fragile X genetic status of her fetus.<sup>91</sup>

The physician’s personal views have also sometimes been an issue in wrongful birth and wrongful life cases. For example, in one case the mother underwent alpha-fetoprotein testing which indicated a high risk of Down syndrome in the fetus.<sup>92</sup> The

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<sup>81</sup> *Id.* at \*5.

<sup>82</sup> Verdict and Settlement Summary, *Woodhouse v. Reynard*, No. SC027106, 1997 WL 852559, at \*2, (Cal. Super. Ct., Sept. 18, 1997).

<sup>83</sup> *Provenzano v. Integrated Genetics*, 66 F.Supp. 2d 588 (D.N.J. 1999).

<sup>84</sup> *Id.* at 589–90.

<sup>85</sup> *Id.* at 590.

<sup>86</sup> *Id.* at 593.

<sup>87</sup> *Thornhill v. Midwest Physician Ctr.*, 787 N.E.2d 247 (Ill. App. Ct. 2003).

<sup>88</sup> *Id.* at 252.

<sup>89</sup> *Id.* at 252–53.

<sup>90</sup> *Id.* at 263.

<sup>91</sup> Verdict and Settlement Summary, *Salib v. St. Peter’s U. Hosp.*, 2007 WL 7953014 (N.J. Super. Ct. Law Div. 2007).

<sup>92</sup> Verdict and Settlement Summary, *Confidential v. Confidential*, 1998 WL 34336528 (Cal. Super. 1998).

treating physician, who was personally opposed to abortion, ordered the test results to be recalculated and reported only the altered results to the mother, which indicated no increased risk.<sup>93</sup> When the child was born with Down syndrome, the altered tests were revealed and the parents sued the physician, who settled for \$887,500.<sup>94</sup>

In part due to this connection with abortion, some states have now abolished wrongful birth lawsuits. For example, Utah adopted its Wrongful Life Act,<sup>95</sup> which prohibited a cause of action “based on the claim that but for the act or omission of another, a person would not have been permitted to have been born alive but would have been aborted.”<sup>96</sup> A family that gave birth to a Down syndrome child due to alleged physician negligence immunized under the act argued that such a statute provides a “safe harbor” for an anti-abortion physician to deliberately withhold genetic information about an abnormal fetus from expecting parents in order to avoid an abortion.<sup>97</sup> The Utah Supreme Court rejected this argument, stating that “this possible scenario is too tenuous to hold that the statute has the effect of placing a substantial obstacle in the path of a woman who seeks an abortion.”<sup>98</sup>

In some states that do recognize wrongful birth claims, courts have sometimes allowed such cases to go forward under other names. For example, the North Carolina Supreme Court allowed a case with the same facts as a wrongful birth case to go forward as a medical negligence claim instead.<sup>99</sup> A court in Oregon adopted the same strategy, expressly “eschew[ing] the use of those potentially ‘loaded’ labels [of wrongful birth and wrongful life] as unhelpful to our analysis, which turns on established negligence principles in Oregon.”<sup>100</sup>

Another wrinkle was raised in a wrongful life case that involved pre-implantation genetic diagnosis (PGD), in which embryos created *in vitro* undergo genetic screening before they are placed in a woman’s uterus to induce pregnancy.<sup>101</sup> In this case, the parents tried to distinguish the case from a prenatal testing case, in which a fetus already present in the womb undergoes genetic screening: “Here, plaintiffs contend that the infant plaintiff’s causes of action for negligence and medical malpractice are distinct from a wrongful life claim, as the defendants actually created the embryo with mutated genetic material, resulting in the infant plaintiff being born with cystic fibrosis.”<sup>102</sup> The New York Superior Court rejected this argument, however, stating

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<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> Utah Code Ann. §§ 78-11-23–25 (2002) (repealed 2008). *See* Utah Code Ann. § 78B-3-109.

<sup>96</sup> Utah Code Ann. § 78-11-24 (2002) (repealed 2008). *See* Utah Code Ann. § 78B-3-109.

<sup>97</sup> *Wood v. Univ. of Utah Med. Ctr.*, 67 P.3d 436, 445 (Utah 2002).

<sup>98</sup> *Id.*

<sup>99</sup> *McAllister v. Ha*, 496 S.E.2d 577, 582 (N.C. 1998) (holding the plaintiffs stated a claim of medical malpractice, not a claim of “wrongful birth,” because the plaintiffs alleged the pregnancy was a result of the defendant’s negligent failure to report blood tests and did not allege the child’s existence itself was the injury for which they were seeking damages).

<sup>100</sup> *Tomlinson v. Metro. Pediatrics, LLC*, 366 P.3d 370, 375–76 (Or. Ct. App. 2015).

<sup>101</sup> *Cremisio v. CNV Fertility*, No. 46-1-2014-0319, 2015 WL 13091494, at \*1 (N.Y. Sup. Ct. Apr. 17, 2015).

<sup>102</sup> *Id.*

that the infant plaintiff should not be entitled to any greater rights based on the manner of her conception.”<sup>103</sup>

## 2. *Informed Consent*

With the imposition of various limitations on medical malpractice actions by state legislatures in many jurisdictions, plaintiffs’ attorneys often try to present genomic malpractice cases in alternative formulations. One such formulation is to style a case in which the physician fails to recommend genetic testing as a lack of informed consent claim. Such claims have generally not fared well in the genomic malpractice context to date. For example, a California court rejected such an informed consent claim by holding that a physician holds no duty to disclose remote or small risks for which there was no specific evidence of an increased risk in that plaintiff.<sup>104</sup> As stated by the court, “[p]laintiffs would have us impose on defendants a duty to give plaintiffs information regarding a genetic test defendants did not recommend because it was not indicated by any facts which plaintiffs told to defendants, or even any facts of which plaintiffs were aware. Reason, as well as precedent, compels our refusal to impose such a duty.”<sup>105</sup>

Similarly, Maryland’s highest court held that no cause of action was available for lack of informed consent when a physician failed to offer a genetic test.<sup>106</sup> The court stated that the plaintiffs seek “a rule that the appropriate tests for predictive genetic counseling will be determined by what reasonable persons, similarly situated to the plaintiffs, would want to know. But the rule cannot focus exclusively on the plaintiff. A fair rule would have to look at all of the possible tests that might be given and evaluate the reasons for excluding some and perhaps recommending one or more others. That approach requires expert testimony.”<sup>107</sup>

## 3. *Infliction of Emotional Distress*

Another strategy for circumventing limits on medical malpractice cases is to bring a claim for infliction of emotional distress relating to failure to conduct genetic testing. In a case rejecting an intentional infliction of emotional distress claim for a physician’s failure to offer genetic testing, a California Court of Appeal held that there was no evidence of fraud and there is no duty for a physician to disclose minor risks: “Such a line, like one drawn with a finger in the air, is without precision and predictability. It would impose significant new burdens on already harried doctors without awarding demonstrable benefits to their patients.”<sup>108</sup> In 1987, the Illinois Supreme Court rejected a claim for negligent infliction of emotional distress associated with allegedly negligent genetic counseling on the grounds that the family members of a child born with a genetic disease suffered no direct injury or endangerment from the defendant’s negligence.<sup>109</sup> However, in 2011, the Illinois Supreme Court partially overturned that decision, and held that parents bringing a wrongful birth lawsuit could bring a claim

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<sup>103</sup> *Id.*

<sup>104</sup> *Munro v. Regents of Univ. of Cal.*, 263 Cal. Rptr. 878, 885, 988 (1989).

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

<sup>106</sup> *Reed v. Campagnolo*, 630 A.2d 1145, 1152–54 (Md. 1993).

<sup>107</sup> *Id.* at 1154.

<sup>108</sup> *Munro*, 263 Cal. Rptr. at 884.

<sup>109</sup> *Siemieniec v. Lutheran Gen. Hosp.*, 512 N.E.2d 691, 707 (Ill. 1987).

for emotional distress as an element of damages for wrongful birth, rather than as a free-standing tort.<sup>110</sup>

#### 4. *Duty to Patient's Family*

Another type of novel legal claim that comes up in genomic malpractice cases is the physician's possible duty to a patient's family members, given the attribute of genetic information that is shared within families. This has been one of the most discussed claims associated with genomics in the academic literature and amongst healthcare providers.<sup>111</sup> This discussion is often focused on three well-known cases, summarized below:

*Pate v. Threlkel*:<sup>112</sup> In this Florida case, a father's physician was sued for failing to warn the patient's adult children of a genetically transmitted disease. The Florida Supreme Court held that the daughter's lawsuit can proceed because the patient's children are within the "zone of foreseeable risk" and thus a physician has a duty to them.<sup>113</sup> However the court held that this duty is discharged by the physician warning the patient to inform his children: "To require the physician to seek out and warn various members of the patient's family would often be difficult or impractical and would place too heavy a burden upon the physician. Thus, we emphasize that in any circumstances in which the physician has a duty to warn of a genetically transferable disease, that duty will be satisfied by warning the patient."<sup>114</sup>

*Safer v. Pack*:<sup>115</sup> The following year, in a case involving a heritable form of colon cancer, a New Jersey appellate court agreed with the Florida Supreme Court that a physician may have a duty to disclose genetic risks to a patient's relatives, but disagreed that a physician can always discharge that duty by telling the patient rather than the patient's relatives directly.<sup>116</sup> The court reasoned that "[w]e need not decide, in the present posture of this case, how, precisely, that duty is to be discharged, especially with respect to young children who may be at risk, except to require that reasonable steps be taken to assure that the information reaches those likely to be affected or is made available for their benefit."<sup>117</sup>

*Malloy v. Meier*:<sup>118</sup> A mother sued a doctor who was treating her first child for negligence in failing to genetically test the child for Fragile X syndrome, a genetic condition that causes intellectual disabilities, and warn the mother of her risk of giving birth to a subsequent child with Fragile X.<sup>119</sup> The physician had never met the mother face-to-face, but rather was treating the first child who was in the custody of the

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<sup>110</sup>Clark v. Children's Mem'l Hosp., 955 N.E.2d 1065, 1088 (Ill. 2011).

<sup>111</sup>See Kenneth Offit et al., *The "Duty to Warn" a Patient's Family Members About Hereditary Disease Risks*, 292 JAMA 1469, 1470-71 (2004); Kristin E. Schleiter, *A Physician's Duty to Warn Third Parties of Hereditary Risk*, 11 AM. MED. ASS'N J. ETHICS 697, 697-99 (2009).

<sup>112</sup>*Pate v. Threlkel*, 661 So.2d 278 (Fla. 1995).

<sup>113</sup>*Id.* at 282.

<sup>114</sup>*Id.*

<sup>115</sup>*Safer v. Pack*, 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1996).

<sup>116</sup>*Id.* at 1191-92.

<sup>117</sup>*Id.* at 1192.

<sup>118</sup>*Molloy v. Meier*, 679 N.W.2d 711 (Minn. 2004.)

<sup>119</sup>*Id.* at 713-14.

divorced father.<sup>120</sup> The mother did subsequently give birth to a second child with Fragile X, and sued the doctor.<sup>121</sup> The Minnesota Supreme Court held that the fact that the physician did not meet face-to-face with the plaintiff “does not relieve her of her duty of reasonable care to the patient and the patient’s biological parents to provide accurate genetic testing results.”<sup>122</sup> The court decided that given the facts of that case, it need not reach the question of “whether the duty recognized here extends beyond biological parents who foreseeably will rely on genetic testing and diagnosis and therefore foreseeably may be injured by negligence in discharging the duty of care.”<sup>123</sup>

In addition to these three well-known cases, the current analysis revealed several other cases involving a physician’s duty to a patient’s relatives. For example, in a case involving a child with cystic fibrosis, the court held that the physician had a duty to diagnose the child’s condition but also an independent duty to notify the biological parents of the child who could use that information for planning decisions about future children.<sup>124</sup> Children and grandchildren of a woman who had a rare cancer genetic predisposition sued the woman’s physician for failing to inform the patient of the inheritable nature of her disease and also to inform her children and to make sure that the children received adequate medical tests when they became older.<sup>125</sup> The case settled for \$300,000.<sup>126</sup>

A Pennsylvania court held that a physician had a duty to his patient’s son.<sup>127</sup> The physician had allegedly negligently failed to genetically test his patient for hypertrophic cardiomyopathy (HCM), and the patient subsequently died from that condition.<sup>128</sup> Two years later, his son died from the same condition, and the son’s estate brought a lawsuit against the father’s physician alleging he had a duty to the son and thus was negligent in failing to genetically test the father and would have had a duty to instruct the patient to tell his son of his genetic risk.<sup>129</sup> The court rejected the physician’s summary judgment motion, holding that the physician had such a duty to his patient’s son.<sup>130</sup>

Some cases go the other way and hold that a physician has no duty to a patient’s relatives. In a New York case, the parents sued physicians who failed to diagnose a rare genetic condition in their first child, and claimed that they are entitled to damages when they gave birth to a second child with the same condition, which they alleged they could have avoided had the physicians not been negligent in failing to diagnose the genetic condition in their first child.<sup>131</sup> The court held that any duty the physicians

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<sup>120</sup>*Id.* at 714.

<sup>121</sup>*Id.* at 715.

<sup>122</sup>*Id.* at 720.

<sup>123</sup>*Id.*

<sup>124</sup>*Mydske v. Univ. of Wash.*, 8 No. 10 VST 252 (King Cty. Super. Ct. Wash. 1988).

<sup>125</sup>*Id.*

<sup>126</sup>*Id.*

<sup>127</sup>*Polaski v. Whitson*, No. 2011-C-2583, 2015 WL 5244960, at \*7 (Pa. Com. Pl. Civil Div. June 30, 2015).

<sup>128</sup>*Id.* at \*\*1–2.

<sup>129</sup>*Id.* at \*2.

<sup>130</sup>*Id.* at \*5–7.

<sup>131</sup>*Klein v. Bialer*, 899 N.Y.S.2d 297 (NY App. Div. 2010).

had to the infant did not extend to the infant's parents, and dismissed the parents claim on summary judgment.<sup>132</sup>

In the multi-generational case of *Houser v. Kaufman*, a physician failed to disclose a positive phenylketonuria (PKU) test result in a newborn girl under his care.<sup>133</sup> The girl had various disabilities that could have been prevented with a timely diagnosis but was never diagnosed with the condition until she gave birth to a severely impaired son caused by her untreated PKU.<sup>134</sup> The Missouri Court of Appeals held that the (deceased) physician had no duty to the son, as too much time had gone by, but the mother was permitted to recover in medical malpractice for her injuries as a result of the missed diagnosis when she was a newborn.<sup>135</sup>

In a 1998 decision, a New York court held that a physician treating a man with retinoblastoma, a cancer of the eye, did not commit malpractice by failing to advise his patient of his reproductive risks—namely, that any of his children would have a 50 percent chance of being affected by the same disease.<sup>136</sup> The father subsequently gave birth to two children with retinoblastoma, with the court holding that “the children were not identifiable beings within the zone of danger when the alleged malpractice was committed, and defendant owed no duty to them independent of the duty owed to their father.”<sup>137</sup>

In summary, the question of whether physicians have a duty to warn their patients' relatives of genetic risks, at least by informing the patient and recommending that they warn their relatives, remains a litigated issue, with most courts holding that there may be such a duty, but with the contours of that duty very much still uncertain.

### 5. *Statutes of Limitations Cases*

Although not a claim, statutes of limitations and repose defenses have been an important factor in genomic malpractice cases. Genetic conditions will often present statute of limitations issues, because the discovery of the genetic condition may not occur until several years after a physician commits the allegedly negligent act, by which time the traditional statute of limitations may have run. This is demonstrated by the finding in the present study that genomic malpractice cases take almost twice as long as other medical malpractice claims to resolve from the time of conduct to final resolution.<sup>138</sup> Recognizing that such a delay can produce results that are “shocking” and “absurd,” the Texas Supreme Court held in 1984 that the statute of limitations cannot start to run until the plaintiff discovered, or should have discovered, that a physician committed genomic malpractice many years previously.<sup>139</sup>

In a case against a hospital and physician for failing to conduct newborn genetic testing which involved a child who was diagnosed with a genetic condition at age 10, the court of appeals ruled that the statute of limitations started to run on the date that a physician notified the parents that their child had a genetic condition. The court noted

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<sup>132</sup>*Id.* at 298–99.

<sup>133</sup>972 N.E.2d 927, 930–31 (Ind. Ct. App. 2012).

<sup>134</sup>*Id.* at 930–31.

<sup>135</sup>*Id.* at 940.

<sup>136</sup>*Weed v. Meyers*, 674 N.Y.S.2d 242, 243 (N.Y. App. Div. 1998).

<sup>137</sup>*Id.* at 243–44.

<sup>138</sup>*See supra* note 68 and accompanying text.

<sup>139</sup>*Nelson v. Krusen*, 678 S.W.2d 918, 923 (Tex. 1984).

that “[i]n a more straightforward medical negligence case, for example, a discrete surgical error occurs and causes immediate damages—the negligence and the resulting harm occur at a discrete, identifiable point in time. In the context of a long-running relationship between patient and physician, however, where the negligence is a failure to properly diagnose and treat a condition, it may be difficult to determine when in the course of treatment the physician breached a duty.”<sup>140</sup> The court in this case extended the date on which the statute of limitations started to run to the date on which the second affected child (the plaintiff in this case) was conceived, rather than the default rule of using the date of misdiagnosis which in this case was several years earlier, thus putting the patient’s claim within the statute of limitations.<sup>141</sup>

In the *Houser v. Kaufman* case involving PKU described above,<sup>142</sup> a case involving several decades between the alleged negligence and the filing of a lawsuit, a physician failed to report a positive PKU test of a newborn, who although disabled throughout her life was never diagnosed with PKU. Decades later she gave birth to a son who had microcephaly, and during the treatment of her son it was discovered that the mother had PKU, and the high levels of phenylalanine in the mother’s blood caused the son’s severe impairment. The court held that although the missed diagnosis and malpractice had occurred decades earlier, the statute of limitations did not start to run until the mother discovered her PKU status and the physician’s malpractice decades later. 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 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.<sup>143</sup>

Other courts have been less flexible in using their discretion to avoid unjust results. For example, the Florida Supreme Court’s treatment of the statute of repose for medical malpractice actions in that State shows difficult implications for genetic malpractice. The Court addressed this issue in a case in which a family had their first child who was affected by multiple disabilities tested for genetic abnormalities that

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<sup>140</sup>Molloy v. Meier, 679 N.W.2d 711, 721. (Minn. 2004).

<sup>141</sup>*Id.* at 722 (“We reaffirm the long-standing principle that malpractice actions based on failures to diagnose generally accrue at the time of the misdiagnosis, because some damage generally occurs at that time. However, where the claim is that if the diagnosis of Fragile X had been properly made a tubal ligation would have been performed and conception avoided, we conclude that damage does not occur until the point of conception, and the cause of action then accrues.”).

<sup>142</sup>See *Houser v. Kaufman*, *supra* notes 134–36.

<sup>143</sup>*Id.* at 938.

might affect future children.<sup>144</sup> Even though the first child did have a genetic abnormality (trisomy of part of chromosome 10), that result was never communicated to the family, which had two miscarriages before finally giving birth to an affected child with the same trisomy five years after the physician failed to communicate the genetic test results.<sup>145</sup> The Court ruled that the family's action was barred by the statute of repose because more than four years had passed since the negligent act, even though the birth of the child which created the cause of action did not arise until after the statute of repose had expired.<sup>146</sup>

Another statute of repose case is one in which a five-year old child was admitted for a tonsillectomy and adenoidectomy and the hospital performed an EKG which produced a readout that stated "prolonged QT."<sup>147</sup> The physician read and signed the report but took no further action on the prolonged QT finding.<sup>148</sup> Four years later the patient died suddenly, and genetic testing revealed a prolonged QT syndrome mutation that was later determined to be the cause of death.<sup>149</sup> The patient's family subsequently brought a medical malpractice lawsuit alleging the physician was negligent in failing to diagnose the long QT syndrome when he examined the patient in 2005.<sup>150</sup> The Michigan Court of Appeals held that, although the 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 at the time of the initial examination in 2005 and therefore the lawsuit was precluded by the statute of repose.<sup>151</sup>

In a statute of limitations case, a pregnant mother was a known carrier for the sickle cell trait so the father of her fetus was genetically tested.<sup>152</sup> The hospital misread the test results and incorrectly reported that father was not a carrier, and plaintiff gave birth to child with sickle cell disease.<sup>153</sup> The mother brought suit after the child was diagnosed with the condition, and the defendant argued that the 18-month statute of limitations had run.<sup>154</sup> The lower court held that the statute of limitations had been tolled by the continuous treatment doctrine on the grounds that the physician had continued to treat the mother during her pregnancy.<sup>155</sup> On appeal however, the appellate court over-ruled the lower court and held that the father's genetic test "was simply not committed in relation to the ongoing obstetric care the plaintiff

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<sup>144</sup>Kush v. Lloyd, 616 So.2d 415 (Fla. 1992).

<sup>145</sup>*Id.* at 417

<sup>146</sup>*Id.* at 418.

<sup>147</sup>Burton v. Macha, 846 N.W.2d 419 (Mich. Ct. App. 2014).

<sup>148</sup>*Id.* at 420.

<sup>149</sup>*Id.*

<sup>150</sup>*Id.* at 421.

<sup>151</sup>*Id.* at 422–23.

<sup>152</sup>Jorge v. N.Y.C. Health & Hosps. Corp., 590 N.E.2d 239, 239 (N.Y. 1992).

<sup>153</sup>*Id.* at 239–40.

<sup>154</sup>*Id.* at 240.

<sup>155</sup>Jorge v. N.Y.C. Health & Hosps. Corp., 563 N.Y.S.2d 411, 413–14 (N.Y. App. Div. 1991), *rev'd* 590 N.E.2d 239, 239 (N.Y. 1992).

received.”<sup>156</sup> The mother’s claim was then dismissed because the statute of limitations had run.<sup>157</sup>

A convicted murderer brought a failure to warn claim against Eli Lilly, the manufacturer of the antidepressant medication, Prozac.<sup>158</sup> The plaintiff claimed that the drug, for which he had discovered he was a poor metabolizer resulting in higher than normal drug levels in his system, which caused him to act violently, and thus Eli Lilly was negligent for failing to warn him of such a risk.<sup>159</sup> The court held that the claim was precluded under the statute of limitations, which began to run when the plaintiff first claimed that Prozac may have such effects, rather than the later date on which he learned he was a poor metabolizer.<sup>160</sup>

Another litigation timing requirement that can have harsh consequences for plaintiffs is the statutory notice requirement for lawsuits against most governmental entities. For example, a five-year old girl being treated at a public university clinic died from a genetic heart condition discovered post-mortem. The mother brought a medical malpractice lawsuit alleging that the treating physician was negligent in failing to diagnose her daughter’s genetic heart condition. The court dismissed the case because the mother had failed to comply with the 90-day notice requirement to a public entity, even though genetic nature of disease was not known until after the 90-day period from the date of the girl’s death had run.<sup>161</sup>

#### 6. *Other Unusual Claims*

Genomic malpractice litigation has created a number of other unusual claims and situations. In one case, parents brought their four-month old child to the Walter Reed Army Medical Center for a well-baby checkup where the doctors accused the parents of abusing their child and contacted Child Protective Services (CPS) who took away the child and brought criminal charges against the parents.<sup>162</sup> The parents explained they had a family history of a genetic bone disease causing bones to easily fracture (Osteogenesis Imperfecta (OI)) and requested genetic testing, which was initially ignored, but eventually genetic testing was conducted and confirmed the child had OI.<sup>163</sup> Although the criminal charges were dropped, the treating doctors continued to assert that the father had abused the child and based on those claims CPS listed the father in the Registry of Child Abusers.<sup>164</sup> The parents hired lawyers and eventually got their child returned after 18 months in foster care.<sup>165</sup> They then brought a medical

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<sup>156</sup>*Jorge*, 590 N.E.2d at 240.

<sup>157</sup>*Id.*

<sup>158</sup>*Danysh v. Eli Lilly*, 461 Fed. App’x. 75 (3d Cir. 2012).

<sup>159</sup>*Id.* at 76.

<sup>160</sup>*Id.* at 77–78.

<sup>161</sup>*Hood v. Ramagopal*, No. L5323-13, 2015 WL 5008979, at \*6 (N.J. Super. Ct. App. Div. Aug. 18, 2015).

<sup>162</sup>Press Release, Surovell, Markle, Issaci & Levy PLC, United States Military Settles Case for Medical Negligence and Intentional Infliction of Emotional Distress (Oct. 15, 2005), [http://www.siplfirm.com/Press-Room/SUROVELL\\_Dorothy\\_Isaacs\\_Velasquez\\_Case\\_Announcement-wpd.pdf](http://www.siplfirm.com/Press-Room/SUROVELL_Dorothy_Isaacs_Velasquez_Case_Announcement-wpd.pdf).

<sup>163</sup>*Id.*

<sup>164</sup>*Id.*

<sup>165</sup>*Id.*

malpractice lawsuit against the military alleging the Center had “failed to meet the standard of care in refusing to test the child for the genetic bone disease which would have proven the child suffered from OI.”<sup>166</sup> The United States, as defendant, contended that the doctors met the standard of care, had no obligation to perform the test for OI, and acted appropriately in reporting child abuse.<sup>167</sup> The case eventually settled, with the judge apologizing to the family when the settlement was entered for the emotional trauma the physician caused their family.<sup>168</sup>

Another unusual case was that of a pregnant Connecticut woman who had an abortion after she was erroneously informed that her baby had a serious chromosomal defect.<sup>169</sup> A second genetic test reported just hours after the fetus was aborted indicated that the first test was erroneous and the fetus had no genetic abnormalities.<sup>170</sup> This case, like several other of the cases in this study,<sup>171</sup> came down to a “he said, she said” dispute about what exactly the physician told the patient.<sup>172</sup> The physician claimed she did tell the patient that the first test was only preliminary and a second test being conducted would be determinative, while the patient claimed that she had been told that the first test was determinative and the second test was being done for another reason, and she claimed that she was not informed that she could delay her abortion for a day or less to get the second set of test results.<sup>173</sup> The jury sided with the defendants.<sup>174</sup>

Another erroneous testing case was *Held v. Ambry Genetics*.<sup>175</sup> Nancy Held had breast cancer, and genetic testing revealed she had a mutation of the p53 gene that represented Li-Fraumeni syndrome.<sup>176</sup> This is a genetic disease that greatly increases the risk of a person developing many different types of cancers, and Held had her ovaries and uterus removed to try to reduce her risk, but was told she would likely nevertheless die from the condition.<sup>177</sup> She was also concerned her children would inherit the same conditions.<sup>178</sup> Many months later, Ambry revealed that they had

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<sup>166</sup>*Id.*

<sup>167</sup>*Id.*

<sup>168</sup>*Id.*

<sup>169</sup>*Meleney-Distasio v. Weinstein*, 59 Conn L. Rptr. 392 (Conn. Super. Ct. 2013).

<sup>170</sup>*Id.*

<sup>171</sup>*See, e.g., Confidential v. Confidential*, 2011 WL 7403607 (Cal. Super. Ct. 2011) (physician claimed that she informed pregnant patient that blood test indicated genetic risk of Down syndrome, but plaintiff denied any such conversation. Conversation was not charted, case settled for \$1.75 million); Alan Scher Zagier, *Jury Sides with Oncologist in Chemo-Drug Case*, MO. LAW. MEDIA, Jan. 8, 2016 (physician’s tape recording of discussion with patient about genetic side effect of drug was “particularly important and helpful” in helping physician successfully defend against medical malpractice claim). These examples demonstrate the importance of physicians charting their discussion of genetic testing issues with patients.

<sup>172</sup>Robert Storace, *Jury Sides with Stamford Hospital after Lab Error Led to Woman’s Abortion*, CONN. L. TRIB., Nov. 10, 2016, <http://www.law.com/sites/articles/2016/11/10/jury-sides-with-stamford-hospital-after-lab-error-led-to-womans-abortion/>.

<sup>173</sup>*Id.*

<sup>174</sup>*Id.*

<sup>175</sup>Complaint, *Held v. Ambry Genetics Corp.*, No. 15-CV-8683, 2015 WL 6750024 (S.D.N.Y. Nov. 4, 2015).

<sup>176</sup>*Id.* at 2.

<sup>177</sup>*Id.* at 2.

<sup>178</sup>*Id.* at 2–3.

inadvertently switched the blood samples and the test result was erroneous.<sup>179</sup> Hand brought suit, which settled for an undisclosed amount prior to trial.<sup>180</sup>

### 7. *Novel Claims Not Observed*

Just as important as the types of claims that have been asserted in genomic malpractice litigation to date are the types of claims that have yet to be brought. In particular, while scholars have pointed to the potential liability risks related to reporting of incidental findings<sup>181</sup> and a potential duty to revisit genetic test results,<sup>182</sup> no such cases have yet to have been brought in genomic malpractice cases decided to date.<sup>183</sup> These types of claims are likely to result in the future, however, with the advent of high-throughput genetic technologies such as whole genome or whole exome sequencing which will generate large numbers of variants of unknown significance (VUS), which are genetic changes without a known effect.<sup>184</sup> As additional research gradually identifies the clinical significance of these VUS, the results of genetic sequencing performed in the past will provide much more clinically actionable information in any given patient,<sup>185</sup> creating unique challenges for the medical malpractice liability system.<sup>186</sup>

A case still pending in South Carolina comes closest to raising this changing interpretation of genetic findings issue.<sup>187</sup> In this case, a child with seizures was genetically tested in 2007 and determined to have a variant of unknown significance in a gene (*SCN1A*) known to be associated with epilepsy. The child subsequently died in 2008, and the testing lab issued a revised report in 2015 recategorizing the VUS now as a pathogenic or disease-causing mutation. The mother then brought a lawsuit, claiming that the testing lab should have known her son's genetic variant was pathogenic at the initial time of testing in 2007.<sup>188</sup> However, even if the lab did not know the variant was pathogenic on the date the initial test results were provided to the family, they may still be liable if they should have discovered the variant was pathogenic before the child died and failed to provide a warning at that time.<sup>189</sup>

Surprisingly, there were relatively few cases where a patient alleged that a physician failed to adopt or apply new genetic testing technologies, such as gene panels or whole

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<sup>179</sup>*Id.* at 3.

<sup>180</sup>Order of Dismissal, *Held v. Ambry Genetics Corp.*, No. 15-CV-8683, (S.D.N.Y. Dec. 6, 2016).

<sup>181</sup>McGuire et al., *supra* note 10, at 720; Clayton et al., *supra* note 57, at 627–28.

<sup>182</sup>Stevens et al., *supra* note 58, at 372.

<sup>183</sup>*See* McGuire et al., *supra* note 10, at 720; Clayton et al., *supra* note 57, at 626.

<sup>184</sup>Stevens et al., *supra* note 58, at 372.

<sup>185</sup>*Id.* at 368–69.

<sup>186</sup>Adrian Thorogood, Robert Cook-Deegan & Bartha Maria Knoppers, *Public Variant Databases: Liability?*, 19 *GENET. MED.* 838 (2017).

<sup>187</sup>*Id.* at 838–39.

<sup>188</sup>Turna Ray, *Mother's Negligence Suit Against Quest's Athena Could Broadly Impact Genetic Testing Labs*, (Mar. 14, 2016), <https://www.genomeweb.com/molecular-diagnostics/mothers-negligence-suit-against-quests-athena-could-broadly-impact-genetic>. [<https://perma.cc/KZ96-MQ8Q>].

<sup>189</sup>It is alleged that the child was treated with a drug that may have hastened his death, and which would not have been prescribed if it were known he had the pathogenic variant. *Id.* Moreover, it was the testing lab itself that discovered the true nature of the variant, right around the time the child was genetically tested, and so it seems likely the lab knew or should have known about the pathogenic status of the variant at the time the child was genetically tested or shortly thereafter. *Id.*

genome or exome sequencing to help evaluate their condition. One of the few such cases is one in which a breast cancer patient was diagnosed as having a non-invasive cancer, but which later became metastatic. The patient sued her physician alleging that if the doctor had given her the gene expression oncotype test for cancer recurrence she would have had a score of 41 and that would have led the doctor to advise chemotherapy, which may have prevented the tumor reoccurrence.<sup>190</sup> The case ended up settling.<sup>191</sup>

### *G. Deference and Fairness to Physicians*

The genomic malpractice case law to date shows a deep schism in how judges and juries treat physicians with regard to the implementation of genomic medicine. The incorporation of genetic testing into clinical care presents a major challenge for many physicians who lack the expertise, training, and clinical decision support needed to use genetic information in an informed and beneficial manner. Genomic malpractice litigation also presents challenges to judges and juries, who lack genomic expertise, but must determine the applicable standard of care for the fast-moving practice of genomic medicine. In our medical malpractice system there is no list of standards of care that the parties or fact finders can rely on, but rather the standard of care is determined by the jury on a case-by-case basis after the events relating to the litigation have occurred.<sup>192</sup>

This system puts a lot of pressure and expectations on judges and juries who are called upon to decide technically complex liability cases such as genomic malpractice claims. The present empirical study finds that some judges and juries have been very sympathetic to the plight of such physicians, providing strong deference, in some cases perhaps excessively to the detriment of their poorly treated patients. In other cases, judges or juries apply a strict standard to the physician, holding them to unrealistically high expectations of knowledge and expertise. Examples of both types of cases are provided below.

#### *1. Strong Deference to Physicians*

In some cases, judges or juries have been very deferential to physicians in their decisions incorporating genetic information, in some cases overlooking clear errors or obvious negligence to the detriment of patients. For example, a woman who was diagnosed with breast cancer, and whose mother and sister also had breast cancer, was not recommended for genetic testing for heritable form of cancer caused by a mutation in the BRCA gene.<sup>193</sup> This is the most highly studied and publicized form of heritable cancer, and she should have been recommended for BRCA testing based on every testing guideline.<sup>194</sup> Two years later, she was diagnosed with ovarian cancer which

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<sup>190</sup>Virginia Lawyers Media, *Verdicts & Settlements: Metastatic Cancer Originally Diagnosed as Non-Invasive*, VIRGINIA LAWYERS WEEKLY, Dec. 29, 2014; Emily R. Carrie et al., *High Physician Concern About Malpractice Risk Predicts More Aggressive Diagnostic Testing in Office-Based Practice*, 32 HEALTH AFFAIRS 1383 (2013).

<sup>191</sup>*Id.*

<sup>192</sup>Edward B. Hirshfield, *Practice Parameters and the Malpractice Liability of Physicians*, 263 JAMA 1556, 1557 (1990).

<sup>193</sup>Cohen v. Rashba, 2005 WL 4044514 (Mass. Super. Ct. 2005).

<sup>194</sup>NATIONAL CANCER INSTITUTE, BRCA1 AND BRCA2: CANCER RISK AND GENETIC TESTING (2015). <https://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet>.

killed her; this type of cancer is strongly associated with BRCA mutations.<sup>195</sup> Yet the jury held that the physician had no duty to refer this patient for genetic testing.<sup>196</sup> In another BRCA related case, the plaintiff was treated for various ovarian problems.<sup>197</sup> Later that year, plaintiff's mother was found to carry a BRCA mutation, and plaintiff then also tested positive for BRCA.<sup>198</sup> However, her physicians did not associate her ovarian problems with the BRCA genetic mutation until the plaintiff subsequently was diagnosed with ovarian cancer while undergoing a hysterectomy.<sup>199</sup> The jury held that the physicians were not negligent in their failure to connect the patient's BRCA mutation with her ovarian problems, despite the fact that this connection is clearly documented in medical literature and genetic counseling guidelines.<sup>200</sup>

In a prenatal case, a pregnant woman had a blood test which reportedly indicated a 20 percent risk of Down syndrome in the fetus, but the physician did not tell the patient this result or recommend further testing.<sup>201</sup> A California appellate court nevertheless held that the physician was not negligent when the pregnancy resulted in a child with Down syndrome.<sup>202</sup> The court reasoned that holding physicians liable in such situations would encourage excessive use of defensive medicine and open the judicial floodgates:

It would unwisely encourage costly and unreasonable overtesting and overtreatment for defensive purposes. Physicians would find it necessary to place the requirements of the legal system before the needs and the finances of the patient. In addition, the physicians' increased exposure to liability would adversely impact already high medical malpractice premiums, resulting in an upward spiral of consumer costs. The uncertainty fostered by such a ruling would undoubtedly open the proverbial floodgates of our overburdened judicial system.<sup>203</sup>

## 2. *Unfair Burdens on Physicians*

Some courts have adopted a much more pro-plaintiff position, sometimes at the cost of imposing unfair or unrealistic expectations on physicians. An example of a court recognizing the importance of courts protecting the interests of patients as we enter the era of genetic medicine is this statement by a federal district court:

The increasing importance of these [genetic] procedures in modern life and their entry into the mainstream of accepted medical practices . . . as well as the extreme sensitivity of the issues and interests involved, dictate that plaintiffs' rights be afforded some protection. The most appropriate

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<sup>195</sup>Cohen v. Rashba, 2005 WL at 4044514.

<sup>196</sup>*Id.*

<sup>197</sup>Fox v. Frankel, 33 Pa. J.V.R.A. 6:C3, 2013 WL 10740207 (Pa. Com. Pl. Oct, 10, 2013).

<sup>198</sup>*Id.*

<sup>199</sup>*Id.*

<sup>200</sup>*Id.* See NATIONAL CANCER INSTITUTE, *supra* note 195.

<sup>201</sup>Simmons v. West Covina Medical Clinic, 260 Cal. Rptr. 772 (Cal. Ct. App. 1989).

<sup>202</sup>*Id.* at 775–78.

<sup>203</sup>*Id.* at 778.

mechanism for this protection is the ancient, yet vital and constantly evolving doctrine of negligence.<sup>204</sup>

In some cases, however, the courts' protection of patients' interests goes too far and puts unrealistic and unfair burdens on physicians. In one case, a family had two children who died from an unknown condition.<sup>205</sup> They consulted with a geneticist who suggested that they use in vitro fertilization (IVF) with a donated egg, as the unidentified genetic condition appeared to be either an autosomal recessive or mitochondrial disease.<sup>206</sup> The couple gave birth using a donated egg and IVF to a third affected child, which was subsequently diagnosed as a rare recessive autosomal genetic disease named Alper syndrome.<sup>207</sup> It appears that by bad luck the donated egg happened to carry the same rare genetic mutation, which had not yet been diagnosed at the time of the IVF.<sup>208</sup> The parents sued the geneticist for medical malpractice, and the jury awarded \$1.086 million, even though the chances of producing a child with one parent a known carrier using IVF by donor was less than 1 in 1000, and there was no allegation that the geneticist had any way to diagnose Alper syndrome prior to the birth of the third child, or to test the donated egg for its carrier status.<sup>209</sup>

In another case, a Florida physician was treating an infant with a number of symptoms, but did not diagnose the child with a rare genetic disease (Smith-Lemli-Opitz syndrome) until the parents gave birth to a second child with the same genetic condition.<sup>210</sup> This genetic condition is rare, present in only 1 in 20,000 to 1 in 40,000 live births, has no established clinical diagnostic criteria, has a broad range of expression, and has symptoms that overlap with other syndromes.<sup>211</sup> Most physicians are unlikely to ever see a patient with such a rare condition over the course of their career, and the symptoms overlap with many other potential diseases or syndromes. The parents nevertheless sued the physician for failing to properly diagnose their first child before getting pregnant with their second child, and received a jury verdict of \$21.125 million.<sup>212</sup>

#### IV. ANALYSIS AND CONCLUSIONS

This first ever empirical analysis of genomic malpractice litigation shows that there has been a modest increase in such litigation, but not as big of increase as may be predicted by the various "red flags" of litigation risk discussed in Section II. After more than forty years of such litigation, there are still less than a dozen reported cases closed per year alleging genomic malpractice. There are no doubts many more claims settled even before litigation is filed or which are otherwise not reported. Yet, the

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<sup>204</sup>Phillips v. United States, 508 F. Supp. 544, 551 (D.S.C. 1981).

<sup>205</sup>Wagner v. Shoffner, 2013 FL Jury Verdicts Rptr. LEXIS 158, 33 No. 3 Verdicts, Settlements & Tactics art. 11.

<sup>206</sup>*Id.*

<sup>207</sup>*Id.*

<sup>208</sup>*Id.*

<sup>209</sup>*Id.*

<sup>210</sup>Estrada v. University of South Florida Board of Trustees, 2007 WL 2491545 (Fla. Cir. Ct. 2007).

<sup>211</sup>Nowaczyk, et al., *Smith-Lemli-Opitz Syndrome*, in *GENEREVIEWS* (Adam et al. eds., 2013), <https://www.ncbi.nlm.nih.gov/books/NBK1143/>.

<sup>212</sup>Estrada, 2007 WL at 2491545.

relatively low numbers of cases and modest increase in frequency after forty years of such litigation suggests that genomic malpractice has not become a major trend in medical malpractice litigation. At least not yet.

This analysis has also shown that genomic malpractice cases appear to have a higher likelihood of success for plaintiffs than do traditional medical malpractice cases, take almost twice as long to be resolved compared to other medical malpractice cases, and provide monetary payouts almost an order of magnitude higher on average than other medical malpractice cases.<sup>213</sup> These high payouts likely reflect that errors in genetic testing often have devastating impacts on the patients' health (and perhaps other family members). But why then has there not been more genomic malpractice cases filed? There is certainly no shortage of potential cases—the large number of women with family histories of breast cancer who are not recommended for BRCA testing, the continued birth of babies with cystic fibrosis that could have been prevented with recommended carrier screening, the large number of patients harmed by drug side effects that could have been prevented by pharmacogenomics testing consistent with many FDA drug labels.

The most likely explanation for the limited proliferation of genomic malpractice litigation is the slower than expected roll-out of genomic medicine. While there has been tremendous progress in genomic science, the translation of that scientific knowledge into clinical implementation has proceeded at a much slower pace,<sup>214</sup> due to a number of factors described above including the lack of evidence of clinical utility, the lack of experience and expertise of many physicians in handling genetic information, the limited availability of reimbursement for genetic testing, and the lack of adequate clinical decision support and other infrastructure to integrate genetic testing into mainstream clinical care.<sup>215</sup>

The slow uptake of genomic medicine in the clinic slows the rate of genomic malpractice litigation in a couple ways. First, in states that still apply a custom-based malpractice standard, the fact that most doctors do not practice genetic medicine is self-protecting against liability. Second, the fewer providers applying genetic tests and data, the fewer mistakes will be made in the implementation of genomics. This is parallel to the advent of the kidney dialysis machine, where significant litigation about alleged errors in treating kidney patients only arose after the kidney dialysis machine was available to improve the treatment of such patients, thereby raising patients' expectations for better outcomes.<sup>216</sup> This is consistent with the history of medical technology in which new improvements in healthcare technology are a leading driver of malpractice litigation.<sup>217</sup> In addition, as high-throughput technologies such as whole genome sequencing enter widespread clinical application, the ever-changing clinical significance of variants initially classified as having unknown significance will create new liability pitfalls for providers.<sup>218</sup>

A second likely reason for the relative lack of genomic malpractice litigation is the lack of interest of medical malpractice plaintiff's lawyers in genomic cases. Plaintiffs'

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<sup>213</sup>See *supra* notes 68–76 and accompanying text.

<sup>214</sup>Roberts et al., *supra* note 15, at 858.

<sup>215</sup>See *supra* notes 32–35 and accompanying text.

<sup>216</sup>See *supra* note 45 and accompanying text.

<sup>217</sup>See *supra* note 42 and accompanying text.

<sup>218</sup>See *supra* notes 185–87 and accompanying text.

lawyers are the gatekeepers of medical malpractice litigation since they fund most such cases on a contingency basis.<sup>219</sup> Given that these attorneys will receive no payment, and will lose all their out-of-pocket costs associated with the case if they do not obtain a settlement or a favorable jury verdict, the plaintiffs' bar is necessarily conservative and will shy away from risky, uncertain or novel cases.<sup>220</sup> Few plaintiffs' attorneys have expertise in genetics, and are dissuaded by the highly uncertain and transitional status of genomic medicine, without a lot of clear responsibilities and duties that lead to clear negligence claims.<sup>221</sup>

However, there is no assurance that these two primary factors restraining the proliferation of genomic malpractice cases will continue for much longer. The uptake of genomic information into clinical care is continuing to grow steadily even if slowly, and the anticipated widespread adoption of non-invasive prenatal diagnosis and whole genome sequencing will further accelerate the general spread of genomics into medical care.<sup>222</sup> As the uptake of genomics into clinical care progresses, the pace of genomic malpractice litigation should grow as well. While most medical malpractice plaintiff lawyers are currently skeptical about genomic malpractice cases, that will change as more opportunities and clear decision rules emerge. Plaintiffs' lawyers follow a herd behavior: as more of their colleagues achieve success in bringing genomic malpractice cases, the interest and pursuit of the medical malpractice plaintiffs' bar in bringing these cases could grow exponentially.

The current lag in genomic malpractice litigation provides a window of opportunity for the medical profession to get its house in order for implementing genomic medicine. This might include better training of physicians,<sup>223</sup> clearer guidelines on when genetic testing is indicated,<sup>224</sup> more consistent and evidence-based reimbursement policies for genetic testing, and better clinical decision support infrastructure for physicians.<sup>225</sup>

The relatively low rate of genomic malpractice litigation also reduces concerns that have been expressed that physicians may be feeling pressure to engage in defensive medicine in genetic testing and order more genetic tests than medically appropriate in

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<sup>219</sup>James C. Mohr, *American Medical Malpractice Litigation in Historical Perspective*, 283 JAMA 1731, 1735 (2000).

<sup>220</sup>William B. Schwartz & Neil K. Komesar, *Doctors, Damages and Deterrence: An Economic View of Medical Malpractice*, 198 NEW ENGL. J. MED. 1282, 1288 (1978).

<sup>221</sup>As part of this project, we convened two workshops under Chatham House rules (no public attribution of any claims) of participants in the medical malpractice system – including physicians, medical malpractice plaintiffs' lawyers, medical malpractice defendants' lawyers, judges, and scholars – to discuss the dynamics of genomic malpractice litigation. At those workshops, the plaintiffs' attorneys confirmed that they were reluctant to pursue genomic malpractice cases because of the complex subject matter and high costs of getting attorneys and experts up to speed, and the uncertain outcomes of such cases given the unclear status of when and how genetic testing should be done.

<sup>222</sup>Christensen et al., *supra* note 41, at 232–33.

<sup>223</sup>Demmer & Waggoner, *supra* note 39, at 509–514.

<sup>224</sup>Carabello et al., *supra* note 15, at 427 (calling for “a national consensus between PGx experts and medical societies in charge of the clinical guidelines to widely disseminate standardized PGx knowledge that can be easily accepted by clinicians and quickly implemented in clinical practice.”); Amstutz & Carleton, *supra* note 16, at 926–27.

<sup>225</sup>Reza Mirnezami, Jeremy Nicholson & Ara Darzi, *Preparing for Precision Medicine*, 366 NEW ENGL. J. MED. 489, 491 (2012).

order to protect themselves from liability.<sup>226</sup> The problem from the empirical analysis provided here is more likely that physicians are under-utilizing genetic tests rather than over-using them. Yet, this all could change if genomic malpractice litigation “catches fire” and starts to grow at an exponential pace.

In conclusion, genomic malpractice litigation has continued a slow growth over the past forty years, with a definite upward tick in frequency the past decade. However, the rate of such litigation remains more of a trickle than a flood. A 2011 article described the advance of genomic medicine as follows:

The genomic revolution is sometimes described as a tidal wave that’s racing toward the shore . . . [T]hat’s the wrong metaphor. New ideas are flooding in . . . but they are filtering through the health care system in spurts, as they always have. Most people will perceive the changes not as a tsunami but as a “slowly rising tide.”<sup>227</sup>

Several years later, the same metaphors describe the dynamics of genomic malpractice – more of a slowly rising tide than a tsunami, with occasional spurts of new ideas and holdings making their way through the filters of the litigation system. The question of whether the pace of genomic malpractice liability will remain so limited will depend largely on how the medical profession is able to adapt to and accommodate the inevitable—even if delayed—surge in medical genomic applications and use.

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<sup>226</sup>See, e.g., William Young, *Wrongful Birth and Life Suits Hit Med-mal Nerve*, 12(17) N.J. LAWYER 1 (Apr. 28, 2003) (growth in genetic medicine is creating “a problem because it leads to prophylactic medicine and doctors performing tests essentially to shield themselves from lawsuits”).

<sup>227</sup>Eliot Marshall, *Waiting for the Revolution*, 331 SCIENCE 526, 529 (2011).