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Genetic Duties

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GENETIC DUTIES

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ABSTRACT

Most of our genetic information does not change, yet the results of our genetic tests might. Labs reclassify genetic variants in response to advances in genetic science. As a result, a person who took a test in 2010 could take the same test with the same lab in 2020 and get a different result. However, no legal duty requires labs or physicians to inform patients when a lab reclassifies a variant, even if the reclassification communicates clinically actionable information. This Article considers the need for such duties and their potential challenges. In so doing, it offers much-needed guidance to physicians and labs, who may face liability, and to courts, which will hear these cases.

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INTRODUCTION

Imagine this scenario. A thirty-seven-year-old woman arrives at a medical center with stage 4 breast cancer. Despite a family medical history of breast and ovarian cancers, she was not getting additional cancer screenings. Why? Because the patient took a genetic test in 2010, and the results did not indicate an increased risk for *BRCA1/BRCA2* hereditary breast/ovarian cancer.[1] The patient, therefore, took no special precautions.

Following the breast cancer diagnosis in 2020, the patient sees a clinical geneticist. The clinical geneticist looks at the patient's pedigree and is puzzled. "This looks like a *BRCA1/BRCA2* family," she thinks, and decides to order another genetic test. The second time, the patient's *BRCA1* test comes back positive for a heightened cancer risk. However, because the patient already has breast cancer, this newfound knowledge is of little help to her personally,[2] and she later dies. So what happened? And, more importantly, was her death preventable?

At first blush, it may seem incomprehensible that a patient could take a test for a *BRCA1* mutation in 2010 and again in 2020 and get such different results. After all, our genetics do not generally change.[3] Much of our genome is determined before birth and—apart from the occasional random mutation here and there—largely stays

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1. Some common forms of breast cancer have a large hereditary component. Although several genes play a part in their development, most heredity cases can be attributed to mutations in the *BRCA1* or *BRCA2* genes. T. R. Rebbeck, F.J. Couch, J. Kant, K. Calzone, M. DeShano, Y. Peng, K. Chen, J.E. Garber & B.L. Weber, *Genetic Heterogeneity in Hereditary Breast Cancer: Role of* BRCA1 *and* BRCA2, 59 AM. J. HUM. GENETICS 547, 547 (1996). In fact, 5-10 percent of breast cancers are inherited, and of those, about 50 percent are attributed to *BRCA1*. *Id.*; BARBARA T. ZIMMERMAN, UNDERSTANDING BREAST CANCER GENETICS 46 (2004). *BRCA1* is a large gene, with about one hundred thousand base pairs. ZIMMERMAN, *supra*, at 45. And there are about five hundred known mutations of the normal *BRCA1* allele. *Id.* at 46. Although carriers of certain *BRCA1* mutations have a higher chance of developing the disease, it is not well understood why some people with a specific mutation develop the condition early in life, while others never go on to develop breast cancer at all. *See id.*

2. That said, her family members could still benefit, particularly first-degree family members who will have a 50 percent risk of being carriers.

3. Orhan Soykan, *Biological Sensors for Diagnostics*, *in* MEDICAL DEVICES AND HUMAN ENGINEERING 8-1 (Joseph D. Bronzino & Donald R. Peterson eds., 2015).

the same throughout our lives.[4] How, then, can we explain our patient's experience? Did the original lab botch the test? Did the doctor give her another patient's results in 2010? Was she the victim of a rare environmental exposure that radically altered her DNA? The answer to all of these questions is no. The lab performed the test properly, the ordering physician gave her the right test results the first time, and her genetic sequence remained the same. Our understanding of genetics simply changed.

When scientists completed a rough draft of the human genome in 2000, it was only the beginning.[5] Although we had the genetic code, we did not—and indeed may never—fully appreciate its meaning. Researchers are constantly uncovering new genetic links and deepening our knowledge of how genetic variations impact our health.[6] Scientists make claims of new genetic discoveries, a new genetic link, or a newly discovered genetic function almost daily.[7]

Because so much of our genome is still a mystery, we may not fully understand the medical impact of a particular genetic variation.[8] We call those variations "variants of uncertain (or unknown) significance," or VUSs.[9] A VUS result reveals that the patient's

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4. *Id.* There are, however, exceptions to the general rule. Under certain circumstances our DNA and its functions do, in fact, change. *See* A. Bird, *Perceptions of Epigenetics*, 447 NATURE 396, 397-98 (2007). Epigenetic changes, or changes in gene function that cannot be explained by changes in DNA sequence, are sometimes heritable. *Id.* Random mutations in our DNA happen all of the time. *See Changes in Genes*, AM. CANCER SOC'Y (June 25, 2014), https://www.cancer.org/cancer/cancer-causes/genetics/genes-and-cancer/gene-changes.html [https://perma.cc/ZSG3-2AMA]. Occasionally, these changes may lead to a person developing cancer. *Id.* Exposure to radiation is also known to induce structural changes and chemical modifications in DNA. *See, e.g.*, Lin Ou, Yang Chen, Ying Su, Changyan Zou & Zhong Chen, *Detection of Genomic DNA Damage from Radiated Nasopharyngeal Carcinoma Cells Using Surface-Enhanced Raman Spectroscopy (SERS)*, 70 APPLIED SPECTROSCOPY 1821, 1822 (2016).

5. JANEY LEVY, THE HUMAN GENOME PROJECT 28-29 (2018).

6. ALAN PETERSEN & ROBIN BUNTON, THE NEW GENETICS AND THE PUBLIC'S HEALTH 113 (2002).

7. *Id.* at 113, 115-16 ("Rarely a day goes by without the announcement of some new gene discovery or of a likely new genetic-based treatment or prevention strategy.... [I]t should be of no surprise that a significant number of each of the newspapers report the discovery of a new gene, a gene link, a gene mutation.").

8. INST. OF MED. OF THE NAT'L ACADS., GENES, BEHAVIOR, & THE SOCIAL ENVIRONMENT 3 (Lyla M. Hernandez & Dan G. Blazer eds., 2006).

9. *See generally* Sue Richards, Nazneen Aziz, Sherri Bale, David Bick, Soma Das, Julie Gastier-Foster, Wayne W. Grody, Madhuri Hedge, Elaine Lyon, Elaine Spector, Karl Voelkerding & Heidi L. Rehm, *Standards and Guidelines for the Interpretation of Sequence Variants: A Joint Consensus Recommendation of the American College of Medical Genetics and*

genes differ from the majority of the population.[10] However, at the time of the testing, the science is not yet clear whether that difference is good, bad, or neutral.[11] Sometimes a genetic variation that we did not fully understand will take on new meaning. When a VUS gains clinical significance, it is no longer a VUS.[12] Based on this new knowledge, scientists can reclassify the variant from a VUS to benign, likely benign, likely pathogenic, or pathogenic.[13] A lab may then interpret the same genetic sequence differently depending on the scientific knowledge at the time of the testing.[14]

Such a scenario is what happened to our hypothetical patient. Around the time of her first genetic test in 2010, most research on *BRCA1* genes had been done on women of predominantly European descent.[15] The science then was fairly good at detecting dangerous genetic variants in that population.[16] We did not, however, know as much about the genetics of breast cancer in people with non-European ancestry.[17] Imagine that our patient had genetic ancestors in sub-Saharan Africa. As a result, her *BRCA1* variation came back

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Genomics and the Association for Molecular Pathology, 17 GENETICS MED. 405 (2015).

10. Noralane M. Lindor, David E. Goldgar, Sean V. Tavtigian, Sharon E. Plo & Fergus J. Couch, BRCA1/2 *Sequence Variants of Uncertain Significance: A Primer for Providers to Assist in Discussions and in Medical Management*, 18 ONCOLOGIST 518, 518 (2013).

11. *See* Daniele Carrieri, Heidi C. Howard, Caroline Benjamin, Angus J. Clarke, Sandi Dheensa, Shane Doheny, Naomi Hawkins, Tanya F. Halbersma-Konings, Leigh Jackson, Hülya Kayserili, Susan E. Kelly, Anneke M. Lucassen, Álvaro Mendes, Emmanuelle Rial-Sebbag, Vigdís Stefánsdóttir, Peter D. Turnpenny, Carla G. van El, Irene M. van Langen, Martina C. Cornel & Francesca Forzano, *Recontacting Patients in Clinical Genetics Services: Recommendations of the European Society of Human Genetics*, 27 EUR. J. HUM. GENETICS 169, 170 (2018).

12. *See, e.g.*, Lindor et al., *supra* note 10, at 523.

13. *See, e.g.*, *id.* at 521.

14. *See* Sarah Macklin, Nisha Durand, Paldeep Atwal & Stephanie Hines, *Observed Frequency and Challenges of Variant Reclassification in a Hereditary Cancer Clinic*, 20 GENETICS MED. 346, 348-49 (2018).

15. Tuya Pal, Jenny Permuth-Wey, Tricia Holtje & Rebecca Sutphen, BRCA1 *and* BRCA2 *Mutations in a Study of African American Breast Cancer Patients*, 13 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 1794, 1794 (2004) ("[M]ost studies of *BRCA1* ... have been done in Caucasian families.... The spectrum of mutations in the African American population is slowly beginning to be characterized.").

16. *See id.*

17. *See* Sudeshna Chatterjee, E. Chapman-Davis, J.C. Fields, S. Chatterjee-Paer, K.J. Sapra, Z.N. Zhou, B. Jordan, M.K. Frey, D. Nasioudis & K.M. Holcomb, *Does Race Play a Role in Genetic Screening for Hereditary Cancer Syndromes?*, 35 J. CLINICAL ONCOLOGY 1578, 1578 (2017) ("Non-white patients had higher rates of VUS, emphasizing the need for improved VUS reclassification in non-[w]hite populations.").

as a VUS. Because the variant lacked known clinical significance, her doctor did not report the result as pathogenic. In the ensuing years, scientists began to study breast cancer in a wider range of patients. That research led the lab to reclassify the patient's genetic variant as likely pathogenic and, ultimately, as pathogenic in 2015.[18] When she took her second genetic test in 2020, her result was positive for a pathogenic variant. Had she known of this risk sooner, perhaps the patient could have caught the cancer at an earlier stage or even have had a prophylactic mastectomy, maybe saving her life.

At present, genetic testing laboratories and physicians have no recognized legal duties to take any action when a VUS gains clinical significance.[19] This Article considers the need for those genetic duties. Failing to inform patients of variant reclassifications can have life-or-death consequences. While we appreciate the gravity of this topic for patients, we also recognize the potential costs of these duties and the looming uncertainties regarding how the science and technology will develop.

Our proposal for imposing genetic duties has three parts: (1) proactive measures, (2) a legal duty to reinterpret, and (3) a legal duty to recontact. First, we encourage laboratories and physicians to act proactively by educating patients about the possibility of variant reclassification at the outset and by outlining the steps that the laboratories and physicians will (or perhaps will not) take to share the updated results. However, when that is not possible, we suggest that courts split the legal duties related to variant reclassification. Drawing from the concept of the cheapest cost avoider, we argue that labs are in the best position to reinterpret genetic test results, whereas ordering physicians are in the best position to recontact patients. Our liability framework would, therefore, impose the duty

18. This hypothetical is based on an actual reclassification of the *BRCA1* gene. *See Database of* BRCA1 *and* BRCA2 *Sequence Variants That Have Been Clinically Reclassified Using a Quantitative Integrated Evaluation*, LEIDEN OPEN VARIATION DATABASE (Aug. 28, 2019), http://hci-exlovd.hci.utah.edu/home.php?select_db=BRCA1 [https:perma.cc/WKJ6-TYD4].

19. *See, e.g.*, Yvonne A. Stevens, Grant D. Senner & Gary E. Marchant, *Physicians' Duty to Recontact and Update Genetic Advice*, NAT'L INSTS. OF HEALTH, NAT'L LIBR. OF MED.: PUBMED CENT. (June 8, 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5693364/ [https://perma.cc/K25S-3CRU].

to reinterpret on the lab and the duty to recontact on the physician. Given the potential impact that legal liability could have on genetic testing and clinical care, we encourage courts to proceed with caution and to make these liability determinations on a case-by-case basis. Thus, while we advocate recognizing these duties, what constitutes a breach may vary significantly depending on the individual circumstances.

This Article is novel in at least two ways. One, it is among the first in the legal literature to address the need for potential legal duties related to variant reclassification.[20] Two, it proposes a solution to the cutting-edge question of how to fairly impose those potential duties. As such, it provides an important contribution to the conversation surrounding variant reclassification and can serve as a valuable resource for lawyers, medical professionals, judges, and scholars alike.

We discuss the legal implications of variant reclassification in three Parts. Part I gives the relevant scientific background and explores the existing tort doctrines likely to apply to variant reclassification. In Part II, we consider the arguments in favor of genetic duties related to variant reclassification, noting that laboratories are best situated to bear the costs of reinterpretation, while ordering physicians are best situated to bear the costs of recontacting patients. Part III proposes our framework for providing patients with access to updated test results. We begin by urging laboratories and physicians to take action now by developing policies to educate patients and to inform them of variant reclassifications. In older cases, when these proactive processes would not apply, we argue for bifurcating the duties associated with variant reclassification into (1) a duty to reinterpret and (2) a duty to recontact, and imposing those duties on their respective cheapest cost avoiders. We then analyze what would constitute a breach of these novel legal duties using a variety of case studies. We conclude that whether a defendant violated a genetic duty will depend heavily on the facts of the individual case.

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20. *See, e.g.*, Alexandra L. Foulkes, Jessica L. Roberts, Paul S. Appelbaum, Wendy K. Chung, Ellen Wright Clayton, Barbara Evans & Gary E. Marchant, *Can Clinical Genetics Laboratories Be Sued for Medical Malpractice?*, 29 ANNALS HEALTH L. & LIFE SCIS. 153, 153-55 (2020).

I. SCIENCE AND LAW OF VARIANT RECLASSIFICATION

Most of a person's genetic information is fixed before birth.[21] Yet, genetic test results—and the diagnoses of genetic conditions—can change over time, even while the content of the underlying genetic code remains exactly the same.[22] This somewhat counterintuitive reality is what lies at the heart of variant reclassification. This Part provides an overview of the science behind VUSs and explores the bodies of law that would apply to potential legal disputes relating to reclassifying variants.

A. Scientific Background

Here, we provide a brief explanation of exactly what VUSs are and how laboratories decide whether to reclassify them. We then turn to the harms that could occur when patients lack access to their updated results following a reclassification.

1. Reclassification

We can start with a review of high school biology. Our bodies are made up of cells.[23] The nuclei of our cells hold most of our DNA in the form of chromosomes.[24] Humans have twenty-three pairs of chromosomes, forty-six total, and those chromosomes contain our genes.[25] We have about twenty-four thousand genes.[26]

Technically speaking, genes are molecules of deoxyribonucleic acid (DNA) that store genetic information as a series of base pairs.[27] Only four letters exist in the genetic "alphabet": adenine (A), cytosine (C), guanine (G), and thymine (T).[28] While most humans have largely the same set of genes—in fact we are all 99.9 percent

21. *See* Soykan, *supra* note 3, at 8-9.
22. *See id.*
23. *See* DAVID P. CLARK & NANETTE J. PAZDERNIK, MOLECULAR BIOLOGY 4 (2d ed. 2013).
24. *Id.* at 116.
25. *Id.* at 25.
26. MARK STONEKING, AN INTRODUCTION TO MOLECULAR ANTHROPOLOGY 21 (2017).
27. *See generally* CLARK & PAZDERNIK, *supra* note 23, at 71-74.
28. *Id.* at 66.

genetically similar[29]—the individual "spellings" of our genes may vary.[30] For example, all humans have two copies of the *BRCA1* gene, one from each parent.[31] That gene codes for a protein that acts as a tumor suppressor.[32] However, some people have a *version* of the *BRCA1* gene that makes them more susceptible to breast and ovarian cancer.[33] We call the different versions of these genes "variants."[34] While we all have a *BRCA1* gene, certain variants of that gene correlate with an increased cancer risk.[35]

Geneticists can use the variations in genetic spelling to give patients information about their health.[36] Genetic research has generated something that can be thought of as a genetic reference text.[37] When a person gets a genetic test, we compare the individual's version of the gene to the versions of the gene contained in the reference text.[38]

The methods that labs use to analyze genetic variants, as well as the different kinds of genetic testing services that they offer, will affect labs' legal obligations to their patients. A *BRCA1* test identifies which version of the *BRCA1* gene the patient has and cross-references that information with the knowledge of cancer risk

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29. GARY KEENEY, SHOOTING LADDERS: VARIOUS THOUGHTS, BELIEFS, STORIES, AND ADVICE FOR TORI 657 (2010) ("Everyone on this planet shares approximately 99.9% of our genes with everyone else.").

30. Alexandra Keller, David Smith, Brenda Harrop, Louis Lamit, Melanie Schroer, Adam Wymore & Catherine Ueckert, *Genes Are Us: Analyzing DNA Differences Using DNA Fingerprinting*, 36 SCI. SCOPE 52, 53 (2012).

31. Recall that human beings have forty-six chromosomes, made up of twenty-three pairs. We therefore each have two copies of all of our autosomal genes. These copies are called alleles. *See* Zimmerman, *supra* note 1, at 99. The result is that we each have two versions of any given gene. A person then has two copies of the *BRCA1* gene, two copies of the *BRCA2* gene, two copies of the *SCN1A* gene, etc. *See id.* at 45.

32. *See id.*

33. *Id.*

34. *Id.*

35. *Id.* at 45-47.

36. *See id.* (describing gene mutations that indicate an increased risk of certain cancers).

37. James C. Wilson, *Disability and the Human Genome*, *in* THE DISABILITY STUDIES READER 52, 52 (Lennard J. Davis ed., 3d ed. 2010).

38. *See How Does Genetic Testing Work?*, IOWA INST. OF HUM. GENETICS, https://medicine.uiowa.edu/humangenetics/clinical-genetics/patients-and-families/how-does-genetic-testing-work [https://perma.cc/88HG-9KBX] (describing genetic testing as a search for gene variations from the norm).

associated with the known *BRCA1* variants.[39] That is an example of a "single-gene" test.[40]

Labs may also run "gene panels" rather than single-gene tests. A panel of genes might involve several individual genes, perhaps for a single type of condition.[41] Tests known as "virtual panels" can generate a significant amount of genetic data.[42] When labs run virtual panels, they sequence—and perhaps analyze—more genes than they actually report back to the ordering physician.[43] Imagine a doctor orders a lab to run a gene panel on fifty of a patient's genes. Depending on the available technology, the lab may streamline its workflow by generating data on five hundred different genes that it regularly encounters. However, the lab will only analyze and report the results on the fifty genes requested. In fact, some labs may generate data on *all* of the patient's genes before analyzing and reporting the relevant, requested genetic information.[44] Depending on their practices, laboratories may thus house troves of patient data unrelated to the genetic tests ordered by the patients' treating physicians.

Moreover, when traditional genetic testing is either inappropriate or inconclusive, physicians may order full exome or full genome sequencing.[45] Full genome sequencing determines a person's entire genetic makeup at a given point in time.[46] Full exome sequencing provides a more affordable alternative to full genome sequencing by examining only a person's protein-coding genes.[47] Because both

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39. *See* Heather Fecteau, Kristen J. Vogel, Kristen Hanson & Shannon Morrill-Cornelius, *The Evolution of Cancer Risk Assessment in the Era of Next Generation Sequencing*, 23 J. GENETIC COUNSELING 633, 634 (2014).

40. *See id.*

41. Sami S. Amr & Birgit Funke, *Targeted Hybrid Capture for Inherited Disease Panels*, *in* CLINICAL GENOMICS 251, 262 (Shashikant Kulkarni & John Pfeifer eds., 2015).

42. *See* Andrew J. Wallace, *New Challenges for* BRCA *Testing: A View from the Diagnostic Laboratory*, 24 EUR. J. HUM. GENETICS S10, S12 (2016); *see also* Leslie G. Biesecker, *Secondary Findings in Exome Slices, Virtual Panels, and Anticipatory Sequencing*, 21 GENETICS MED. 41, 41 (2019).

43. Amr & Funke, *supra* note 41, at 262.

44. *See* Alex Nord, Stephen J. Salipante & Colin Pritchard, *Copy Number Variant Detection Using Next-Generation Sequencing*, *in* CLINICAL GENOMICS, *supra* note 41, at 165, 172-73.

45. *See id.*

46. *Id.*

47. *Id.*

kinds of genomic sequencing look at many more genes than single-gene or panel tests, they can offer greater insights about the potential causes of a health condition.

After generating the patients' data—whether in the form of a single-gene test, a gene panel, or a full sequence—the labs will then analyze the results. As mentioned in the Introduction, laboratories conducting genetic tests may label variants across a spectrum as benign, likely benign, uncertain, likely pathogenic, or pathogenic.[48]

Sometimes a genetic test will reveal that a patient has a version of a gene *without* a known risk profile. That version is what we call a variant of uncertain significance, or VUS.[49] In such cases, the patient does not receive clinically actionable genetic information.[50] Clinically actionable information allows the patient to make decisions that could prevent the onset or the progression of a disease.[51] For example, if a genetic test finds a pathogenic *BRCA1* variant, the patient could undergo prophylactic surgeries or agree to more frequent screenings. These decisions could then lead to either prevention or early detection. However, a VUS does not tell the patient whether she is at greater, comparable, or lesser risk than the rest of the population.[52] The results simply tell the patient that her variant differs from the majority of people in the database. However, the results say nothing about what that difference actually means for the patient's health.

Further complicating matters, different labs may classify the same variant differently.[53] Labs use their own internal protocols and

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48. *See generally* Richards et al., *supra* note 9. These categories come from the ACMG guidelines that most labs use to classify variants. *Id.* at 405-06. Today, some labs use the ACMG guidelines to classify variants. *See* Cristi Radford & Michele Gabree, *Variants of Uncertain Significance—Frequently Asked Questions*, THE ONCOLOGY NURSE, http://www.theoncologynurse.com/ton-issue-archive/2018/july-2018-vol-11-no-3/17516-variants-of-uncertain-significance [https://perma.cc/NK5E-5PPU].

49. *See, e.g.*, Lindor et al., *supra* note 10, at 522.

50. *See id.* at 523.

51. *See* Gabriel Lázaro-Muñoz, John M. Conley, Arlene M. Davis, Anya E.R. Prince & R. Jean Cadigan, *Which Results to Return: Subjective Judgments in Selecting Medically Actionable Gene*s, 21 GENETIC TESTING & MOLECULAR BIOMARKERS 184, 184 (2017) (defining "medically actionable genes" as "those genes that may contain pathogenic variants associated with a poor health outcome that can be mitigated by an available intervention").

52. *See* Lindor et al., *supra* note 10, at 523.

53. Steven M. Harrison, Jill S. Dolinsky, Amy E. Knight Johnson, Tina Pesaran, Danielle R. Azzariti, Sherri Bale, Elizabeth C. Chao, Soma Das, Lisa Vincent & Heidi Rehm, *Clinical*

have different sets of genetic reference data.[54] For example, one lab might weigh a certain piece of evidence suggesting a variant is pathogenic more heavily than another lab.[55] Consequently, the first lab might report the variant as "likely pathogenic," whereas another lab might report the exact same variant as "uncertain."[56] Thankfully, over time these discrepancies tend to remedy themselves, and laboratories eventually reach a consensus about how to interpret a given variant, allowing their classifications to converge.[57]

As our understanding of the genome deepens, we gain additional knowledge about the clinical significance of VUSs and can reclassify them. While reclassification is relatively rare currently,[58] the number of reclassified VUSs will likely rise as more patients have increasingly comprehensive genetic tests.[59]

Laboratories Collaborate to Resolve Differences in Variant Interpretations Submitted to ClinVar, 19 GENETICS MED. 1096, 1096 (2017).

54. *Id.* at 1097.

55. *Id.*

56. *Id.* at 1096 (describing examples of "inconsistencies in variant interpretations" including "53% discordance of uncertain significance interpretations from one clinical laboratory compared to another").

57. *See* Laura M. Amendola, Gail P. Jarvik, Michael C. Leo, Heather M. McLaughlin, Yassmine Akkari, Michelle D. Amaral, Jonathan S. Berg, Sawona Biswas, Kevin M. Bowling, Laura K. Conlin, Greg M. Cooper, Michael O. Dorschner, Matther C. Dulik, Arezou A. Ghazani, Rajarshi Ghosh, Robert C. Green, Ragan Hart, Carrie Horton, Jennifer J. Johnston, Matthew S. Lebo, Aleksandar Milosavljevic, Jeffrey Ou, Chrstine M. Pak, Ronak Y. Patel, Sumit Punj, Carolyn Sue Richards, Joseph Salama, Natasha T. Strande, Yaping Yang, Sharon E. Plon, Leslie G. Biesecker & Heidi L. Rehm, *Performance of ACMG-AMP Variant-Interpretation Guidelines Among Nine Laboratories in the Clinical Sequencing Exploratory Research Consortium*, 98 AM. J. HUM. GENETICS 1067, 1071 (2016); Joshua L. Deignan, Wendy K. Chung, Hutton M. Kearney, Kristin G. Monaghan, Catherine W. Rehder & Elizabeth C. Chao, *Points to Consider in the Reevaluation and Reanalysis of Genomic Test Results: A Statement of the American College of Medical Genetics and Genomics (ACMG)*, 21 GENETICS MED. 1267, 1269 (2019); *see also* Heidi L. Rehm, *A New Era in the Interpretation of Human Genomic Variation*, 19 GENETICS MED. 1092, 1092 (2017).

58. *See* Thomas P. Slavin, Lily R. Van Tongeren, Carolyn E. Behrendt, Ilana Solomon, Christina Rybak, Bita Nehoray, Lili Kuzmich, Mariana Niell-Swiller, Kathleen R. Blazer, Shu Tao, Kai Yang, Julie O. Culver, Sharon Sand, Danielle Castillo, Josef Herzog, Stacy W. Gray & Jeffrey N. Weitzel, *Prospective Study of Cancer Genetic Variants: Variation in Rate of Reclassification by Ancestry*, 110 J. NAT'L CANCER INST. 1059, 1059-60 (2018).

59. *See* Jacqueline Mersch, Nichole Brown, Sara Pirzadeh-Miller, Erin Mundt, Hannah C. Cox, Krystal Brown, Melissa Ashton, Lisa Esterling, Susan Manley & Theodora Ross, *Prevalence of Variant Reclassification Following Hereditary Cancer Genetic Testing*, 320 JAMA 1266, 1273 (2018).

In deciding whether to reclassify a variant, labs may consider several factors, including new guidelines, new reference databases, new functional data about the variants, new methods to predict pathogenicity, and newly identified mutations.[60] Not surprisingly, given the amount of information that it requires, the reclassification process takes time. Studies have reported a lag of up to ten years.[61] Some genetics labs employ a proactive variant reclassification process by conducting periodic reviews of the variants in their databases.[62] A 2019 American College of Medical Genetics (ACMG) policy document recommends that laboratories focus on reclassifications with potential clinical implications because periodically reevaluating variants is time-consuming, expensive, and undercompensated.[63] For instance, a lab might reevaluate the clinical significance of variants classified as benign or likely benign less often than variants classified as uncertain.[64] However, at present, no governing body formally dictates when it is appropriate to

60. *See, e.g.*, *id.* at 1267; Jacqueline Mersch, Nichole Brown, Sara Pirzadeh-Miller, Erin Mundt, Hannah C. Cox, Krystal Brown, Melissa Ashton, Lisa Esterling, Susan Manley & Theodora Ross, *Prevalence of Variant Reclassification Following Heredity Cancer Genetic Testing: Supplementary Online Content*, eMethods, Figure 1, https://cdn.jamanetwork.com/ama/content_public/journal/jama/937531/joi180097supp1_prod.pdf?Expires=2147483647&Signature=FqHIkhYauJIVhRx-y7Ge7l-8s83rV41N9jKIlveArvWKO5nfOY6Z8ynlm3yrL7A2YRoaTT1FiDIKqCGf1JQJZdXzSDTzwMxg9YeuMaTLvCHIWnBfP9wupPpSu27uvaC9xGS41yrCs-~onaOmcDgxc5sktwjLVIiVmJLTLxK-Wh8K-iUdaNupassM~ck53v8RRCBYDkm9Y-TWFRgBebu2YGjaiLyTLi9yTO6bJKCHlUaSeJ6LcjhXbLrcc2LCP2EUfFtZ662-4UXfVfhnHkEGBCsAv8Wqq79TVezIiFHO2DN1icoR-T47~2oZ60GeOAjneZRrejlmew4TXSIe3WnQYQ__&Key-Pair-Id=APKAIE5G5CRDK6RD3PGA [https://perma.cc/XR9E-H6LP] [hereinafter Mersch et al., *Supplementary Online Content*] (describing Myriad Genetics' variant reclassification and reclassification system); *Variant Classification and Reanalysis in Exome Testing*, JACKSON LAB'Y, https://www.jax.org/education-and-learning/clinical-and-continuing-education/genetic-testing/variant-classification-and-reanalysis-in-exome-testing [https://perma.cc/56K5-7DGR] (describing Jackson Laboratory's reclassification methods); *see also* Slavin et al., *supra* note 58, at 1059-60 ("Despite the fact that variant reclassification may have profound implications for patient care and medical decision-making, little is known about the factors associated with variant reclassification.").

61. *See* Mersch et al., *Supplementary Online Content*, *supra* note 60, eFigure 2 (reporting a lag time of up to ten years); *see also* Slavin et al., *supra* note 58, at 1059-60.

62. *See* Thomas P. Slavin, Sophia Manjarrez, Colin C. Pritchard, Stacy Gray & Jeffrey N. Weitzel, *The Effects of Genomic Germline Variant Reclassification on Clinical Cancer Care*, 10 ONCOTARGET 417, 419 (2019).

63. *See* Deignan et al., *supra* note 57, at 1268-69.

64. *Id.* at 1269.

consider reclassifying a particular variant.[65] And once a lab reclassifies a variant, there is no standard operating procedure to update patients.[66]

With these realities in mind, let us return to our original hypothetical.[67] At the time of the testing in 2010, the *BRCA1* mutation that our patient carried was a VUS.[68] Sometime after reporting her results, the laboratory encountered reliable scientific evidence indicating that our patient's *BRCA1* variant was in fact deleterious. The lab technicians reanalyzed their available data, factoring in their patients' clinical histories.[69] Based on these and other considerations, the lab then reclassified the patient's variant as pathogenic in 2015.[70] Had our patient gone to a different lab, that lab might have reclassified her variant faster. But another lab could have taken longer or not reclassified the variant at all. And even if a different lab *had* reclassified the variant more quickly, nothing guarantees that it would have notified the patient of the reclassification. Due in part to its newness, variant reclassification is currently ad hoc and relatively unregulated.

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65. The ACMG notes that "there is currently no consensus for when and how often laboratories should review the classification of a particular variant." Karen L. David, Robert G. Best, Leslie Manace Brenman, Lynn Bush, Joshua L. Deignan, David Flannery, Jodi D. Hoffman, Ingrid Holm, David T. Miller, James O'Leary & Reed E. Pyeritz, *Patient Re-Contact After Revision of Genomic Test Results: Points to Consider—A Statement of the American College of Medical Genetics and Genomics (ACMG)*, 21 GENETICS MED. 769, 770 (2019); *see also* KELLY EAST, WENDY CHUNG, KATE FOREMAN, MARI GILMORE, MICHELE GORNICK, LUCIA HINDORFF, TIA KAUFFMAN, DONNA MESSERSMITH, CINDY PROWS, ELENA STOFFEL, JOON-HO YU & SHARON PLON, CLINICAL SEQUENCING EXPLORATORY RESEARCH CONSORTIUM, GUIDE TO INTERPRETING GENOMIC REPORTS: A GENOMICS TOOLKIT 4 (2019), https://www.genome.gov/sites/default/files/media/files/2020-04/Guide_to_Interpreting_Genomic_Reports_Toolkit.pdf [https://perma.cc/TU6S-NUTF]; Moriah Wright, Vijay Menon, Lindsay Taylor, Maniamparampil Shashidharan, Twilla Westercamp & Charles Ternent, *Factors Predicting Reclassification of Variants of Unknown Significance*, 216 AM. J. SURGERY 1148, 1157 (2018).

66. Stevens et al., *supra* note 19, at 1096.

67. *See supra* Introduction.

68. *See supra* Introduction.

69. These are the reasons Myriad Genetics cited for reclassifying *BRCA1* c.5453A>G(p.Asp1818Gly) from a VUS to pathogenic. *See* Mersch et al., *Supplementary Online Content*, *supra* note 60, eTable 8.

70. *See supra* Introduction.

2. Harms

Before discussing the potential harms associated with failing to notify patients of variant reclassifications, it is useful to take a step back and consider the role of genetic science in the practice of medicine. Genetics can have an immensely beneficial impact on clinical care. Individuals typically take medical genetic tests for at least one of four reasons: (1) to diagnose health conditions and to identify treatment options;[71] (2) to predict health risks;[72] (3) to make educated decisions about reproduction;[73] and (4) to identify which medications are likely to be effective or to have fewer adverse effects.[74] Put simply, people take genetic tests because they want health-related information. However, if no one updates patients when that information changes, patients cannot take the appropriate action for their health.

Based on the reasons that people take genetic tests, patients could experience three classes of potential harms related to variant reclassification. First, VUSs themselves can be unsettling.[75] Patients with VUSs may not fully understand their results, leading to anxiety and distrust. Failing to inform a patient of a reclassification can needlessly prolong those negative feelings. Second, the unease associated with a VUS could lead a patient to take unnecessary medical action in response to a perceived threat.[76] Informing patients that a VUS is in fact benign could avoid that negative result. Finally, if a lab reclassifies a VUS as pathogenic and fails to share that information, patients could lose the opportunity to take potentially life-saving clinical action.[77] We consider each type of harm in turn.

Although labs may not always report VUSs to patients, when they do, it could create distress. Ambiguous results can frequently lead

71. R.O. Mason & G.E. Tomlinson, *Genetic Research, in* THE CONCISE ENCYCLOPEDIA OF THE ETHICS OF NEW TECHNOLOGIES 165, 179 (Ruth Chadwick ed., 2001).

72. *Id.*

73. *Id.*

74. Allen D. Roses, *Pharmacogenetics and the Practice of Medicine*, 405 NATURE 857, 857 (2000).

75. *See infra* notes 78-82 and accompanying text.

76. *See infra* notes 83-89 and accompanying text.

77. *See infra* notes 90-104 and accompanying text.

to feelings of insecurity, frustration, and helplessness.[78] A study on the experiences of patients who received VUS results revealed that patients often express confusion about the uncertain results and dismay about the lack of answers.[79] Sometimes the VUS report even led to patients feeling distrust toward their providers. One patient was left so dissatisfied by her clinical experience that she described it as "dreadful."[80] Others said the physician communicating the VUS information "really didn't seem to know what to do with the results" or that their doctor "[had] totally dropped the ball."[81] The reclassification of variants likewise can be unsettling if the patient does not find out about the reclassification until much later. The delay could further exacerbate these feelings of ambiguity and lead to a lack of trust in the medical establishment.[82]

Beyond simply feeling stress from uncertain results, frightened patients may decide to take medical action based on a VUS, such as prophylactic surgery, only to discover later that their variant is benign.[83] For example, between 2016 and 2017, seven family members made the difficult choice to undergo prophylactic surgeries to reduce their cancer risk.[84] They had all taken a genetic test in

78. *See* Sukh Makhnoon, Lauren Thomas Garrett, Wylie Burke, Deborah J. Bowen & Brian H. Shirts, *Experiences of Patients Seeking to Participate in Variant of Uncertain Significance Reclassification Research*, 10 J. CMTY. GENETICS 189, 192-93 (2019); Gina Kolata, *When Gene Tests for Breast Cancer Reveal Grim Data but No Guidance,* N.Y. TIMES (Mar. 11, 2016), https://www.nytimes.com/2016/03/12/health/breast-cancer-brca-genetic-testing.html [https://perma.cc/LTH9-4BZE] ("It was scary. There are times I regret ever having genetic testing.").

79. Makhnoon et al., *supra* note 78, at 192. A participant in the Makhoon et al. study expressed dismay at his or her inability to help his or her family because of the VUS classification: "Why was I the one who got cancer? Well, because it was my job to go through this and I'm the strong one to figure it out, and now I can save everybody else. So [the VUS] kind of ruined my whole reason." *Id.*

80. *Id.* at 193.

81. *Id.*

82. *See id.*

83. *See* Scott A. Turner, Smita K. Rao, R. Hayes Morgan, Cindy L. Vnencak-Jones & Georgia L. Wiesner, *The Impact of Variant Classification on the Clinical Management of Hereditary Cancer Syndromes*, 21 GENETICS MED. 426, 429 (2019).

84. Amy Dockeser Marcus, *A Genetic Test Led Seven Women in One Family to Have Major Surgery. Then the Odds Changed.,* WALL ST. J. (Dec. 20, 2019, 11:43 AM), https://www.wsj.com/articles/seven-women-in-a-family-chose-surgery-after-a-genetic-test-then-the-results-changed-11576860210 [https://perma.cc/6Y5M-GBNJ]. Because we do not know these family members' preferred pronouns, we have chosen to use gender-expansive pronouns (i.e. they, them, their) when telling their story.

2015 that had detected a mutation on one of their *BRCA* genes, putting them at a heightened risk of hereditary breast and ovarian cancer.[85] All seven family members had their ovaries and fallopian tubes removed.[86] Two also underwent double mastectomies.[87] Then, in the fall of 2019, a genetic counselor called to share earth-shattering information.[88] The lab that did the family's testing no longer believed that they were at an increased risk.[89] They had removed their healthy organs for nothing. While the family's genetic variant was not a VUS at the time when they got tested—it was re-classified from pathogenic to VUS after their surgeries—this story demonstrates how important it is to convey accurate risk information to patients in a timely fashion. We focus our analysis on the reclassification of VUSs, yet it would apply with equal force to other kinds of variant reclassification.

Finally, failing to give patients up-to-date risk information—in genetics and beyond—could deny them the chance to seek appropriate treatment. Patients may interpret a VUS as a negative result because it does not affirmatively communicate risk or lead to a diagnosis.[90] Without the appropriate genetic counseling, VUSs may then give patients a false sense of security, perhaps even leading them to forgo additional screening despite their family medical histories.[91] Take our hypothetical patient.[92] If she knew that she had an increased genetic risk of cancer, her doctor could have monitored her health more closely and either acted preventively or diagnosed the cancer at an earlier stage. Patients—especially those with family medical histories of cancer—may incorrectly assume that they did not inherit certain genetic risk factors, and that assumption could influence their behavior in undesirable, and even life-threatening, ways.

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85. *Id.*
86. *Id.*
87. *Id.*
88. *Id.*
89. *Id.*
90. *See* EAST ET AL., *supra* note 65, at 10-12 (explaining the relationship between variants of uncertain significance and patient symptoms).
91. *See* Makhnoon et al., *supra* note 78, at 194.
92. *See supra* Introduction.

A reclassified variant may also give patients crucial information about which treatments to pursue. The recent case *Williams v. Quest Diagnostics* demonstrates how.[93] *Williams* dealt with the alleged *misclassification* of a variant known to be pathogenic as a VUS.[94] During his first year of life, Amy Williams's son, Christian, started having seizures.[95] Over time, the seizures got worse, leading the family to seek genetic testing.[96] The lab reported that Christian's variant of the *SCN1A* gene was a VUS.[97] The absence of a clear diagnosis ultimately led Christian down an unsuccessful treatment route.[98] Specifically, his doctors dismissed a diagnosis of Dravet syndrome, a rare genetic condition that results in a serious seizure disorder, based on the report.[99] In 2008, at the age of almost three, Christian died after a seizure.[100] Years later, Williams discovered studies—including one authored by the lab's director—predating Christian's testing that linked his *SCN1A* variant to Dravet syndrome.[101] Tragically, he had received medications that exacerbate seizures in people with Dravet syndrome.[102] In 2016, Williams sued the laboratory for the wrongful death of her son.[103] She alleged that had he been properly diagnosed and treated, Christian would not have suffered his fatal seizure.[104]

Troublingly, variant reclassification will not affect everyone equally. The potential harms outlined above could disparately impact certain populations. Most genetic databases contain disproportionate amounts of data from people of predominantly European descent.[105] Not surprisingly then, VUSs occur more frequently in

93. 353 F. Supp. 3d 432 (D.S.C. 2018).

94. Thus, *Williams* is not about the failure to reinterpret genetic test results following a reclassification, but rather is a dispute about the lab's alleged failure to correctly interpret the results in the first place. *See id.* at 437.

95. *Id.* at 436.

96. *Id.*

97. *Id.*

98. *See id.* at 437.

99. *Id.*

100. *Id.* at 436-37.

101. *Id.* at 447.

102. *Id.* at 437.

103. *Id.* at 436.

104. *Id.* at 437; *see also* Foulkes et al., *supra* note 20, at 155 n.16 (recounting the *Williams* facts).

105. Slavin et al., *supra* note 58, at 1060, 1064.

populations with non-European ancestry.[106] Because those populations have higher rates of VUSs, there are more opportunities for reclassification. In short, the more VUSs a patient has, the more VUSs a lab can reclassify. Thus, research shows that variant reclassification occurs more frequently in people with African and Asian genetic ancestries.[107] To be sure, genetic ancestry and race are not coextensive categories.[108] However, people of color are more likely to have non-European ancestry, making them more vulnerable to the potential harms that may result from failing to update patients following a reclassification. Insofar as those populations already face disadvantages, this disparate impact could, in turn, exacerbate existing health disparities.[109]

To sum up, variant reclassifications can communicate valuable—and sometimes clinically actionable—health information to patients. If patients never receive updated results, it may prolong psychological discomfort, engender distrust, create the opportunity for unnecessary medical interventions, give a false sense of security, or deny the ability to make appropriate decisions regarding prevention, detection, and treatment. However, it is currently unclear whether patients can recover legally for these potential harms. Next, we turn to the legal frameworks most likely to govern these disputes.

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106. *Id.* at 1060; *see* Paul S. Appelbaum, Erik Parens, Sara M. Berger, Wendy K. Chung & Wylie Burke, *Is There a Duty to Reinterpret Genetic Data? The Ethical Dimensions*, 22 GENETICS MED. 633, 634 (2020); *see, e.g.*, Allison W. Kurian, Kevin C. Ward, Ann S. Hamilton, Dennis M. Deapen, Paul Abrahamse, Irina Bondarenko, Yun Li, Sarah T. Hawley, Monica Morrow, Reshma Jagsi & Steven J. Katz, *Uptake, Results, and Outcomes of Germline Multiple-Gene Sequencing After Diagnosis of Breast Cancer*, 10 JAMA ONCOLOGY 1066, 1066 (2018) (observing that the switch from single-gene testing to "multiple-gene sequencing" resulted in increased findings of "variants of uncertain significance, especially in minorities (multiple-gene sequencing: white patients, 23.7%; black patients, 44.5%; and Asian patients, 50.9%)").

107. *See, e.g.*, Slavin et al., *supra* note 58, at 1062.

108. Trina Jones & Jessica L. Roberts, *Genetic Race? DNA Ancestry Tests, Racial Identity, & the Law*, 121 COLUM. L. REV. (forthcoming 2020) (manuscript at 35-36) (on file with author).

109. *See* Appelbaum et al., *supra* note 106, at 634; Arjun K. Manrai, Birgit H. Funke, Heidi L. Rehm, Morten S. Olesen, Bradley A. Maron, Peter Szolovits, David M. Margulies, Joseph Loscalzo & Isaac S. Kohane, *Genetic Misdiagnoses and the Potential for Health Disparities*, 375 NEW ENG. J. MED. 655, 662-63 (2016).

B. Legal Background

As any first-year law student will tell you, negligence principles describe legal responsibilities in terms of "duties."[110] To sue for negligence, a plaintiff must typically establish four elements: (1) the defendant owed the plaintiff a duty of care; (2) the defendant breached that duty; (3) the patient suffered a legally cognizable injury; and (4) the breach caused that injury.[111] Here we deal only with the crucial first steps on the path to liability: should laboratories and physicians have legal duties associated with variant reclassification? And what kinds of conduct should constitute a breach of those duties? As such, we leave a variety of intriguing—and essential—legal questions with respect to causation and damages unanswered. We turn first to duty.

1. Duties

Courts recognize duties for several reasons. As one set of scholars put it, in recognizing a legal duty, courts are "really just saying that for reasons of policy or principle, liability ought or ought not to attach in this case."[112] Yet, despite the harms described in the previous Subsection, reclassifying a VUS does not trigger any clearly recognized legal duties.[113] That is not to say that courts would be unwilling to find liability, but it appears that no court has addressed these issues head-on yet. The lack of applicable cases could be due, at least in part, to the relative novelty of genetic science. A recent study revealed that—despite the potential for liability—less than a dozen reported genomic malpractice cases are litigated each year.[114] Thus, patients may not have filed claims

110. DAVID HOWARTH, MARTIN MATTHEWS, JONATHAN MORGAN, JANET O'SULLIVAN & STELIOS TOFARIS, HEPPLE AND MATTHEWS' TORT LAW 1 (2015).

111. *See* 70 C.J.S. *Physicians & Surgeons* § 122 (2020); RESTATEMENT (SECOND) OF TORTS §§ 281-82 (AM. L. INST. 1965).

112. John C.P. Goldberg & Benjamin C. Zipursky, *Seeing Tort Law from the Internal Point of View: Holmes and Hart on Legal Duties*, 75 FORDHAM L. REV. 1563, 1579 (2006).

113. *See, e.g.*, Ellen Otten, Mirjam Plantinga, Erwin Birnie, Marian A. Verkerk, Anneke M. Lucassen, Adelita V. Ranchor & Irene M. Van Langen, *Is There a Duty to Recontact in Light of New Genetic Technologies? A Systematic Review of the Literature*, 17 GENETICS MED. 668, 674 (2015).

114. *See* Gary E. Marchant & Rachel A. Lindor, *Genomic Malpractice: An Emerging Tide*

related to variant reclassification because the opportunity for reclassification and reanalysis simply did not exist. Here, we consider the bodies of tort law that courts would likely consider when deciding whether to recognize duties related to variant reclassification.

a. Professional Negligence

Because patients undergo genetic testing as part of their care, medical malpractice law could presumably apply.[115] Medical malpractice law is a form of professional negligence,[116] with health care providers acting as their patients' fiduciaries.[117] Hence, whether medical malpractice law applies involves two important threshold inquiries: (1) whether the defendant is, in fact, a health care provider who could potentially owe patients heightened duties and (2) whether a sufficient treatment relationship existed between the plaintiff and the defendant to trigger those fiduciary obligations.[118] Physicians who see patients certainly meet the legal definition of health care providers.[119] Thus, medical malpractice law applies to a physician who orders a genetic test. However, the laboratories that process those tests—and ultimately make the decision to reclassify a variant—present greater ambiguity. States are currently split on this issue.[120] Whether the laboratories that reclassify genetic

or Gentle Ripple?, 73 FOOD & DRUG L.J. 1, 15, 35-36 (2018) (attributing the low number of cases to the slow uptake of genetic medicine by providers and the lack of interest in such claims by lawyers).

115. Sonny B. Bal, *An Introduction to Medical Malpractice in the United States*, 2 CLINICAL ORTHOPAEDICS & RELATED RSCH. 339, 340 (2008).

116. It involves a special relationship that warrants a greater duty of care than what ordinary negligence requires. Unequal power within the relationship forms the basis for these increased obligations. *See* Nadia M. Sawicki, *Choosing Medical Malpractice*, 93 WASH. L. REV. 891, 936 (2018).

117. Jessica Mantel, *Refusing to Treat Noncompliant Patients Is Bad Medicine*, 39 CARDOZO L. REV. 127, 153 (2017).

118. Bal, *supra* note 115, at 342.

119. *See* Sawicki, *supra* note 116, at 936.

120. We conducted a fifty-state survey examining whether clinical labs are health care providers for purposes of malpractice law. We found that six states expressly include laboratories, or their personnel, in their medical malpractice statute's definition of health care provider. Foulkes et al., *supra* note 20, at 160-61. For the remaining states, we looked to judicial opinions. The courts in fifteen states have held that clinical laboratories meet the medical malpractice definition of health care provider. *Id.* The South Carolina Supreme Court

variants are health care providers could impact the outcomes of these cases. In addition to requiring a heightened duty of care, medical malpractice law may invoke caps on damages,[121] shorter statutes of limitations,[122] statutes of repose,[123] and procedural idiosyncrasies.[124] In fact, the lab in *Williams* argued *in favor* of being classified as a health care provider to invoke the shorter statute of limitations and to assert that the case was time barred.[125]

However, establishing that the defendant is a health care provider is not sufficient to warrant a heightened duty of care. The plaintiff must usually also demonstrate that she was the defendant's patient at the time of the alleged wrongdoing.[126] Generally, the provider's obligations to the patient begin and end with the treatment relationship.[127] In most cases, when the treatment

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decided this issue as part of the *Williams* litigation in response to a certified question from the federal court that heard the case. *See* Williams v. Quest Diagnostics, Inc., 816 S.E.2d 564, 566 (S.C. 2018). Courts in four states came to the opposite conclusion, holding that medical malpractice law should *not* apply to clinical labs. Foulkes et al., *supra* note 20, at 160-61. That leaves twenty-five states without a clear answer on this important threshold question. *Id.*

121. Sometimes compensatory damages are limited; other caps restrict noneconomic damages. *Malpractice Caps in All 50 States*, MILLER & ZOIS: ATT'YS AT L. (2020), https://www.millerandzois.com/malpractice-damage-caps.html [https://perma.cc/Q9YL-NP58]. Malpractice legislation often caps damages, placing limits on recovery ranging from $250,000 to $2,250,000. *Id.* Note that courts in some states have found caps to be in violation of the state constitution. *See, e.g.*, Moore v. Mobile Infirmary Ass'n, 592 So. 2d 156, 171 (Ala. 1991) (declaring the $400,000 damage cap unconstitutional).

122. Malpractice laws also often incorporate statutes of limitations different than those for ordinary negligence claims. *See* Foulkes et al., *supra* note 20, at 157.

123. *See* Marchant & Lindor, *supra* note 114, at 26. These statutes are significant, as they do not allow equitable tolling based on when the plaintiff discovered, or should have discovered, the cause of action. *See id.*

124. Some compel arbitration, while others modify expert witness standards or shift the costs and burdens of litigation from the provider to the injured patient. *See* Lauren K. Saunders, *The Quest for Balance: Public Policy & Due Process in Medical Malpractice Arbitration Agreements*, 23 HARV. J. ON LEGIS. 267, 268 (1986); *see also* Foulkes et al., *supra* note 20, at 156-57.

125. *Williams*, 816 S.E.2d at 565.

126. *See supra* note 119 and accompanying text.

127. The requirements for establishing the treatment relationship differ by jurisdiction. *Compare* Crisp Reg'l Hosp., Inc. v. Oliver, 621 S.E.2d 554, 560 (Ga. Ct. App. 2005) ("The relationship is considered consensual where the patient knowingly seeks the assistance of the physician and the physician knowingly accepts him as a patient." (citing Peace v. Weisman, 368 S.E.2d 319 (Ga. Ct. App. 1988); Bradley Ctr., Inc. v. Wessner, 296 S.E.2d 693 (Ga. 1982)), *with* Oja v. Kin, 581 N.W.2d 739, 741 (Mich. Ct. App. 1998) ("A physician-patient relationship exists where a doctor renders professional services to a person who has contracted for such services." (quoting Hill v. Kokosky, 463 N.W.2d 265 (Mich. Ct. App. 1990))). Consent by both

relationship is over, the provider no longer has heightened duties.[128] Important to our analysis here is that certain providers, such as geneticists, may see many of their patients only once. However, it is possible that learning of a clinically actionable variant reclassification could—on its own—trigger a duty to the patient.[129]

Malpractice law requires health care providers to conform to the applicable standard of care.[130] Courts typically determine the standard of care in one of two ways: (1) as a matter of professional custom[131] or (2) as a matter of reasonableness.[132] Professional custom presumes that providers who do not follow the accepted practices within their specialties have been negligent.[133] Providers

parties, however, is traditionally enough. *See* Irvin v. Smith, 31 P.3d 934, 941 (Kan. 2001) ("A physician-patient relationship is consensual." (quoting Adams v. Via Christi Reg'l Med. Ctr., 19 P.3d 132 (Kan. 2001))). But note also that an "implied physician-patient relationship may arise when a physician gives advice to a patient, even if that advice is communicated through another health care professional." Campbell v. Haber, 710 N.Y.S.2d 495, 495 (N.Y. App. Div. 2000). There must be more than an "informal interest and involvement in the patient's condition." *Id.* (quoting Cogswell v. Chapman, 672 N.Y.S.2d 460 (N.Y. App. Div. 1998)). Terminating the treatment relationship typically requires some kind of specific action on the part of either the patient or the provider. For example, both could agree to terminate the relationship, the patient could dismiss the provider, the patient may no longer need the provider's services, or the provider could withdraw from the case. 46 AM. JUR. 2d *Proof of Facts* § 373 (2020) (collecting cases, notably citing Tierney v. Univ. of Mich. Regents, 669 N.W.2d 575 (Mich. Ct. App. 2003)).

128. For example, following treatment, a doctor might breach her duty by not alerting a patient that she needs follow-up care. Theresa K. Porter, *Cause of Action Against Physician or Surgeon for Breach of the Duty of Attention and Care,* 21 CAUSES OF ACTION 1 (2020) (collecting cases).

129. *See, e.g.*, Stuart v. Loomis, 992 F. Supp. 2d 585, 595 (M.D.N.C.), *aff'd sub nom.* Stuart v. Camnitz, 774 F.3d 238 (4th Cir. 2014).

130. *See* Thomas v. Burack, No. 35782/04, 2009 WL 4481656, at *3 (N.Y. Sup. Ct. Oct. 21, 2009) (explaining how the standard of care is established and noting that malpractice jurisprudence has evolved to accommodate advances in medicine).

131. JAMES A. HENDERSON, DOUGLAS A. KYSAR & RICHARD N. PEARSON, THE TORTS PROCESS 234 (9th ed. 2017) ("For most courts in medical malpractice cases, professional custom is not just evidence of the standard of care, it *is* the standard of care."); WILLIAM P. STATSKY, ESSENTIALS OF TORTS 131, 178-79 (3d ed. 2012).

132. Phillip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 201 (2000) (noting that there is no longer a judicial consensus favoring deference to custom in medical malpractice litigation).

133. Trimarco v. Klein, 436 N.E.2d 502, 505-06 (N.Y. 1982) (explaining that although deviation from custom creates a presumption of negligence, the jury must also determine whether the custom was reasonable); *see also* Peter Moffett & Gregory Moore, *The Standard of Care: Legal History and Definitions: The Bad and Good News*, 12 W.J. EMERGENCY MED. 109, 109 (2011) (explaining that the jury must decide "whether this 'custom' was reasonable and whether the deviation from this 'custom' was so unreasonable as to cause harm").

can rebut that presumption by showing that the custom itself is unreasonable.[134] While courts previously looked to the medical customs of the locality where the defendant practiced (the "locality rule"),[135] many states have recently turned to a national standard.[136] And some jurisdictions have moved away from professional custom altogether, instead adopting a reasonableness standard.[137] Reasonableness simply asks whether the provider acted like a reasonably prudent person under the circumstances.[138] This move represents a trend toward a single reasonableness standard for all of tort litigation.[139] More than a dozen states have explicitly rejected professional custom in medical malpractice,[140] and at least nine others articulate their standard in terms of reasonableness.[141]

One particularly salient feature of medical malpractice law is a willingness to consider not only the defendant's area of expertise but also her available resources.[142] Historically, courts were reluctant to hold rural family doctors with humble medical practices to the same standards as health care providers seeing patients in high-tech medical facilities with access to cutting-edge technologies.[143] Hence,

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134. Moffett & Moore, *supra* note 133, at 109.

135. HENDERSON ET AL., *supra* note 131, at 235.

136. *Id.* (citing Brune v. Belinkoff, 235 N.E.2d 793 (Mass. 1968); Hawes v. Chua, 769 A.2d 797 (D.C. 2001)). There are, of course, exceptions. For example, Arizona still uses local custom, not reasonableness. Peters, *supra* note 132, at 182.

137. *See* Peters, *supra* note 132, at 201.

138. *Id.* at 177. To make this determination, courts look to the practices of others in the trade. *Id.* Failing to adhere to professional custom typically shifts the burden onto the defendant to show that the custom itself is unreasonable. *See, e.g.*, *supra* notes 133-34 and accompanying text. This is a heavy burden for a defendant to meet; for example, some courts allow for directed verdicts when a health care professional has failed to comply with a professional standard of care established through expert witnesses. *See, e.g.*, Hurlock v. Park Lane Med. Ctr., Inc., 709 S.W.2d 872, 884 (Mo. Ct. App. 1985).

139. Peters, *supra* note 132, at 201.

140. *Id.* at 164.

141. *Id.*

142. *See, e.g.*, N.C. GEN. STAT. § 90-21.12(a) (2019) (codifying the requirements of standard of care); TENN. CODE ANN. § 29-26-115 (2020); Shipley v. Williams, 350 S.W.3d 527, 571 (Tenn. 2011) (holding that to testify as an expert witness, a medical professional must have at least some knowledge of the applicable community's medical resources); Barham v. Hawk, 600 S.E.2d 1, 4 (N.C. Ct. App. 2004) (stating that one issue was whether an expert witness was sufficiently familiar with the medical resources available in defendant's community).

143. *See* G.E. Hall, *The "Locality" Rule*, 207 JAMA 627, 627 (1969); *Causes of Action Under the Patient Protection and Affordable Care Act*, 2012 U.S. Comp. Gen., B-322525, *1 (Mar. 23, 2012).

the locality rule baked the defendant's resources into the standard of care.[144] However, as technology has made information more readily available—regardless of location—some courts have moved away from the locality rule.[145] Yet, even in jurisdictions with a national professional custom or reasonableness standard, courts have considered a health care provider's resources when deciding liability.[146] Yet, as discussed below, those inquiries may relate not to the standard of care but rather to breach.

Beyond the general standard of care, courts may also identify specific duties that providers owe their patients. While no cases have dealt with variant reclassification directly, courts have recognized certain relevant legal duties, such as (1) the duty to continue treatment; (2) the duty to warn patients of foreseeable risk; and (3) the duty to address incidental or secondary findings.[147]

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144. Michelle Huckaby Lewis, John K. Gohagan & Daniel J. Merenstein, *The Locality Rule and the Physician's Dilemma: Local Medical Practices vs. the National Standard of Care*, 297 JAMA 2633, 2634 (2007). To establish the standard of care, experts would testify about what it would be like to practice under the defendant's specific circumstances. *See, e.g.*, *Shipley*, 350 S.W.3d at 532 ("Claimants are required by statute to prove by expert testimony the recognized standard of acceptable professional practice in the community where the defendant medical provider practices or a similar community."); *see also* Bal, *supra* note 115, at 342 (indicating that expert witness testimony is essential to establishing breach of a standard of professional care).

145. Peters, *supra* note 132, at 201.

146. The distinction between jurisdictions that have adopted a national standard and those that adhere to a locality rule is not a clear one, and these cases often still regularly include the presentation of expert testimony. *See, e.g.*, Bates v. Dodge City Healthcare Grp., 291 P.3d 1042, 1049 (Kan. 2013) (explicitly recognizing the coexistence of the locality rule and a national standard and noting that available resources "'is simply one of the factors to be considered' in the standard of care" (quoting Chandler v. Neosho Mem'l Hosp., 574 P.2d 136 (Kan. 1977))); D'Orta v. Margaretville Mem'l Hosp., 62 N.Y.S.3d 620, 623 (N.Y. App. Div. 2017) (holding that defendant hospital met their burden of showing the standard of care was not breached by submitting an affiant's testimony as to the hospital's resources); Ervin *ex rel*. Wrongful Death Beneficiaries v. Delta Reg'l Med. Ctr., 55 So. 3d 190, 193 (Miss. Ct. App. 2010) (noting the jurisdiction's inclusions of a resource-based component to the physician's nondelegable duty of care); Avivi v. Centro Medico Urgente Med. Ctr., 71 Cal. Rptr. 3d 707, 713 (Cal. Ct. App. 2008) ("[T]here may be areas of medicine in which geographic location is especially relevant to a determination of an expert witness's qualifications. For example, some locations may only have access to limited resources.").

147. *See* Stevens et al., *supra* note 19, at n.6 and accompanying text (citing A.G.W. Hunter, N. Sharpe, M. Mullen, W.S. Meschino, *Ethical, Legal, and Practical Concerns About Recontacting Patients to Inform Them of New Information: The Case in Medical Genetics*, 103 AM. J. MED. GENETICS 265, 267, 270-71 (2001)).

The duty to continue treating comes from the doctrine of abandonment.[148] To prove abandonment, the patient must demonstrate that her provider stopped treating her so abruptly while she still needed care that she could not find a suitable replacement.[149] Following a variant reclassification, the duty to continue treatment could potentially obligate a provider to update the patient's results and share that information.

Second, courts have recognized a duty to warn of foreseeable risks in certain cases, such as following Food and Drug Administration (FDA) recalls.[150] Thus, a court could theoretically find that a provider has a duty to warn her patients following a variant reclassification, especially when the updated results contain clinically actionable health information.

Finally, providers may also have a duty to address clinically actionable incidental or secondary findings.[151] When laboratories

148. *See, e.g.*, Cole v. Ferrell-Duncan Clinic, 185 S.W.3d 740, 744-45 (Mo. Ct. App. 2006) (describing treatment as "covering all the steps taken to effect a cure of an injury or disease; *including examination and diagnosis* as well as application of remedies" (citing BLACK'S LAW DICTIONARY 1502 (6th ed. 1990))).

149. *See* Burnett v. Layman, 181 S.W. 157, 158 (Tenn. 1915) (involving a physician who performed a procedure on his patient's bladder and, when he heard a popping sound, the physician told his patient that he needed a surgeon and left immediately without any further communication). Of course, it is not enough to show patient dumping. The abandonment must have directly caused the patient's injury. Barbara E. Calfee, *What You Don't Know Will Hurt You: Physicians' Duty to Warn Patients About Newly Discovered Dangers in Previously Initiated Treatment*, 31 CLEV. ST. L. REV. 649, 665 (1982).

150. The Indiana Supreme Court held that a health care provider who is aware of a treatment's potentially dangerous side effects may have a duty to warn her patients following an FDA recall. Cox v. Paul, 828 N.E.2d 907, 913-14 (Ind. 2005). Although far from universally accepted, some courts have extended the duty to warn to third parties—mainly family members—if a condition is inheritable. *See* Pate v. Threlkel, 661 So. 2d 278, 280 (Fla. 1995); Safer v. Estate of Pack, 677 A.2d 1188, 1192 (N.J. Super. Ct. App. Div. 1996). However, Congress enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which limits the ability of health care providers to disclose their patients' protected health information. *See* 45 C.F.R. §§ 164.500 to 534. Thus, if the warning involves private health data, federal law may limit the ability to warn third parties. Mark A. Rothstein, *Reconsidering the Duty to Warn Genetically At-Risk Relatives*, 20 GENETICS MED. 285, 287 (2018). Regardless, at least one recent decision has found that providers may have a limited duty to warn their patients of potentially deadly genetic risks. *See Safer*, 677 A.2d at 1192.

151. Incidental findings are medical information discovered in the course of a screening or test that is unrelated to the reason for that test, such as when a radiologist finds a pancreatic cyst during a liver scan. *See* Lo v. Burke, 455 S.E.2d 9, 10 (Va. 1995); Lincoln L. Berland, Stuart G. Silverman, Richard M. Gore, William W. Mayo-Smith, Alec J. Megibow, Judy Yee, James A. Brink, Mark E. Baker, Michael P. Federle, W. Dennis Foley, Isaac R. Francis, Brian

handle massive amounts of genetic data, such as in the context of full genome or exome sequencing, they might find genetic risk factors unrelated to the reason for testing.[152] That is to say, these technologies open the door for potential secondary findings.[153] The ACMG created significant controversy in 2013 by recommending that labs providing whole exome or whole genome sequencing analyze—and return results from—over fifty genes with highly penetrant, actionable pathogenic variants, regardless of the clinical

R. Herts, Gary M. Israel, Glenn Krinsky, Joel F. Platt, William P. Shuman & Andrew J. Taylor, *Managing Incidental Findings on Abdominal CT: White Paper of the ACR Incidental Findings Committee*, 7 J. AM. COLL. RADIOLOGY 754, 754 (2010). Incidental findings can also occur in research. *See* Benjamin D. Solomon, Donald W. Hadley, Daniel E. Pineda-Alvarez, Aparna Kamat, Jamie K. Teer, Praveen F. Cherukuri, Nancy F. Hansen, Pedro Cruz, Alice C. Young, Benjamin E. Berkman, Settara C. Chandrasekharappa & James C. Mullikin, *Incidental Medical Information in Whole-Exome Sequencing*, 129 PEDIATRICS 1605, 1606 (2012).

152. *See* Lainie Friedman Ross, Mark A. Rothstein & Ellen Wright Clayton, *Mandatory Extended Searches in All Genome Sequencing: "Incidental Findings," Patient Autonomy, and Shared Decision Making*, 310 JAMA 367, 367 (2013).

153. The ACMG uses the phrase "secondary" findings while others refer to these as "incidental" findings. *See* Isaac S. Kohane, Daniel R. Masys & Russ B. Altman, *The Incidentalome: A Threat to Genomic Medicine*, 296 JAMA 212, 212 (2006); Joel B. Krier & Robert C. Green, *Management of Incidental Findings in Clinical Genomic Sequencing*, 87 CURRENT PROTOCOLS HUM. GENETICS 9, 9 (2015); Susan M. Wolf, Frances P. Lawrenz, Charles A. Nelson, Jeffrey P. Kahn, Mildred K. Cho, Ellen Wright Clayton, Joel G. Fletcher, Michael K. Georgieff, Dale Hammerschmidt, Kathy Hudson, Judy Illes, Vivek Kapur, Moira A. Keane, Barbara A. Koenig, Bonnie S. LeRoy, Elizabeth G. McFarland, Jordan Paradise, Lisa S. Parker, Sharon F. Terry, Brian Van Ness & Benjamin S. Wilfond, *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*, 36 J.L. MED. & ETHICS 219, 220 (2008) ("Commentators are beginning to recognize the tremendous importance of [incidental findings] in genetic and genomic research, particularly as we now face a genomic revolution in medicine.").

reasons for the sequencing.[154] Thus, some providers could arguably have duties to return incidental or secondary findings.

b. Ordinary Negligence

Importantly, not all legal duties require professional judgments or occur in the context of fiduciary relationships. Absent a professional or fiduciary relationship, plaintiffs can sue defendants—including health care providers—for ordinary negligence.[155] Ordinary negligence simply requires that providers of products or services act reasonably.[156] Whether a court decides to apply medical malpractice or ordinary negligence will depend on the facts of the case, usually whether the health care provider was rendering medical services.[157] Ordinary negligence may also provide a useful

154. *See, e.g.*, Wylie Burke, Armand H. Matheny Antommaria, Robin Bennett, Jeffrey Botkin, Ellen Wright Clayton, Gail E. Henderson, Ingrid A. Holm, Gail P. Jarvik, Muin J. Khoury, Bartha Maria Knoppers, Nancy A. Press, Lainie Friedman Ross, Mark A. Rothstein, Howard Saal, Wendy R. Uhlmann, Benjamin Wilfond, Susan M. Wolf & Ron Zimmern, *Recommendations for Returning Genomic Incidental Findings? We Need to Talk!,* 15 GENETICS MED. 854, 854 (2013) (calling the ACMG conclusions "premature practice recommendations," and calling "for robust dialogue among stakeholders to define a pathway to normatively sound, evidence-based guidelines"). The ACMG, therefore, supported analyzing and reporting clinically actionable secondary findings related to certain conditions. *Id.* at 854-55. Physicians, geneticists, bioethicists, and law professors spoke out against the policy as a violation of patients' rights. *See* Robert Klitzman, Paul S. Appelbaum & Wendy Chung, *Return of Secondary Genomic Findings vs. Patient Autonomy: Implications for Medical Care*, 310 JAMA 369, 369-70 (2013); Ross et al., *supra* note 152, at 367.

155. *See supra* Part I.B.1.

156. *See supra* Part I.B.1. Likewise, a health care provider must act reasonably with respect to her "nonmedical, administrative, ministerial, or routine care." Williams v. Quest Diagnostics, Inc., 816 S.E.2d 564, 565 n.2 (S.C. 2018) (quoting Dawkins v. Union Hosp. Dist., 758 S.E.2d 501, 504 (S.C. 2014)). Say a patient slips and falls in a hospital. In many jurisdictions, negligence will turn on reasonableness—not a professional standard of care—much as if the person had taken a tumble in a grocery store. *See id.* In the context of variant reclassification, to successfully sue, plaintiffs must establish that it was unreasonable for the defendant to fail to take action in light of the reclassification. *See id.*

157. Annunziata v. Quest Diagnostics, Inc., 8 N.Y.S.3d 168, 168-69 (N.Y. App. Div. 2015); *see* Est. of French v. Stratford House, 333 S.W.3d 546, 569 (Tenn. 2011) (Koch, Jr., J., dissenting); Dyer v. Trachtman, 679 N.W.2d 311, 317 (Mich. 2004). For example, in *Annunziata*, a plaintiff sued a lab for allegedly misreading a tissue sample test, thereby delaying the detection of cervical cancer. 8 N.Y.S.3d at 168-69. Along with malpractice claims, the plaintiff brought a claim for ordinary negligence, in which she accused the lab of failing to properly employ a plan for error reduction and quality assurance. *Id.* Because the plaintiff's ordinary negligence claim would not be actionable absent the malpractice claim, the court dismissed the ordinary negligence claim. *Id.* In contrast, when the conduct of the lab or

alternative to medical malpractice. In *Williams*, the South Carolina Supreme Court held that the lab was a health care provider and, therefore, subject to the shorter statute of limitations for medical malpractice.[158] However, the federal district court hearing the case declined to dismiss the lawsuit, despite the untimely malpractice claims, reasoning that Williams could still have claims for ordinary negligence.[159] Although some states allow plaintiffs to sue doctors only for medical malpractice, ordinary negligence may be an important framework for liability in variant reclassification cases in the jurisdictions that allow it.[160]

In sum, courts confronted with torts claims related to variant reclassification could approach the potential legal duties at stake from a variety of different vantages. These duties could be part and parcel of medical malpractice's standard of care, a special professional duty imposed on labs and doctors, or a matter of ordinary negligence. Yet, regardless of which body of law courts choose, many jurisdictions will—as a practical matter—likely apply a reasonableness standard.[161] To start, the reasonableness standard for medical malpractice operates almost identically to ordinary negligence: both standards ask what the reasonable lab or physician would do.[162] Courts could also resort to reasonableness when assessing professional customs or imposing other kinds of professional duties. Without accepted policies or practices to consider, courts may simply turn to whether it was reasonable to reinterpret results or to

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physician was incidental—opposed to integral—to medical treatment, courts have employed ordinary negligence. *See, e.g.*, Pascarelli v. Corning Clinical Lab'ys, Inc., No. 325312, 1997 WL 155381, at *3 (Conn. Super. Ct. Mar. 25, 1997) (employing ordinary negligence after concluding that alleged negligent communication of lab results did not rise to the level of a medical malpractice claim because no uniquely medical issues were required to be determined); Delaney v. Newington Children's Hosp., No. CV-93-0524063, 1994 WL 228322, at *1-2 (Conn. Super. Ct. May 9, 1994) (applying ordinary negligence after concluding that alleged negligent supervision of minor psychiatric patient did not amount to a medical malpractice claim because no uniquely medical issues were required to be determined).

158. *See Williams*, 816 S.E.2d at 566.

159. *See* Williams v. Quest Diagnostics, Inc., 353 F. Supp. 3d 432, 445 (D.S.C. 2018) (denying summary judgment on claims against a genetics lab, despite malpractice actions being time barred, because some claims were still sound in ordinary negligence).

160. *See id.*

161. *See, e.g.*, *Dyer*, 679 N.W.2d at 316.

162. *See id.*

recontact the patient under the circumstances.[163] Thus, despite the variety of potential legal frameworks, liability will most likely boil down to the reasonableness of the defendant's conduct.

2. Breach

Among the most popular approaches to deciding tort liability is Learned Hand's test for negligence. Under this formula, parties who engage in potentially costly behaviors should consider three factors before acting: (1) the probability of an injury, (2) the severity of that injury, and (3) the costs of precautions to avoid the injury.[164] Put in reasonableness terms, a defendant acts unreasonably by failing to take precautions if the benefit of avoiding the injury outweighs the costs of preventing it.[165] Thus, courts will look to the Learned Hand formula when deciding what constitutes a breach of reasonable care.[166]

Resources could then factor into the reasonableness of the defendant's conduct following a variant reclassification. While the probability and severity of the patient's injuries may remain constant, the costs of avoiding that injury might vary from defendant to defendant.[167] For example, given her *BRCA1* mutation, the patient from the Introduction had a 50 to 85 percent chance of developing breast cancer by age seventy.[168] This risk speaks to both the probability and severity of her potential injury.[169] Other relevant factors include the available treatment options and the likely

163. Simply, custom is common practice. *See* T. J. Hooper, 60 F.2d 737, 740 (2d Cir. 1932). Where no custom has been established, what is objectively reasonable is a logical guidepost. *See* James A. Henderson, Jr. & John A. Siliciano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1382, 1386-87 (1994).

164. United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947) ("[I]f the probability be called P; the injury, L; and the burden, B; liability depends upon whether B is less than L multiplied by P: i.e., whether B < PL.").

165. *See, e.g.*, McCarty v. Pheasant Run, Inc., 826 F.2d 1554, 1558 (7th Cir. 1987).

166. *See id.*

167. *See* Rachael Rettner, *Ovarian, Breast Cancer Risk Vary According to Subtle Changes in Two Genes*, SCI. AM. (Apr. 8, 2015), https://www.scientificamerican.com/article/ovarian-breast-cancer-risk-vary-according-to-subtle-changes-in-two-genes/ [https://perma.cc/RY5N-QMJ6].

168. *Id.*

169. *See id.*

survival rates.[170] These circumstances would be the same regardless of which physician ordered the *BRCA1* test.[171]

However, recontacting the patient could impose different costs on a physician, depending on the situation. On one hand, recontacting would appear to be more costly for a rural family doctor than for a geneticist practicing in a state-of-the-art medical center.[172] The family doctor has a less comprehensive knowledge of genetics, sees patients for a diversity of medical issues, and has fewer resources at her disposal. Tracking down patients following a variant reclassification could consequently seem more burdensome as compared to a highly specialized geneticist with access to cutting-edge tools. On the other hand, the opposite could also be true. A rural family doctor likely knows all of her patients and how to contact them. It could be as easy as picking up the phone. In contrast, a geneticist at a major medical center may see large numbers of patients but only once or twice. The geneticist might not recall a patient from several years ago and could need time to review the patient's record. Moreover, both the patient's health and contact information could have changed over the years. Breach is, therefore, a very fact-intensive inquiry. What might be reasonable for one defendant could be unreasonable for another. In fact, what might be reasonable for one rural family doctor could be unreasonable for another rural family doctor, depending on the circumstances.[173]

As the discussion above suggests, calculating the costs and benefits of reinterpreting results and recontacting patients may not always be a straightforward math problem. As Judge Richard Posner pointed out, juries rarely have the quantified variables necessary for truly performing the Learned Hand analysis.[174] Thus, the test "has greater analytic than operational significance."[175] Put

170. *See id.*

171. *See id.*

172. These and other scenarios discussed throughout the Article were developed in conversation with our colleagues on the grant. We based these examples on our understanding of the experiences of health care providers and labs in dealing with these issues.

173. We explore these possible variations in greater detail with our case studies in Part III.

174. McCarty v. Pheasant Run, Inc., 826 F.2d 1554, 1557 (7th Cir. 1987) (Posner, J.) ("Conceptual as well as practical difficulties in monetizing personal injuries may continue to frustrate efforts to measure expected accident costs.").

175. *Id.*

another way, juries rely more on their intuitions of reasonableness than actual cost-benefit analysis.[176] Nonetheless, we find the Learned Hand test useful in thinking through the potential breaches of genetic duties that we explore in Part III.

3. Causation, Damages, and Defenses

As noted, we focus our analysis here on duty and breach. Of course, plaintiffs also need to show that the defendant's breach actually injured them.[177] Simply demonstrating that the lab or the ordering physician failed to provide updated results will not be sufficient.[178] If no clear harm resulted from failing to give the patient reinterpreted results post-reclassification, then she cannot recover.[179] For these reasons, we have confined our analysis only to reclassifications that communicate clinically actionable information. But even then, only patients who have actually manifested a genetic condition may have valid claims.[180] For example, if a lab failed to communicate that it reclassified a patient's *BRCA1* VUS as pathogenic but that patient never develops breast or ovarian cancer, she may not have experienced a legally actionable harm.

Proving a legally cognizable injury could even pose challenges when patients get sick and die. In cases of highly deadly, unpreventable diseases, patients may die no matter what, even with the knowledge of their greater genetic risk and access to earlier intervention and treatment. Even if the hypothetical patient from the Introduction was aware of her increased breast cancer risk, it is hard to predict what difference knowing and acting on that risk might have made. Would she have had prophylactic surgeries? Or caught the cancer sooner and survived? And if the cancer had been diagnosed at an earlier stage, how much longer would she have lived? One year? Five years? Twenty-five years? Or perhaps, early detection and intervention would not have made a difference and she would have died anyway. What is the injury of failing to notify

176. *See id.*

177. *See supra* note 111 and accompanying text.

178. *See supra* note 111 and accompanying text.

179. *See supra* note 111 and accompanying text.

180. *But see supra* Part I.A.2 (arguing for the legal duties to reinterpret and recontact extending to benign reclassifications).

the patient in those cases? No one—including judges and juries—can know for sure.[181]

Moreover, it is not enough to simply show that the patient suffered an injury following the defendant's breach. She must also demonstrate that the defendant's conduct actually and proximately caused that harm.[182] Proximate cause requires that the injury be foreseeable.[183] While it might seem that reclassifying a VUS as pathogenic clearly communicates a foreseeable risk,[184] genetics involves probabilities.[185] Even clinically actionable genetic information does not perfectly predict health outcomes. Sometimes the causation inquiry will be relatively straightforward. For example, in *Williams*, the lab's allegedly negligent misclassification led Christian's care team to pursue a treatment shown to exacerbate—not reduce—seizures in patients with Dravet syndrome.[186] Williams could, therefore, draw a causal link from the negligence to the harm. But in cases in which the failure to share updated results denies the patient access to prevention and treatment, the connection between the breach and the injury is less clear. Put differently, what killed our hypothetical patient? The failure to give her clinically actionable genetic information or breast cancer? Courts may struggle with whether failing to reinterpret or to recontact actually caused the harm the patient experienced.

Even if a patient presents a convincing prima facie case, the labs and physicians may have defenses at their disposal that will allow them to escape liability.[187] For example, in cases in which patients

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181. That will not, however, prevent them from trying to guess. In some jurisdictions, plaintiffs can sue for the "loss of a chance." *See, e.g.*, Dickhoff *ex rel.* Dickhoff v. Green, 836 N.W.2d 321, 336-37 (Minn. 2013) ("Minnesota law permits a patient to recover damages when a physician's negligence diminishes or destroys a patient's chance of recovery or survival."); Matsuyama v. Birnbaum, 890 N.E.2d 819, 823 (Mass. 2008) (permitting recovery for loss of chance in case of medical injury); McKellips v. Saint Francis Hosp., Inc., 741 P.2d 467, 475 (Okla. 1987) (adopting "the loss of chance doctrine in Oklahoma").

182. *See generally* Richard W. Wright, *Causation in Tort Law*, 73 CALIF. L. REV. 1735 (1985) (detailing the causation requirement in tort litigation).

183. *See, e.g.*, KEITH N. HYLTON, TORT LAW: A MODERN PERSPECTIVE 248 (2016).

184. *See* Brawn v. Oral Surgery Assocs., 819 A.2d 1014, 1028 (Me. 2003).

185. DANIEL L. HARTL & ELIZABETH W. JONES, ESSENTIAL GENETICS: A GENOMICS PERSPECTIVE 105 (4th ed. 2006).

186. *See* Williams v. Quest Diagnostics, Inc., 353 F. Supp. 3d 432, 437 (D.S.C. 2018).

187. *See generally* Kirby v. Larson, 256 N.W.2d 400 (Mich. 1977) (discussing the long history of contributory and comparative negligence in the United States).

fail to keep their contact information up to date, courts may apply doctrines of comparative or contributory negligence to limit the physician's liability for failing to recontact.[188]

Moreover, several agreements—both formal and informal—are lurking in the background of these issues. Clinical laboratories have terms of service that will likely apply to these disputes.[189] These terms may include a variety of provisions that could affect a patient's ability to recover, such as arbitration clauses and choice-of-law clauses.[190] And while not exactly contracts per se, patients also enter into agreements with their health care providers.[191] The treatment relationship itself is "quasi-contractual."[192] The doctor triggers her fiduciary duties by accepting the patient.[193] Likewise, patients consent to various tests and treatments, sometimes signing forms that explain the risks and benefits. Further, even fiduciaries may be able to contract around their obligations.[194] Laboratories in particular may try to define the scope of their liability related to re-interpreting results or contacting doctors in their terms of service.[195] They could go as far as trying to waive their liability.[196] Should such waivers become boilerplate provisions of their terms of service, that development could undermine a patient's ability to recover for the failure to reinterpret.

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188. *See id.* at 413-25 (discussing the history of comparative and contributory negligence, the relationship between the doctrines, and their application in several states).

189. *See infra* note 307 and accompanying text.

190. *See* Michael Scopulous & Jeffrey J. Segal, *Limiting Exposure to Medical Malpractice Claims and Defamatory Cyber Postings via Patient Contracts*, 467 CLINICAL ORTHOPAEDICS & RELATED RSCH. 427, 427 (2009).

191. *See supra* notes 127-28 and accompanying text.

192. *See supra* note 127 and accompanying text.

193. *See* Mantel, *supra* note 117, at 153.

194. *See* Scopulous & Segal, *supra* note 190, at 427; *see also* Sosa v. Paulos, 924 P.2d 357, 361-62 (Utah 1996) (holding that an arbitration clause requiring an arbitration panel of neutrally selected physicians was not substantively unconscionable); Sanford v. Castleton Health Care Ctr., LLC, 813 N.E.2d 411, 419-20 n.3 (Ind. Ct. App. 2004) ("[Q]ualified providers need to be cognizant that, should they include these exclusive arbitration clauses in their contracts, they might be relinquishing ... their right to avail themselves of the Medical Malpractice Act."). *But see* Hernandez v. Crespo, 211 So. 3d 19, 27 (Fla. 2016) ("We find that arbitration agreements which change the cost, award, and fairness incentives of the [Medical Malpractice Act's] statutory provisions ... are ... void as against public policy.").

195. *See infra* Part III.A.1.

196. *See, e.g.*, Scopulous & Segal, *supra* note 190, at 427.

While we confine our analysis to duty and breach, we nonetheless acknowledge the complexities that these additional issues raise for courts. Thus, recognizing genetic duties is simply the first step on the road to liability, not a guarantee that patients will recover.

* * *

While our genetic makeups remain relatively stable across our lifetimes, the scientific understanding of our genomes is always in flux. Sometimes new research reveals previously unknown information about a patient's genetics. That new understanding can have a profound impact on a person's emotional and physical health. Despite these serious implications, no clearly recognized legal duty requires any action when a laboratory reclassifies a VUS. The next Part turns to what legal duties—if any—laboratories and physicians should have to encourage them to share that new information with their patients.

II. IMPOSING GENETIC DUTIES

Growing knowledge about the genome may lead labs to reclassify VUSs. However, patients cannot benefit from that reclassification without updated genetic test results. Here, we consider the arguments in favor of imposing legal duties to reanalyze genetic test results and to inform patients after a laboratory reclassifies a VUS. We conclude that while laboratories are in the best position to reinterpret results, ordering physicians are in the best position to recontact patients.

A. In Favor of Genetic Duties

Legal duties communicate important social values. When deciding whether to impose a legal duty, courts will look to any number of factors, "including the guidance of history, our continually refined concepts of morals and justice, the convenience of the rule, and social judgment as to where the loss should fall."[197] Here, we

197. Tresemer v. Barke, 150 Cal. Rptr. 384, 393 (Cal. Ct. App. 1978). This proposition stems from a law review article authored by Professor Prosser and recently has been

consider whether the law should include a duty to inform patients following a variant reclassification. We draw our analysis from professional ethics and norms, tort theories, and tort doctrine.

1. Professional Ethics & Norms

Experts in both biomedical ethics and genetics support recognizing duties related to variant reclassification. A recent article in *Genetics in Medicine* argued in favor of a duty to reinterpret VUSs, supported by the ethical principles of autonomy, beneficence, and nonmaleficence.[198] The authors, a group of medical ethicists and genetic clinicians, break that duty into four elements: (1) storing the relevant data; (2) initiating the reinterpretation; (3) reinterpreting the data; and (4) returning reinterpreted results to the patient.[199] They assert that certain aspects of modern genetic testing make it uniquely suited for an ethical duty to reinterpret, including the increased ability to identify VUSs using recent genetic innovations, the amount of currently inconclusive data that will be subject to reliable future interpretation, and the stability of genetic information across a person's lifespan.[200] These facts distinguish genetics from other kinds of clinical testing, as well as support an ethical duty to reinterpret.[201]

According to the authors, ordering and performing genetic tests triggers an ethical duty to reinterpret the results when more reliable information becomes available.[202] Both labs and ordering physicians have a role to play. The authors propose that laboratories are currently in the best position to (1) store data, (2) know when to

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repeatedly cited by courts in different contexts. *See, e.g.*, Mussivand v. David, 544 N.E.2d 265, 270 (Ohio 1989) (finding that, generally, a specific formula cannot be used to determine whether one owes a duty of care to another (citing William L. Prosser, *Palsgraf Revisited*, 52 MICH. L. REV. 1, 15 (1953))); Elabiad v. Trans-W. Express, LLC, No. 3:03CV7452, 2005 WL 1223804, at *4 (N.D. Ohio May 23, 2005).

198. *See* Appelbaum et al., *supra* note 106, at 634-35.

199. *Id.* at 634. The authors of this paper are members of the Ethics Working Group of NIH Grant 1R01HG010365-01, Development of Recommendations and Policies for Genetic Variant Reclassification. *Id.* at 638.

200. *Id.* at 635.

201. *Id.*

202. *Id.*

reinterpret, and (3) perform the genetic analysis.[203] By contrast, responsibility for the fourth element— returning those results to the patient—should lie with the ordering physician, who is more likely than the lab to have direct access to the patient.[204] While law and ethics are certainly distinct, the existence of an ethical duty raises the question of whether there should be a corresponding legal duty.

Medical associations have also supported imposing duties on labs and physicians in the wake of a variant reclassification. Two professional organizations have already weighed in on this issue: the American College of Medical Genetics and Genomics (ACMG)[205] and the American Society of Human Genetics (ASHG).[206]

A 2019 ACMG policy statement considers the post-reclassification role of physicians. To start, the statement recommends that providers inform patients taking genetic tests that their results could change.[207] Similar to the ethicists cited above, the ACMG opines that—even absent a legal duty[208]—beneficence requires doctors to at least attempt to recontact patients when the updated results could affect treatment.[209] The ACMG emphasizes the importance of ensuring that the doctor's office has the patient's current contact information on file.[210] Yet, recontacting the patient may not always be easy. If a patient receives genetic testing from a specialist who

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203. *Id.* at 636.

204. *Id.*

205. David et al., *supra* note 65, at 770.

206. *See* Yvonne Bombard, Kyle B. Brothers, Sara Fitzgerald-Butt, Nanibaa' A. Garrison, Leila Jamal, Cynthia A. James, Gail P. Jarvik, Jennifer B. McCormick, Tanya N. Nelson, Kelly E. Ormond, Heidi L. Rehm, Julie Richer, Emmanuelle Souzeau, Jason L. Vassy, Jennifer K. Wagner & Howard P. Levy, *The Responsibility to Recontact Research Participants After Reinterpretation of Genetic and Genomic Research Results*, 104 AM. J. HUM. GENETICS 578, 581 (2019).

207. David et al., *supra* note 65, at 770.

208. The statement also notes that, as electronic health records and other technologies improve, the costs of recontacting will go down, perhaps making courts more open to recognizing a legal duty to recontact. *Id.*

209. *Id.* Older policy documents also support imposing a duty to recontact. *See* Kurt Hirschhorn, Lynn D. Fleisher, Lynn Godmilow, R. Rodney Howell, Robert R. Lebel, E.R.B. McCabe, Matthew J. McGinniss, Aubrey Milunsky, Mary Z. Pelias, Reed E. Pyeritz, Eva Sujansky, Barry H. Thompson & Randi-Ellen Zinberg, *ACMG Policy Statement: Duty to Re-Contact*, 1 GENETICS MED. 171, 171-72 (1999). A 1999 ACMG policy statement asserted that family doctors are "expected to know the family and ask if new developments in the family history have occurred and to be alert to new potential opportunities that could affect the health and future of his/her patients." *Id.* at 171.

210. David et al., *supra* note 65, at 770.

she sees one time, the scope of the treatment relationship could then be a single visit.[211] While doctors have no legal duty, they may still have an ethical duty to try to recontact.[212]

Moreover, a physician may not know when a lab has reclassified a VUS. Not surprisingly then, the ACMG writes that "[t]he responsibility to inform the ordering physician of variant reclassification or discovery of a new gene-disease relationship rests with the clinical laboratory."[213] Thus, like the authors in *Genetics in Medicine*, the ACMG supports both imposing ethical duties following a variant reclassification and dividing those responsibilities between the lab that performed the test and the doctor who ordered it.[214]

Around the same time as the ACMG statement, the ASHG issued similar guidance regarding the responsibility to recontact research participants.[215] Unlike the ACMG, the ASHG gives the subjects of the test the explicit right to decline the reinterpretation.[216] The recommendations state that the reasons for recontacting patients are most compelling when (1) a likely pathogenic or pathogenic variant gets downgraded to a VUS, likely benign, or benign, and (2) a VUS or likely benign or benign variant is reclassified as likely pathogenic or pathogenic.[217] However, it also explains in no uncertain terms "that there is no responsibility for researchers to hunt or scan genetic and genomic data or literature for changes in variant interpretation."[218] The ASHG states that researchers should only

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211. That is not to say no opportunity for liability will exist. *See* Poirrier v. Richardson, No. 17-864, 2018 WL 1471458, at *7 (E.D. La. Jan. 4, 2018) (imposing the reasonableness standard on a physician playing a one-time role in a patient's care and treating that one-time physician as a possible intervening force in determining whether the patients' treating physicians were liable).

212. *See* Alasdair G.W. Hunter, Neil Sharpe, Michelle Mullen & Wendy S. Meschino, *Ethical, Legal, and Practical Concerns About Recontacting Patients to Inform Them of New Information: The Case in Medical Genetics*, 103 AM. J. MED. GENETICS 265, 267 (2001).

213. *See* David et al., *supra* note 65, at 771 n.6.

214. *See id.*

215. *See* Bombard et al., *supra* note 206, at 581. The European Society of Human Genetics (ESHG) also issued a statement. *See* Carrieri et al., *supra* note 11, at 173. The ESHG recommends that clinicians recontact patients regarding findings with clinical utility. *Id.* at 179. Recontacting, according to the ESHG, is the shared responsibility of patients and laboratories. *Id.* Requests for reanalysis should be initiated by the patient, clinical laboratory, or the clinician. *Id.* at 174-75.

216. *See* Bombard et al., *supra* note 206, at 584.

217. *Id.* at 585.

218. *Id.*

recontact participants when there are sufficient resources.[219] Under certain circumstances, such as if a study is without funding, it may not be appropriate to expect to be recontacted.[220]

Finally, some labs are adopting a more active role in patient care.[221] Although on an ad hoc basis, those laboratories are already taking it upon themselves to send updated results to ordering physicians following reclassification.[222] Thus, both professional organizations and even sometimes labs themselves support informing patients of a reclassification, even absent an explicit legal duty.

2. Tort Theory

Broadly speaking, tort law allows injured parties to recover directly from those who harmed them.[223] Torts are, then, by their very nature, redistributive, shifting the costs of an unfortunate event from the plaintiff to the defendant.[224] Yet precisely why—and sometimes how—the law compensates tort victims remains a topic of robust philosophical debate. Legal scholars have developed both economic- and justice-based theories to explain the existence of torts and to argue for reform.[225] Proponents of economic theories believe that tort law should reallocate costs efficiently, whereas justice advocates argue for reallocating costs fairly.[226] While impossible to

219. *Id.* at 579.

220. *See id.* at 583.

221. *See* Stevens et al., *supra* note 19.

222. *Id.* (citing J.M. O'Daniel et al., *A Survey of Current Practices for Genomic Sequencing Test Interpretation and Reporting Processes in US Laboratories*, 19 GENETICS MED. 575, 580 (2017); Daniele Carrieri, et al., *Recontact in Clinical Practice: A Survey of Clinical Genetics Services in the United Kingdom*, 18 GENETICS MED. 876, 877 (2016)).

223. *See* Jules Coleman, Scott Hershovitz & Gabriel Mendlow, *Theories of the Common Law of Torts*, *in* STANFORD ENCYCLOPEDIA OF PHILOSOPHY (2015), https://plato.stanford.edu/entries/tort-theories/ [https://perma.cc/W5B8-7CCM].

224. Christine Jolls, *Behavioral Economics Analysis of Redistributive Legal Rules,* 51 VAND. L. REV. 1653, 1656 (1998).

225. *See generally* Coleman et al., *supra* note 223 (providing a broad overview of tort theory).

226. *See id.* In recent years, some tort theorists have rejected the notion that tort law functions to achieve certain external goals—whether those goals be economic efficiency or moral justice—and have instead argued for an internal theory of tort law. *See* Cristina Carmody Tilley, *Tort Law Inside Out*, 126 YALE L.J. 1320, 1324 (2017); *see also* Michael L. Rustad, *Twenty-First-Century Tort Theories: The Internalist/Externalist Debate*, 88 IND. L.J. 419, 423 (2013) (gathering distinguished macrolevel theorists to evaluate the claims of civil

offer a complete account here, we consider briefly how each of the major tort theories would support imposing legal duties related to variant reclassification.

Economic theories of tort law seek to minimize costs by creating incentives to avoid harms in the first place.[227] According to this line of thinking—absent legal liability—people may impose unreasonable risks of injury on one another.[228] For example, the owner of an amusement park may be tempted to skimp on expensive ride repairs if she does not bear any of the costs of her patrons' injuries. However, making her legally liable when parkgoers get hurt creates a financial incentive to ensure a certain baseline of safety. Thus, the tort system can encourage socially beneficial behavior—usually taking precautions to prevent injuries—with the threat of liability.[229] Under an economic approach, a liability framework is only defensible when its benefits outweigh the costs that it imposes.[230]

In the context of variant reclassification, patients are currently bearing a substantial number of costs. They are, after all, the people who suffer—and sometimes die—when laboratories and physicians fail to share updated genetic information.[231] Without uniform practices surrounding reclassification, reinterpretation, and recontacting, patients are left to shoulder much of this burden alone. Under the current system, laboratories and doctors share reinterpreted results on an ad hoc basis.[232] While norms surrounding professional ethics and best practices may be developing for both labs and physicians, patients remain vulnerable absent the means for legal recovery.[233] Establishing legal duties for both laboratories and physicians could shift these costs away from patients to the parties who are better equipped to bear them.

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recourse from external perspectives in an authors-meet-critics format). While important, these insights go beyond the scope of this Article.

227. Coleman et al., *supra* note 223.

228. *See id.*

229. *See* Steven Shavell, *A Fundamental Enforcement Cost Advantage of the Negligence Rule over Regulation*, 42 J. LEGAL STUD. 275, 287-88 (2013).

230. *See generally* A. Mitchell Polinsky & Steven Shavell, *The Uneasy Case for Product Liability*, 123 HARV. L. REV. 1437 (2010) (concluding that the costs of products liability may not be worth the benefits).

231. *See, e.g.*, Williams v. Quest Diagnostics, Inc., 353 F. Supp. 3d 432, 437 (D.S.C. 2018).

232. Bombard et al., *supra* note 206, at 579.

233. *See* EAST ET AL., *supra* note 65, at 11.

Absent insurance coverage, labs and doctors will be responsible for bearing these costs. The cost of reinterpreting and recontacting is not confined to the patients who will actually get sick. Should courts opt to impose legal duties related to variant reclassification, laboratories and ordering physicians will have to make updated information available to all potentially impacted patients, not just those who develop symptoms. Of course, the laboratories and physicians could attempt to lower these costs by prioritizing reclassifications of VUSs as pathogenic or likely pathogenic. But even that will require labs to monitor all VUSs. And as the story of the family whose members underwent unnecessary surgeries demonstrates, notifying patients that a variant has been reclassified as benign or a VUS can also be important.[234]

Simultaneously, the costs of reinterpretation and recontacting are likely decreasing. Computational and communication technologies are streamlining the process of genetic analysis and enabling greater communication between patients, laboratories, and physicians.[235] As the burdens associated with updating patients continue to go down, the current distribution of the costs associated with variant reclassification could become increasingly harmful and inefficient. We discuss how to properly allocate the proposed legal duties associated with variant reclassification in Section B below.

Justice-based accounts look not to economic efficiency but rather to fairness.[236] Unsurprisingly, torts scholars have not arrived at a singular, unified theory of which outcomes are just and why. Civil recourse theory argues that tort law empowers individuals who have been wrongly injured to seek redress against the people who harmed them.[237] Similarly, corrective justice creates an obligation on the part of the tortfeasor to repair the wrong that she has caused.[238] Retributive theories take a somewhat related but different approach. They view tort law not as a mechanism to allow

234. *See supra* notes 83-89 and accompanying text.

235. *See* Deignan et al., *supra* note 57, at 1267; Kathryn E. Flynn, Maureen A. Smith & Margaret K. Davis, *From Physician to Consumer: The Effectiveness of Strategies to Manage Health Care Utilization*, 59 MED. CARE RSCH. & REV. 455, 467-68 (2002).

236. *See* Coleman et al., *supra* note 223.

237. *See* Richard A. Posner, *Instrumental and Noninstrumental Theories of Tort Law*, 88 IND. L.J. 469, 470 (2013).

238. *See* Coleman et al., *supra* note 223.

plaintiffs to recover from socially unjustifiable wrongs, but as a tool to punish blameworthy defendants.[239] Finally, distributive justice seeks to ensure that all members of society share the benefits and burdens of risky activity fairly.[240] Distributive justice differs from corrective justice. Corrective justice assumes that the initial distribution of resources is just and that tort law functions to simply restore that previous balance.[241] By this account, corrective justice is merely transactional.[242] It does not consider whether the result of that transaction is, in and of itself, fair.[243] By contrast, distributive justice considers the fairness of the initial resource distribution, as well as the reallocation post-tort.[244] Under each of the justice-based models, tort law seeks to reinforce important social norms related to fairness.

Justice-based theories of tort law also generally endorse imposing legal duties related to variant reclassification. As noted, ethicists and clinicians have recently argued to impose duties on both laboratories and physicians based on a variety of bioethical principles.[245] Concerns related to preserving patient autonomy, promoting patient well-being, and preventing harm all likewise speak to justice.[246] Thus, they reason that the nature of modern genetic testing creates a moral imperative to reinterpret results following a reclassification and to share that information with the patient.[247]

When the labs and the physicians fail to take this ethically appropriate action and the patient suffers a harm as a result, justice-based tort theories would support imposing liability. Under civil recourse, the patient has the right to recover; and, pursuant to corrective justice, the laboratories and the doctors are obliged to

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239. *See* Scott Hershovitz, *Torts as a Substitute for Revenge, in* PHILOSOPHICAL FOUNDATIONS OF THE LAW OF TORTS 86, 87 (John Oberdiek ed., 2014).

240. *See* Gregory C. Keating, *Distributive and Corrective Justice in the Tort Law of Accidents*, 74 S. CAL. L. REV. 193, 194-96 (2000).

241. *See* Hanoch Sheinman, *Tort Law and Distributive Justice*, *in* PHILOSOPHICAL FOUNDATIONS OF THE LAW OF TORTS, *supra* note 239, at 354, 374; Coleman et al., *supra* note 223.

242. Coleman et al., *supra* note 223.

243. *Id.*

244. *Id.*

245. *See, e.g.*, Appelbaum et al., *supra* note 106, at 638.

246. *Id.* at 634-35.

247. *Id.* at 638.

rectify the harms that they generate.[248] Lastly, from a distributive justice perspective, the laboratories and the physicians often have greater knowledge and resources.[249] Patients may then be unable to benefit from clinically actionable variant reclassifications without help from those parties.[250] Patients also must bear the physical, psychological, and financial burdens of any resulting health conditions. Distributive justice theories of tort might then advocate shifting some of the ex ante responsibilities to the labs and doctors, as well as allowing patients to recover ex post for the failure to give them clinically actionable information.

Retributive theories of tort, which seek to punish wrongdoers, are perhaps the most uncomfortable fit here, as certain factors mitigate the blameworthiness of the potential defendants. First, the basis of the proposed torts would be the failure to do something—mainly reinterpret results and recontact patients—rather than affirmative acts.[251] Second, laboratories and physicians provide socially valuable health care services. A tort framework based on punishment is, thus, not desirable given that the moral culpability of the labs and the doctors is less than clear. Of course, retributive justice often plays an important part in correcting situations in which individual harms are difficult to identify yet a public harm needs addressing.[252] Arguably, a failure to reinterpret and to recontact may lead to widespread dissatisfaction and loss of confidence in the medical system.[253] However, labs and physicians are not, at least in most cases, blameworthy bad actors deserving of punishment.[254]

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248. *See* Coleman et al., *supra* note 223.

249. *See* Serena Olsaretti, *Introduction: The Idea of Distributive Justice* to THE OXFORD HANDBOOK OF DISTRIBUTIVE JUSTICE 6, 7 (Serena Olsaretti ed., 2018).

250. *See* Lily Hoffman-Andrews, *The Known Unknown: The Challenges of Genetic Variants of Uncertain Significance in Clinical Practice*, 4 J.L. & BIOSCIENCES 648, 653 (2017).

251. *See, e.g.*, *supra* Introduction.

252. As opposed to corrective justice, in which bilateral private litigation can right the victim's wrong, including her feelings of indignation. *See* Walter J. Blum & Harry Kalven, Jr., *The Empty Cabinet of Dr. Calabresi: Auto Accidents and General Deterrence*, 34 U. CHI. L. REV. 239, 268-69 (1967) ("In large part corrective justice is concerned ... with satisfying the victim's feeling of indignation. If the victim [cannot sue], he will not get the satisfaction of seeing his wrong righted.").

253. Recall, for example, the results of the survey indicating patients lost trust in their doctor as a result of VUS reinterpretation. *See* Makhnoon et al., *supra* note 78, at 192.

254. *See generally* Ronen Perry, *The Role of Retributive Justice in the Common Law of Torts: A Descriptive Theory*, 73 TENN. L. REV. 177 (2006).

Summing up, both economic- and justice-based theories of tort law may support imposing legal duties related to variant reclassification.

3. Tort Doctrines

Lastly, courts have themselves developed tests for assessing when it is appropriate to impose a previously unrecognized legal duty. Most law students are familiar with the infamous California Supreme Court case *Tarasoff v. Regents of the University of California*.[255] In that case, the court held that mental health care providers have a duty to warn third parties of the potential dangers posed by their patients.[256] Quoting William Prosser, who stated that tort duties are "the sum total of [policy] considerations ... which lead the law to say that the particular plaintiff is entitled to protection,"[257] the court looked to a variety of factors, including the foreseeability of harm, the certainty of the injury, the connection between the defendant's actions and the plaintiff's injury, the moral blameworthiness of the defendant, the desire to prevent future harm, the costs to the community of imposing a duty, and the availability and affordability of insurance.[258]

The Supreme Court of New Jersey adopted a similar framework in *Snyder v. American Association of Blood Banks*.[259] Again, the court began with the proposition that "the existence of a [legal] duty ultimately is a question of fairness and policy."[260] It then went on to explain that the foreseeability of injury, the nature of the risk, the parties' relationship, and the effect liability would have on the public were all relevant considerations.[261]

Some—but not all—of the *Tarasoff* and *Snyder* factors support imposing duties related to variant reclassifications. Certainly, in the case of clinically actionable information, the risk of harm to the

255. 551 P.2d 334 (Cal. 1976).
256. *Id.* at 351.
257. *Id.* at 342 (quoting WILLIAM PROSSER, LAW OF TORTS 332-33 (3d ed. 1964)).
258. *Id.* at 358 (citing Rowland v. Christian, 443 P.2d 561, 564 (Cal. 1968)).
259. 676 A.2d 1036 (N.J. 1996).
260. *Id.* at 1048.
261. *Id.*

patient is foreseeable.[262] The failure to update denies the patient the opportunity to take potentially life-saving actions.[263] Additionally, there is a desire to prevent negative health outcomes, and the costs of avoiding those harms are growing increasingly low.[264] Less clear, however, are the certainty of the injury—since not every patient will manifest the condition associated with a genetic risk[265]—and the moral culpability of the labs and the physicians.[266] *Tarasoff* and *Snyder,* thus, provide some support for recognizing genetic duties. Yet, deciding that courts should recognize these genetic duties does not answer the question of who should bear them. We address this issue in the following Section.

B. Allocating Genetic Duties

Judge Guido Calabresi introduced one of the most popular economic accounts of tort law in his path-breaking 1970 book, *The Costs of Accidents*.[267] He advocates placing legal liability on the party who can most readily avoid the potential harms.[268] That party is the "cheapest or [least] cost avoider" because she can avert the harm with the fewest accompanying costs.[269] In other words, she is best situated to prevent the injury in the first place.

Calabresi presented his theory as a cleaner alternative to the fault-based tort system. Instead of engaging in potentially costly and time-consuming negligence analysis, he and Jon Hirschoff propose making the cheapest cost avoiders strictly liable for the torts that they could have prevented.[270] While we do not advocate a

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262. *See* Brawn v. Oral Surgery Assocs., 819 A.2d 1014, 1028 (Me. 2011) (recognizing that a special relationship existed with a former patient and that "[o]nce a safety alert is received 'it can hardly be argued that any harm to a patient is not foreseeble.'" (quoting Harris v. Raymond, 715 N.E.2d 388, 394 (Ind. 1999))).

263. *See supra* Introduction.

264. *See supra* note 235 and accompanying text.

265. *See* Ingrid Lobo, *Same Genetic Mutation, Different Genetic Disease Phenotype*, NATURE EDUC.: SCITABLE (2008), https://www.nature.com/scitable/topicpage/same-genetic-mutation-different-genetic-disease-phenotype-938/ [https://perma.cc/RLA7-TBAH].

266. *See supra* Part II.A.2.

267. GUIDO CALABRESI, THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS (1970).

268. *Id.* at 135.

269. *Id.* at 135 n.1.

270. Guido Calabresi & Jon T. Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 YALE L.J. 1055, 1060 (1972).

strict liability approach here, we nonetheless use the "cheapest cost avoider" epithet as shorthand for assessing the relative costs and benefits shouldered by the parties.[271]

Before considering how to best allocate these potential legal duties, it is worth noting that the dynamics of the treatment relationship are changing.[272] A patient may see a variety of providers in the course of her treatment.[273] For example, a family doctor who suspects that a patient has cancer may refer the patient to an oncologist. The oncologist could then order a genetic test but send the patient to a geneticist for additional testing and follow-up. Thus, one patient could see a team of doctors related to a single health issue.[274]

Additionally, the role of the patient herself is also changing. Medical care is moving toward a more cooperative model. Physicians are no longer the gatekeepers of health information that they once were.[275] Patients can access their test results directly from labs[276] and their medical records online.[277] There have also been efforts to give patients greater control over medical decision-making.[278] Also, as noted, some labs are reaching out to patients to share updated results directly.[279] Thus, any legal duties related to variant reclassification should take into account the increasingly cooperative—and often complex—nature of the modern treatment relationship.

While a number of different parties could be involved in a patient's care, and thus, possibly implicated in a lawsuit, we focus

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271. Although we do not explicitly consider a strict liability approach here, we do not disavow its potential applications in this context.

272. *See generally* R. Kaba & P. Sooriakumaran, *The Evolution of the Doctor-Patient Relationship,* 5 INT'L J. SURGERY 57 (2007).

273. *See, e.g.*, *Who Will Be Involved in My Treatment?*, WEBMD, https://www.webmd.com/a-to-z-guides/treatment-team#1 [https://perma.cc/FTF8-C32L].

274. *See id.*

275. *See* Flynn et al., *supra* note 235, at 455-56. *See generally* Jessica Mantel, *A Defense of Physicians' Gatekeeping Role: Balancing Patients' Needs with Society's Interests*, 42 PEPP. L. REV. 633 (2015).

276. *See HHS Strengthens Patients' Right to Access Lab Test Results*, DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/special-topics/clia/index.html [https://perma.cc/WFS5-5APT].

277. *See Increasing Patient Access to Medical Records*, UIC: HEALTH INFORMATICS, https://healthinformatics.uic.edu/blog/increasing-patient-access-to-medical-records/ [https://perma.cc/97FR-PLEN].

278. Kaba & Sooriakumaran, *supra* note 272, at 59.

279. *See supra* note 222 and accompanying text.

here on three primary stakeholders: (1) the lab conducting the original analysis, (2) the treating physician ordering the genetic test, and (3) the patient seeking care.[280] In the following three Subsections, we discuss each of these stakeholders in turn.

1. Laboratories

Following a reclassification, laboratories could do a few different things.[281] They could simply inform ordering physicians of the reclassification. (From there, the ordering physicians could either request reinterpretation or contact patients.) Alternatively, labs could reinterpret the results and share the updated information with the ordering physicians, who could then contact patients with the new results. Finally, labs could both reinterpret the genetic data and recontact patients directly.

As explained in Part I, laboratories decide how to classify the variants that they interpret, and no uniform standards or processes govern when reclassification occurs.[282] Because they do the reclassifying—as well as the analyzing—laboratories are in the best position to know when reinterpretation would be appropriate. Not all reclassifications are equally relevant to a patient's health.[283] For example, a VUS that is reclassified to likely benign may not be worth the costs of reinterpreting. Consequently, the labs are the cheapest cost avoiders when it comes to reinterpretation. But what should they do with that information? Merely share it with the ordering physicians? Or should the labs attempt to reach out to the patients themselves?

Certainly, having the labs share reinterpreted results directly with patients saves the patients time and money. Yet, while laboratories are uniquely well-situated to know when to reinterpret, they may not be well-equipped to actually provide that information

280. Depending on the facts of each case, other parties—particularly other parties with direct patient contact or those whose actions had a direct impact on a medical decision—might be open to suit. *See* Foulkes et al., *supra* note 20, at 170. But here, we only consider the two parties with the most prominent role in generating and interpreting genetic data: clinical genetics laboratories and the physician ordering and interpreting the genetic tests.

281. These scenarios were developed in conversation with our colleagues on the grant.

282. *See supra* notes 52-56 and accompanying text.

283. *See* Deignan et al., *supra* note 57, at 1268.

to patients. To be sure, patients can now obtain their test results directly from labs.[284] However, the laboratories themselves may not have ready access to patients or to their contact information.[285] Instead, labs communicate primarily with ordering physicians. Although labs are the clear cheapest cost avoiders with respect to reinterpretation, they may not be the cheapest cost avoiders when it comes to actually recontacting the affected patients.

2. Physicians

Unlike laboratories, doctors are not well-equipped to know when reinterpretation is appropriate. Most clinicians are not geneticists. As a general matter, doctors tend to be poorly situated to manage, interpret, and advise patients regarding their genetic test results beyond what is in the lab report.[286] Consequently, physicians may not even know when a reclassification occurs, let alone when to ask labs to reinterpret their individual patients' results.

Doctors may, however, have direct contact with patients in a way that labs often do not. In particular, the physician who ordered the original genetic test is well-positioned to bear some of the duties associated with sharing updated results post-reclassification. The ordering physician has had contact with the patient and possesses some basic knowledge of the genetic factors at play and their potential consequences. After all, if the doctor did not have a sense of the patient's health condition—and a belief that a genetic test could reveal potentially valuable information—she never would have ordered it in the first place.

As a result, although ordering physicians are not the cheapest cost avoiders when it comes to reinterpretation, they are the cheapest cost avoiders (1) for knowing when it is appropriate to share the updated information with the patient (that is, when the

284. *See HHS Strengthens Patients' Rights to Access Lab Test Results*, *supra* note 276.

285. *See* Hoffman-Andrews, *supra* note 250, at 652; *cf.* Colin Mitchell, Corrette Ploem, Valesca Retèl, Sjef Gevers & Raoul Hennekam, *Experts Reflecting on the Duty to Recontact Patients and Research Participants; Why Professionals Should Take the Lead in Developing Guidelines*, 63 EUR. J. MED. GENETICS 103642, 103642 (2020) ("Clinical lab specialists regarded it as currently unfeasible to systematically update records and recontact patients.").

286. *See* Wendy S. Rubinstein, *Roles and Responsibilities of a Medical Geneticist,* 7 FAMILIAL CANCER 5, 13 (2007).

updated results communicate clinically actionable health information) and (2) for actually contacting the patient with that update.[287] Depending on the situation, the ordering physician might not want to give the patient the updated results immediately. The doctor might instead decide to have a conversation with the patient about the reclassification and to ask the patient whether she would like her reinterpreted results. Allowing the patient to decide if she wants new information better respects the recent shift toward cooperative medicine.[288]

While patients may see multiple providers over the course of their treatment, we focus here on the ordering physician. Of course, sometimes the ordering physician will not have the most frequent contact with the patient. For example, a family doctor will often have more regular interactions with a patient than an oncologist or a geneticist. However, the lab will have the readiest access to the *ordering physician*. Thus, although not ideal in every circumstance, we believe that placing the duty to recontact on the ordering physician is the most appropriate allocation of this duty.[289]

3. Patients

Of the three relevant kinds of stakeholders, patients are in the weakest position to bear the costs associated with variant reclassification. To start, patients are unlikely to know when labs reclassify variants, let alone when reinterpretation would be appropriate. Most patients lack medical training and genetic expertise. Perhaps

287. *See supra* notes 267-80 and accompanying text.

288. *See generally* Miguel Cabarrus, David M. Naeger, Alexander Rybkin & Aliya Qayyum, *Patients Prefer Results from the Ordering Provider and Access to Their Radiology Reports*, 12 J. AM. COLL. RADIOLOGY 556, 556-61 (2015) (discussing the benefits of cooperative medicine in the context of radiologist-patient interactions).

289. Of the doctors who have encountered the patient, the ordering physician would also be the most likely to know what to do with the lab's updated report. This is important because, almost uniformly, the available literature points to the fact that physicians are typically not well equipped to manage, interpret, and advise patients as to genetic test results. *See* Ellen Wright Clayton, Susanne Haga, Patricia Kuszler, Emily Bane, Krysta Shutske & Wylie Burke, *Managing Incidental Genomic Findings: Legal Obligations of Clinicians*, 15 GENETICS MED. 624, 626 (2013); Stevens et al., *supra* note 19; Matthew Joseph Westbrook, Comment, *Transforming the Physician's Standard of Care in the Context of Whole Genome Sequencing Technologies: Finding Guidance in Best Practice Standards*, 9 ST. LOUIS U. J. HEALTH L. & POL'Y 111, 148 (2015).

due to the lack of genetic counseling, research shows that patients often misunderstand their genetic test results.[290] If they have difficulty processing their original results, grasping that those results may change over time—despite their genetic information remaining the same—may only add to the confusion. Patients are usually not familiar with the scientific literature and, as a result, will not know when it is appropriate to ask a lab to reinterpret their previous results.

Furthermore, making patients primarily responsible for reinterpretation could potentially deepen health disparities.[291] Fully appreciating the meaning of a reclassification may be challenging even for educated people whose first language is English.[292] Consider that seventy-seven million people—about a third of all U.S. adults—have "difficulty with common health tasks, [like] following directions on a prescription drug label."[293] Certain populations tend to have lower health literacy.[294] Not surprisingly then, the ACMG has cautioned against putting too much responsibility on patients or their families for a variety of reasons, including lack of medical knowledge, cultural or language barriers, difficulty reading, or unfamiliarity with the health care system.[295]

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290. More precisely, physicians may be misunderstanding genetic test results or, in the alternative, the way physicians are communicating these results to the patients results in confusion. *See, e.g.*, Dennis Thompson, *Misunderstood Gene Tests May Lead to Unnecessary Mastectomies*, HEALTHDAY (Apr. 12, 2017), https://consumer.healthday.com/cancer-information-5/breast-cancer-news-94/misunderstood-gene-tests-may-lead-to-unnecessary-mastectomies-721596.html [https://perma.cc/UR9A-K9P2] (discussing Stephen J. Katz et al., *Gaps in Integrating Genetic Testing into Management of Breast Cancer*, 35 J. CLINICAL ONCOLOGY 160 (2017) (addressing the challenges in communicating genetic results to patients)).

291. *See Making Health Care Work Better for Vulnerable Patients*, COMMONWEALTH FUND (Apr. 27, 2018), https://www.commonwealthfund.org/blog/2018/making-health-care-work-better-vulnerable-patients [https://perma.cc/B7Q5-Y3VH] ("We also know health care is often inconvenient or inaccessible to low-income patients, who may lack paid time off work or transportation to visit the doctor, leading many to rely on the emergency department.").

292. *America's Health Literacy: Why We Need Accessible Health Information*, U.S. DEP'T OF HEALTH & HUM. SERVS.: OFFICE OF DISEASE PREVENTION & HEALTH PROMOTION, https://web.archive.org/web/20190730172815/health.gov/communication/literacy/issuebrief/ [https://perma.cc/S96P-ZRNG].

293. *Id.*

294. *Id.*

295. *See* David et al., *supra* note 65, at 770.

In addition to these structural challenges, recall that reclassification may disproportionately impact people with non-European descent.[296] People of color—who are more likely to have non-European ancestry—already experience significant health disparities.[297] The populations who are more likely to benefit from variant reinterpretation are also less likely to have access to the very health care that would allow them to take clinical action. Charging patients with seeking their own reinterpretation could just pile on to those existing burdens.

Patients are, however, in the best position to know how their doctors can get in touch with them. The ACMG recommends that providers who order genetic tests advise patients prior to testing that their results could change and that it is, therefore, important to maintain current contact information.[298] Thus, as courts decide the contours of the legal duties associated with variant reclassification, it may be appropriate to hold patients accountable for providing up-to-date contact information. However, as we describe in the following Part, that expectation should be clearly communicated to patients when they undergo genetic testing. Expecting patients to keep their contact information up to date may sometimes be unreasonable.

* * *

Recall from Part I that no legal duty currently requires labs or physicians to ensure that patients have access to updated test results following a variant reclassification.[299] Regardless, medical ethicists and professional organizations have spoken out in favor of ethical responsibilities to reinterpret and to recontact.[300] Additionally, both tort theory and doctrine offer support for imposing certain genetic duties.[301] However, clinical laboratories may not have access to patients' current contact information, and many ordering

296. Slavin et al., *supra* note 58, at 1059-60.

297. *See* Wayne J. Riley, *Health Disparities: Gaps in Access, Quality and Affordability of Medical Care*, 123 TRANSACTIONS AM. CLINICAL & CLIMATOLOGICAL ASS'N 167, 168-70 (2012).

298. David et al., *supra* note 65, at 770-71.

299. *See supra* Part I.B.1.

300. *See supra* Part II.A.1.

301. *See supra* Parts II.A.2-3.

physicians are not geneticists and will not be aware when a reclassification occurs.[302] We thereby conclude that courts should place the duty to reinterpret on the laboratory that ran the test and the duty to recontact on the physician who ordered it. This allocation imposes the legal burden on the parties best situated to bear the costs for each of the respective duties.

III. BREACHING GENETIC DUTIES

In the preceding Part, we argue in favor of imposing certain genetic duties and consider how to efficiently allocate those responsibilities. In this Part, we take a deeper dive using case studies to consider when defendants might breach the legal duties to reinterpret and to recontact.

As a preliminary matter, we note that what might be reasonable conduct related to current and future patients may differ from what constitutes reasonable conduct for past patients. Going forward, we suggest proactive measures like informing patients that reclassifications are possible and charging them with maintaining up-to-date contact information to facilitate recontacting. We also propose that technology such as email could help ease the potential burdens associated with updating patients after a variant reclassification.

After discussing what can be done going forward, we then turn to past patients. We consider what would constitute reasonable conduct for five potential categories of defendants: (1) boutique labs, (2) high-volume labs, (3) clinical geneticists, (4) oncologists, and (5) family doctors. For our plaintiff, we return to the hypothetical from the Introduction: a thirty-seven-year-old woman with a family medical history of cancer, who was not informed that her variant gained clinical significance.[303]

Pursuant to the Learned Hand test, courts must consider the nature and the likelihood of the plaintiff's injury.[304] Thus, the clinical significance of the variant reclassification might be important.[305] Not all reclassifications communicate clinically actionable

302. *See* David et al., *supra* note 65, at 770-71.
303. *See supra* Introduction.
304. *See* United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947).
305. Deignan et al., *supra* note 57, at 1269 (suggesting labs should prioritize reclassi-

risks. For example, a lab could reclassify a VUS of the *BRCA1* gene to likely benign. But when a reclassification is clinically actionable—particularly if the reclassification is to likely pathogenic or pathogenic—the potential benefit of updating the plaintiff is high. Had the patient in the hypothetical known that the lab reclassified her VUS as pathogenic, she could have taken steps that might have saved her life. For purposes of our analysis, the probability and severity of her resulting injury remain constant for all types of defendants.

For simplicity's sake, we assume that the potential lawsuits are timely and that no other procedural bars arise. We also focus exclusively on breach and do not consider issues related to injury or causation, such as proximate cause or foreseeability. We first discuss proposals and considerations for current and future patients. We then consider legal duties that might apply to former patients.

A. Going Forward

As noted in Part I, variant reclassifications are likely to become increasingly commonplace as genetic science continues to advance.[306] In deciding how to address the potential ethical and legal issues associated with variant reclassification, laboratories and physicians should not sit and wait for patients to sue them. Instead, labs and doctors should proactively adopt policies (1) to inform patients at the front end that variant reclassification may occur, and (2) to outline their procedures for ensuring that patients have access to the reinterpreted results. These processes could shift some of the responsibility onto the patients themselves. It is our hope that, as technology improves, the task of sharing reinterpreted results with patients will grow increasingly easier.

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fications with potential clinical implications); *see also* Bombard et al., *supra* note 206, at 586-87 (recommending reclassifying when there is clinical utility). The ESHG recommends that clinicians recontact patients regarding findings with clinical utility. *See* Carrieri et al., *supra* note 11, at 178.

306. *See supra* Part I.A.1.

1. Proactive Measures

Both labs and physicians could adapt existing infrastructures to apply to variant reclassification. For example, most laboratories have terms of service.[307] If something goes wrong, the terms of service will often govern the dispute.[308] Laboratories should, therefore, consider introducing language into their terms of service that discuss variant reclassification. For example, a term could explain that genetic test results may change over time and that the laboratory will inform either the ordering physician or the patient of any such updates by email. Although research shows that many people fail to actually read the terms of service, labs could adopt policies—such as requiring patients to sign a document or click a box—to encourage patients to review the provisions.[309] Likewise, physicians get their patients' consent prior to medical procedures.[310] Disclosing that both variant reclassification may occur and that the doctor may recontact the patient as a result could, therefore, become part of the informed consent process.[311] Thus, laboratories and doctors could use the current mechanisms that define their relationships with patients to outline the potential rights and obligations associated with variant reclassification.

Despite recommending that both labs and physicians take positive action related to variant reclassification, we acknowledge that efficiency may favor putting primary responsibility on the laboratory. First, recall that the nature of medicine is changing.[312] While perhaps not yet the norm, patients have increasing amounts of

307. *See, e.g.*, *Terms & Conditions*, AMBRY GENETICS (Apr. 10, 2018), https://www.ambrygen.com/legal/terms-and-conditions [https://perma.cc/P4D2-WNTP] ("These terms and conditions govern your rights and responsibilities with regard to [the services].").

308. *See id.*

309. *See* Shankar Vedantam, *Do You Read Terms of Service Contracts? Not Many Do, Research Shows*, NPR: HIDDEN BRAIN (Aug. 23, 2016, 5:06 AM), https://www.npr.org/2016/08/23/491024846/do-you-read-terms-of-service-contracts-not-many-do-research-shows [https://perma.cc/VY9R-GKUE].

310. Mark A. Hall, David Orentlicher, Mary Anne Bobinski, Nicholas Bagley & I. Glenn Cohen, *Informed Consent*, *in* HEALTH CARE LAW AND ETHICS 152, 153 (9th ed. 2018).

311. The ACMG recommends that providers inform patients that their results could be updated and advise them to provide up-to-date contact information. David et al., *supra* note 65, at 770-71.

312. *See supra* notes 272-79 and accompanying text.

direct contact with labs.[313] Second, the laboratory is in the best position to know when reinterpretation is appropriate because it both conducted the original test and subsequently reclassified the variant.[314] Finally, having the lab contact the patient directly avoids burdening the ordering physician and streamlines the process, reducing the chance of a communication breakdown.[315] Although some labs may already have patient contact information on file for billing purposes,[316] they are often not the cheapest cost avoiders with respect to reaching patients.[317] Thus, this approach will not work for older cases because the labs will likely not have patients' contact information on hand. It does, however, present a potentially viable option for variant reclassification in the future.

As labs and physicians adopt policies and practices for updating patients following a variant reclassification, patients could themselves bear some of that responsibility. As explained in Part II, individual patients are often the cheapest cost avoiders with respect to how to best contact them.[318] Laboratories and physicians would, therefore, be wise to tell patients that they must keep their contact information current. In fact, the ACMG goes as far to say that physicians should advise the patient or the family that "[i]t is the patient's obligation to provide updated contact information over time" as part of the informed consent process.[319] Of course, expecting patients to regularly update their contact information could be unreasonable under certain circumstances, such as a single visit to a geneticist. While charging patients with providing current contact information could sometimes be too costly, it is likely efficient in many cases. Making patients responsible for maintaining up-to-date contact information could save valuable time and resources, as labs and physicians will expend less effort tracking down elusive patients.

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313. *See supra* notes 272-79 and accompanying text.

314. *See supra* Part I.A.1.

315. *See* David et al., *supra* note 65, at 770-71.

316. *See, e.g.*, *Test Requisition Form*, COLOR GENOMICS (July 2018), https://static.getcolor.com/pdfs/Color_Hereditary_Cancer_Test_Requisition_Form_Self_Pay.pdf [https://perma.cc/5RCG-KFF6] (providing "email address" form).

317. *See supra* Part II.B.1.

318. *See supra* Part II.B.3.

319. David et al., *supra* note 65, at 771.

2. Technological Ease

Technology could reduce the potential burdens of reinterpreting and recontacting.[320] Technology lowers the costs of communication.[321] In the consumer genetics space, companies like AncestryDNA and 23andMe may email users changes to their policies and updates of their results.[322] Recently, AncestryDNA refined how it determines users' genetic ancestry—a reclassification of sorts—and informed its customers electronically.[323] Similarly, the FDA emails consumers regarding recalls, market withdrawals, and safety alerts.[324] Laboratories or physicians could thus share updated results using email or health care apps. In fact, some providers are already using these tools to contact patients.[325] Some studies show that patients may actually prefer to contact their doctors using email and websites.[326]

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320. Providers once considered reinterpretation and recontacting desirable but unfeasible. *See* Jennifer L. Fitzpatrick, Cecil Hahn, Teresa Costa & Marlene J. Huggins, *The Duty to Recontact: Attitudes of Genetic Service Providers*, 64 AM. J. HUM. GENETICS 852, 852 (1999). Advances in technology may be a key factor in changing that. *See* Corrette Ploem, Colin Mitchell, Wim van Harten & Sjef Gevers, *A Duty to Recontact in the Context of Genetics: Futuristic or Realistic?*, 25 EUR. J. HEALTH L. 537, 553 (2018) ("Developments in health information technology ... will reduce the burden of updating previous test results and communicating new information, including to former patients."); Rothstein, *supra* note 150, at 289 ("Electronic health records and technology that enables the simultaneous contacting of all patients with certain medical conditions make such warnings feasible.").

321. *See* Ploem et al., *supra* note 320, at 553.

322. *See, e.g.*, *Privacy Highlights*, 23ANDME (Jan. 1, 2020), https://www.23andme.com/about/privacy/ [https://perma.cc/3Z5Y-5SGH] ("By creating a 23andMe account, you are agreeing that we may send you product and promotional emails or notifications about our Services.").

323. *See* Ancestry Team, *Ancestry Surpasses 15 Million DNA Customers*, ANCESTRYDNA (May 31, 2019), https://blogs.ancestry.com/ancestry/2019/05/31/ancestry-surpasses-15-million-dna-customers/ [https://perma.cc/LNP6-U5Z7].

324. *See Recalls, Market Withdrawals, & Safety Alerts,* FDA (Apr. 29, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts [https://perma.cc/HX5B-KCU9]. Other government agencies provide similar services to notify consumers of product recalls. *Join Agency Recall Subscription Lists,* RECALLS.GOV, https://www.recalls.gov/list.html [https://perma.cc/K23N-BY33].

325. *See* Ken Abrams, Steve Burrill & Natasha Elsner, *What Can Health Systems Do to Encourage Physicians to Embrace Virtual Care?*, DELOITTE: INSIGHTS (July 18, 2008), https://www2.deloitte.com/us/en/insights/industry/health-care/virtual-health-care-health-consumer-and-physician-surveys.html [https://perma.cc/Y7XB-ZZH8].

326. Joy L. Lee, Niteesh K. Choudhry, Albert W. Wu, Olga S. Matlin, Troyen A. Brennan & William H. Shrank, *Patient Use of Email, Facebook, and Physician Websites to*

It is, of course, worth noting that not all patients have ready access to the internet. While most Americans own smartphones,[327] many people still cannot afford high-speed internet, particularly in rural areas.[328] Additionally, the elderly—although less likely to take genetic tests—might also hesitate to use cell phones or other technologies.[329] Thus, certain people may not be reachable by email or other technology.

Even assuming full technological access, many patients may be unable to understand the updated results without the help of a physician or a genetic counselor. Remember that about a third of all U.S. adults have difficulty with common health tasks, like following prescription drug label instructions.[330] Language and reading barriers could further exacerbate this problem. Populations with lower levels of literacy or who do not speak English could, therefore, lose the opportunity to benefit from their updated results. Yet, there are also technological solutions here, such as software to read emails aloud and services like Google Translate.[331] However, people will need access to those technologies to benefit from them.

In sum, laboratories and physicians should begin developing policies related to variant reclassification proactively. Technology may be able to provide the necessary infrastructure for keeping patients informed cheaply and easily. Yet, as labs and doctors adopt

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Communicate with Physicians: A National Online Survey of Retail Pharmacy Users, 31 J. GEN. INTERNAL MED. 45, 45 (2016); *see* Jason Shafrin, *Physician-Patient Email Communication: A Review*, HEALTHCARE ECONOMIST (Aug. 2, 2006), https://www.healthcare-economist.com/2006/08/02/physician-patient-email-communication-a-review/ [https://perma.cc/8A5M-L64W] ("Among individuals with Internet access, 90% want to communicate with their physician over email.").

327. Eighty-one percent of Americans own smartphones. *Mobile Fact Sheet*, PEW RSCH. CTR.: INTERNET TECH. (June 12, 2019), https://www.pewresearch.org/internet/fact-sheet/mobile [https://perma.cc/T3U6-FGV6]; *see also* Leah R. Fowler & Stephanie R. Morain, *Shrödinger's App*, 46 AM. J.L. & MED. 203, 203-04 (2020) (laying out the relevant statistics).

328. *See* ANN L. CUPP CURLEY, POPULATION-BASED NURSING: CONCEPTS AND COMPETENCIES FOR ADVANCED PRACTICE 142 (3d ed. 2020); *Mobile Fact Sheet*, *supra* note 327.

329. CURLEY, *supra* note 328, at 142.

330. AGENCY FOR HEALTHCARE RSCH. & QUALITY: CONSUMER ASSESSMENT OF HEALTHCARE PROVIDERS & SYS. (CAHPS), Doc. No. 911, CAHPS ADULT HOSPITAL SURVEY: ABOUT THE CAHPS HEALTH LITERACY ITEM SET FOR HOSPITALS 2, https://www.ahrq.gov/sites/default/files/wysiwyg/cahps/surveys-guidance/hospital/about/about-the-health-literacy-item-set-for-hospitals-911.pdf [https://perma.cc/82QF-QRK5].

331. *See, e.g.*, *Google Translate*, GOOGLE, https://translate.google.com/ [https://perma.cc/K9ZV-MXTU] (translating text or audio from one language to another in real time).

processes for reinterpreting and recontacting, they should remain aware of the potential access barriers that could arise for certain patients. Moreover, building infrastructures—even with the benefit of technology—takes time and effort. Labs and physicians may try one approach to informing patients, only to necessarily revise it and try something new. Courts should, therefore, be sympathetic to these issues when deciding whether a breach has occurred.

Having established a framework for dealing with genetic duties to current and future patients, we now turn to the duties to reinterpret variants and recontact former patients.

B. Duty to Reinterpret

We argue that, following variant reclassifications, clinical laboratories have a duty to notify the physicians who originally ordered the tests, as well as to provide them with the updated results. Although this analysis may seem relatively straightforward, labs vary tremendously with respect to the volume of tests that they process, the kinds of testing that they offer, and their relationships with the ordering physicians.[332] Thus, whether the lab has breached its duty to reinterpret would be a highly fact-intensive inquiry.

Labs come in all sizes. One lab might handle approximately one thousand tests each year, while another processes one hundred forty thousand.[333] The size of the lab could impact the costs associated with giving patients access to updated results following a variant reclassification because the more tests that a lab handles the greater the number of patients that a reclassification could impact. Furthermore, larger laboratories may process samples and send results across jurisdictions with different legal rules. Thus, a lab may be subject to medical malpractice law in one state and ordinary negligence in a neighboring state.[334] Such inconsistencies may mean, for example, that a lab could violate one state's law in an

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332. *See* Brian J. Linehan, Mohamed M. El-Nageh, Stephen Cordner & Alan Richter, *Ethics in Laboratory Medicine, in* CLINICAL LABORATORY MEDICINE 134, 135 (Kenneth D. McClatchey ed., 2d ed. 2002) [hereinafter *Ethics in Laboratory Medicine*]; *supra* Part I.A.1.

333. Telephone Interview with Wendy K. Chung, Kennedy Fam. Professor of Pediatrics in Med., Med. Dir. of the Columbia Genetic Counseling Graduate Program, Columbia Univ. Vagelos Coll. of Physicians and Surgeons (Aug. 26, 2019).

334. *See, e.g.*, *supra* Part I.B.1.

effort to comply with another's. Of course, larger labs may have access to greater resources, which could help them offset some of those costs.

Recall too that labs offer different kinds of services—and combinations of services—including single-gene tests, panels of single-gene tests, whole exome sequencing, and whole genome sequencing.[335] The amount of patient data that a laboratory handles will also affect its potential legal duties following reclassification. In particular, labs that do full exome and genome sequencing deal with many more genes than labs that focus on single-gene tests.[336] More genes mean more opportunities for reclassification and, by consequence, reinterpretation. Thus, those labs could face greater legal responsibilities.

Lastly, laboratories have varying levels of contact with the physicians who order the genetic tests.[337] In some circumstances—like certain academic settings—a given lab might work regularly with a handful of providers. By contrast, large reference laboratories may have more arms-length dealings with the ordering physicians.[338] Bearing the legal burdens associated with reclassification may be easier for labs that have ongoing relationships with repeat players.

Courts should take these variations into account when hearing cases related to variant reclassification. To illustrate how some of these issues may play out, we consider two case studies: (1) a boutique lab that offers cancer-focused testing and handles a relatively small number of patients from the same set of ordering physicians, and (2) a lab that offers a wide variety of tests at a very high volume with no ongoing relationship with the providers who order the tests.[339] Of course, not all labs will fall neatly into these

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335. *See generally* Tina M. Hambuch, John Mayfield, Shankar Ajay, Michelle Hogue, Carri-Lyn Mead & Erica Ramos, *Clinical Genome Sequencing, in* CLINICAL GENOMICS, *supra* note 41, at 21, 21-22, 24-25 (discussing different sequencing techniques used in a clinical laboratory).

336. *See supra* notes 37-47 and accompanying text.

337. *See Ethics in Laboratory Medicine*, *supra* note 332, at 134-35.

338. *Cf.* Julie R. Taylor, Pamela J. Thompson, Jonathan R. Genzen, John Hickner & Marisa B. Marquez, *Opportunities to Enhance Laboratory Professionals' Role on the Diagnostic Team*, 48 LAB MED. 97, 100 (2017) (analyzing how the different provider-laboratory relationships affect communication between the two).

339. The scenarios were developed in conversation with Wendy K. Chung, Kennedy Fam. Professor of Pediatrics in Med., Med. Dir. of the Columbia Genetic Counseling Graduate

categories. Some boutique labs may handle a high volume of patients, and some laboratories that provide a variety of tests may regularly service the same physicians' patients. Thus, these case studies are simply examples and do not represent all labs.

Practically speaking, the first question the court must decide is whether the laboratory is a health care provider for purposes of medical malpractice. However, as noted in Part I, the primary differences between medical malpractice and ordinary negligence would likely be procedural, such as the special statutes of limitations and statutes of repose that govern medical malpractice claims.[340]

1. Boutique Lab

Although courts will likely apply some variation of a reasonableness standard either way, we can pause for a moment to consider whether the boutique lab is a health care provider for medical malpractice purposes. The fact that the lab offers medical services to diagnose and treat patients could be sufficient in most states.[341] When the ordering physician is closely affiliated with the lab—say when she is an employee of the same institution, uses the same lab routinely to order testing, or has some supervisory authority over the lab—courts have been more likely to find that the lab is subject to malpractice laws.[342] Therefore, our boutique lab would probably be the patient's fiduciary.

Program, Columbia Univ. Vagelos Coll. of Physicians and Surgeons.

340. *See supra* notes 121-24 and accompanying text.

341. Determining that a lab is a health care provider and therefore subject to malpractice laws is, to all intents and purposes, a determination that a professional relationship exists, and that questions involving medical judgment are involved. *See* Foulkes et al., *supra* note 20, at 165. The facts of the *Williams* case illustrate this well, as the patient was treated with medication that exacerbated his condition because a lab reported a certain genetic variant to his doctor as a VUS, rather than as pathogenic. *See* Williams v. Quest Diagnostics, Inc., 353 F. Supp. 3d 432, 436-37 (D.S.C. 2018). Had the report been different, the doctor would have selected a different course of treatment. *See id.*

342. *See, e.g.*, Annunziata v. Quest Diagnostics, Inc., 8 N.Y.S.3d 168, 169 (N.Y. App. Div. 2015) (finding "laboratory services ... performed at the direction of a physician are an integral part of the process of rendering medical treatment"); Baskette v. Atlanta Ctr. for Reprod. Med., LLC, 648 S.E.2d 100, 101 (Ga. Ct. App. 2007) (finding the laboratory's tasks were "tasks ... under the supervision of physicians").

With regard to the applicable standard of care, the lack of uniformity in lab practices surrounding both reclassification and reinterpretation makes it extremely difficult—if not impossible—to apply a professional custom standard.[343] Yet as more laboratories adopt the recommendations of the ethicists and professional organizations described in Part II, customs and norms may develop. More likely than not, reasonableness will carry the day in many jurisdictions.[344]

Courts will probably apply a reasonableness standard regardless of whether the cause of action is for medical malpractice, ordinary negligence, or the breach of a professional duty to reinterpret.[345] According to the Learned Hand test, whether the laboratory breached would depend in part on the costs of reinterpretation.[346] Our facts tell us the boutique lab has limited resources and handles a small number of patients, often from the same set of providers. Courts might find that the relatively low number of patients—plus the lab's relationship with the ordering physicians—make the benefits outweigh the costs. Moreover, because it specializes in cancer-related tests, the staff of the boutique lab should have been well aware of the potential significance of the reclassification. The court may, therefore, find it was unreasonable to fail to reinterpret our hypothetical patient's results.

2. High-Volume Lab

The case might come out somewhat differently for the high-volume lab. Again, the court will first decide whether the lab is a health care provider for purposes of medical malpractice. Unlike the boutique lab, the high-volume lab does not have a close relationship

343. *See* Caitlin Chisholm, Hussein Daoud, Mahdi Ghani, Gabrielle Mettler, Jean McGowan-Jordan, Liz Sinclair-Bourque, Amanda Smith & Olga Jarinova, *Reinterpretation of Sequence Variants: One Diagnostic Laboratory's Experience, and the Need for Standard Guidelines*, 20 GENETICS MED. 365, 366 (2018); *see also* Collins v. Itoh, 503 P.2d 36, 41 (Mont. 1972) ("The custom and practice of one particular [health care provider], without knowledge of the general custom and practice among the profession, cannot establish a reasonable basis to infer that defendant departed from that practice.").

344. *See supra* notes 161-63 and accompanying text.

345. *See supra* Part I.B.1.

346. *See* Deignan et al., *supra* note 57, at 1268-69; *supra* notes 164-65 and accompanying text.

with the ordering physicians. The ordering physicians will, however, likely use the results in the course of medical treatment. That fact alone may be enough for courts in some jurisdictions to find that the high-volume lab is a health care provider.[347] Again, reasonableness will likely be the standard that the court applies.

As noted above, what constitutes a breach will depend to some extent on the burden that reinterpretation poses. Here, the costs may outweigh the benefits. The high-volume lab handles a larger number of patients, as well as a broad variety of providers in different practice areas. The providers are, thus, less likely to be repeat players in a meaningful way. While the same physicians may use the lab over and over, the lab is handling so many tests that a more intimate working relationship will not develop. Moreover, the high-volume lab is, by nature, less specialized than the boutique lab. Handling a wide variety of tests might make it harder for the high-volume lab to know if a reclassification is clinically actionable for a particular patient. Given the large number of providers and the diversity of tests, a court might hold that it was reasonable for the high-volume lab to simply email ordering physicians updated results without any additional information or follow-up.

Moreover, the amount of data and kinds of testing handled by the high-volume lab raise additional concerns. Recall that some labs run virtual panels, as described in Part I. They generate data on hundreds—even thousands—of genes that they will not even analyze, let alone report back to the patient.[348] Say, for example, that the high-volume laboratory offers a wide range of services that include tests related to both the *BRCA1* and *SCN1A* genes. The doctor ordered a cancer panel for our hypothetical patient, which includes the *BRCA1*—but not the *SCN1A*—gene.[349] Suppose that the high-volume lab has rapid sequencing technology. For ease of operation, it sequences all of its patients' genetic data. If the lab reclassifies a *BRCA1* VUS, it should inform the ordering physician, as outlined above. However, if the lab reclassifies a *SCN1A* VUS, it may have no obligation to do so. It would not be reasonable for the

347. *See generally* Foulkes et al., *supra* note 20, at 160-65 (detailing the factors courts look to in determining when labs might be classified as health care providers).

348. *See supra* notes 41-44 and accompanying text.

349. *See supra* Part 1.A.2 (discussing *BRCA1* and *SCNIA*).

patient to expect updated information about a gene unrelated to the testing that her physician ordered, regardless of whether the lab had sequenced her data for that gene.

Although beyond the scope of our hypothetical patient's case, full sequencing, whether of the entire genome or just the exome, raises somewhat different concerns. In those circumstances, patients tend to be on diagnostic odysseys.[350] Physicians try to provide answers by looking at large amounts of genetic data.[351] Thus, the classification—or reclassification for that matter—of any single variant is unlikely to matter. Unless, of course, the reclassified variant turns out to be the needle in the proverbial haystack. A lab that reclassifies a *BRCA1* variant may need to provide a physician who ordered a cancer panel with updated results. However, the lab would have no obligation to inform that physician of the reclassification of a *SCN1A* variant. Yet, in the case of full genome sequencing, the lab may need to inform physicians whenever it reclassifies *any* variant. While labs may have a duty to reinterpret results following a variant reclassification, what constitutes a breach of that duty will depend on a variety of factors, including the type of lab and the test that was originally ordered.

C. Duty to Recontact

While ordering physicians may not know when a reclassification occurs, they are best situated when it comes to recontacting patients to share updated results. Hence, after a lab sends the reinterpreted results, the physician may then have an obligation to share that updated information with the patient.[352] Yet whether recontacting

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350. "The 'diagnostic odyssey' is what we call that meandering, lengthy, and frustrating quest for a diagnosis. Genetic counselors, medical geneticists, and patients ... are achingly familiar with it. The allusion to Homer's *Odyssey* is apt." BARBARA B. BIESECKER, KATHRYN F. PETERS & ROBERT RESTA, ADVANCED GENETIC COUNSELING: THEORY AND PRACTICE 197 (2019).

351. *See id.*

352. Authors writing about the Canadian legal system came to a similar conclusion. Adrian Thorogood, Alexander Bernier, Ma'n Zawati & Bartha Maria Knoppers, *A Legal Duty of Genetic Recontact in Canada*, 40 HEALTH L. CAN. 58 (2019) (manuscript at 24) (the duty to recontact is only appropriate when "updated genetic information from which clear clinical significance can be inferred is readily made available to physicians").

is appropriate depends in part on the doctor's judgment regarding the clinical value of sharing those new results, in light of the patient's entire medical record.[353] Thus, the individual physician's understanding of the reclassification may affect whether she has breached her duty to update the patient.

Courts will not demand that doctors search to the ends of the earth for their patients. They usually require only a reasonable effort.[354] Reasonable efforts to contact patients may include phone calls, follow-up care, certified letters, and even reaching out to family.[355] Physicians should maintain evidence that they made reasonable efforts.[356]

The status of the treatment relationship could affect findings of breach. When actively seeing a patient, a physician should be able to recontact her following a reclassification without too much effort.[357] However, as explained in Part II, sometimes a physician will see a patient for only a single visit. Traditionally, when there is no active treatment relationship, there are no accompanying legal duties.[358] That said, even absent a clear treatment relationship, the ACMG recommends that physicians should still make a reasonable effort to recontact the patient.[359] It is, therefore, possible that a court may find that the reinterpretation itself could trigger the physician's duty to recontact the patient.

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353. *See* Deignan et al., *supra* note 57, at 1269; Bombard et al., *supra* note 206, at 584; *see also* Est. of Abuaf v. Saint Barnabas Med. Ctr., No. A-3468-14T4, 2017 WL 371473, at *2 (N.J. Super. Ct. App. Div. Jan. 25, 2017) (""The law recognizes that medicine is not an exact science,' and that 'good [medical] treatment will not necessarily prevent a poor result.'" (quoting Schueler v. Strelinger, 204 A.2d 577, 584 (N.J. 1964)) (alteration in original)); Nestorowich v. Ricotta, 767 N.E.2d 125, 131 (N.Y. 2002) (Smith, J., dissenting) ("As the majority states, the error in judgment charge should be given only where there are two or more possible courses of action and a doctor chooses one.").

354. Courts will at least expect physicians to try. *See, e.g.*, Cox v. Paul, 828 N.E.2d 907, 913 (Ind. 2005) (holding that a cursory search of patient records and no further effort was not enough).

355. *See* Tanuz v. Carlberg, 921 P.2d 309, 314 (N.M. Ct. App. 1996). In *Cox v. Paul*, the Indiana Supreme Court held that a health care provider who has notice of possible dangerous side effects of treatment might be held liable for failure to make reasonable efforts to advise or warn patients of such dangers. 828 N.E.2d at 913-14.

356. *See* Chi Yun Ho v. Frye, 880 N.E.2d 1192, 1201 (Ind. 2008) (requiring evidence, not speculation, to establish reasonable efforts).

357. David et al., *supra* note 65, at 770.

358. *See supra* notes 126-28 and accompanying text.

359. David et al., *supra* note 65, at 770-71.

Again, we employ case studies to illustrate how courts might calculate breach. We return to our hypothetical *BRCA1* patient and consider three different ordering physicians: (1) a clinical geneticist, (2) an oncologist,[360] and (3) a family doctor. Because the doctors are health care providers, we apply medical malpractice law.

1. Clinical Geneticist

Imagine that, in the course of our patient's annual checkup in 2010, her family doctor notices the high rates of breast and ovarian cancers in the patient's family medical history. The family doctor refers her to a clinical geneticist who works in a large medical complex. During the patient's appointment, the geneticist decides to order a *BRCA1* test, which comes back with a VUS. The patient and the geneticist meet one final time to go over the results. The geneticist tells the patient that her test results do not indicate hereditary breast/ovarian cancer syndrome. Both parties anticipate no further contact. The treatment relationship therefore ends in 2010. In 2015, the geneticist receives a call from the laboratory informing her that the lab has reclassified the patient's VUS as pathogenic.[361] While courts hearing traditional medical malpractice claims are unlikely to hold physicians liable five years after the treatment relationship ends,[362] the call from the laboratory could be sufficient to trigger a duty to recontact.[363]

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360. Not all specialists are comparably situated. An oncologist could have a better working knowledge of genetics than, for example, a cardiologist who orders a test to diagnose hypertrophic cardiomyopathy. *See generally* Michael J. Hall & Olufunmilayo I. Olopade, *Disparities in Genetic Testing: Thinking Outside the* BRCA *Box*, 24 J. CLINICAL ONCOLOGY 2197 (2006) (discussing the prevalence of genetics in cancer care).

361. *See supra* note 18 and accompanying text.

362. Mark Rothstein and Gil Siegal have proposed using the Medicare billing rule as a guideline, which "deems a patient who has been seen within the past three years as 'established,' whereas a patient who has not been seen within the past three years would be considered 'new' if he or she made a return visit to that physician." Mark A. Rothstein & Gil Siegal, *Health Information Technology and Physicians' Duty to Notify Patients of New Medical Developments*, 12 HOUS. J. HEALTH L. & POL'Y 93, 131 (2012).

363. *See* Stuart v. Loomis, 992 F. Supp. 2d 585, 595 (M.D.N.C.), *aff'd sub nom.* Stuart v. Camnitz, 774 F.3d 238 (4th Cir. 2014) ("States have also long required health care providers to give patients information they need to make informed decisions about medical treatment."); *cf.* Canterbury v. Spence, 464 F.2d 772, 781 (D.C. Cir. 1972) ("[T]he physician is under an obligation to communicate specific information to the patient when the exigencies of reasonable care call for it. Due care may require a physician perceiving symptoms of bodily

The Learned Hand analysis may require courts to consider the relative resources of the defendant in deciding whether there has been a breach.[364] In fact, one primary criticism of imposing a legal duty to recontact patients has been that some physicians lack the resources to meet this potential legal burden.[365] Because the geneticist works in a large, resource-rich setting, a court might expect her to make more of an effort to recontact the patient than the rural family doctor described below.[366] Yet as noted in Part I, it could be more challenging for a clinical geneticist—who may encounter thousands of patients but for only a small number of visits each—to track the affected patients down following a reclassification.[367] Thus, in certain cases it may be too costly to find a particular patient. That said, as physicians gain greater access to computing and communications technologies, those innovations can ease the potential financial and administrative burdens, making recontacting more reasonable.[368] And we might expect a doctor in a state-of-the-art medical center to have access to these technological tools sooner.

2. Oncologist

Now suppose that instead of referring the patient to a geneticist, the patient's family doctor finds a lump in the patient's breast. Following a biopsy that detects a premalignant lesion, the doctor refers the patient to an oncologist. The oncologist diagnoses the patient with stage 0 breast cancer and suggests a lumpectomy. The oncologist also orders the *BRCA1* test based on the patient's family medical history.[369] Following the procedure, the oncologist declares

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abnormality to alert the patient to the condition.").

364. *See supra* Part I.B.2.

365. *See* Martin Letendre & Béatrice Godard, *Expanding the Physician's Duty of Care: A Duty to Recontact?*, 23 MED. & L. 531, 537 (2004); Thomas L. Hafemeister & Selina Spinos, *Lean on Me: A Physician's Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient*, 86 WASH. U. L. REV. 1167, 1178 (2009).

366. *See infra* Part III.C.3.

367. *See supra* Part I.B.2.

368. *See* Rothstein & Siegal, *supra* note 362, at 103 ("The development and continuous progress of the computing and communication sciences and new applications provide a wide range of relevant tools to achieve this end.").

369. *See supra* note 1 and accompanying text.

the patient cancer-free and tells her that—given her genetic test results—she faces only a very low risk that the cancer will recur. Two years later, the laboratory contacts the oncologist to inform her that the lab has reclassified the patient's VUS as pathogenic.[370]

Although it is unlikely that the doctor saw the patient very much since declaring her cancer-free, the relationship between a cancer patient and her oncologist often continues.[371] Courts have concluded that doctors with less frequent contact with their patients owe them fiduciary duties.[372] Moreover, as noted above, new clinically actionable information could reinvigorate a dormant treatment relationship.

Of course, determining that the oncologist owed her patient a duty is not enough. Courts must determine whether she breached that duty.[373] Returning to the Learned Hand analysis, the benefits to the patient might outweigh the potential costs of recontacting.[374] To be sure, oncologists are not necessarily experts in genetics.[375] If the oncologist fails to appreciate the clinical value of the reclassification, a court may not find that she breached her duty to recontact the patient.[376] However, oncologists regularly use genetic tests to inform their treatment decisions, especially when it comes to *BRCA1*.[377] Moreover, unlike the geneticist, the oncologist's obligations to the patient include follow-up care.[378] Thus, the court in our

370. *See supra* note 18 and accompanying text.

371. *See Follow-Up Medical Care*, NAT'L CANCER INST., https://www.cancer.gov/about-cancer/coping/survivorship/follow-up-care [https://perma.cc/U9U9-S3VL] ("All cancer survivors should have follow-up care.").

372. *See* Cox v. Paul, 828 N.E.2d 907, 913-14 (Ind. 2005) (concluding that an oral surgeon owed his patient a duty to make reasonable efforts to contact the patient).

373. *See supra* Part I.B.2.

374. *See supra* note 164 and accompanying text.

375. *See* Richard L. Haspel & Jeffrey E. Saffitz, *Genomic Oncology Education: An Urgent Need, A New Approach*, 20 CANCER J. 91, 93-94 (2014).

376. In *Gardner v. McDonald*, an oncologist did not breach his duty by failing to communicate the results of bone scans and a radiologist's recommendation that there be a follow-up because the oncologist did not view the scans as conclusive proof of metastatic cancer. 660 So. 2d 107, 109, 111-12 (La. Ct. App. 1995).

377. *See* Hall & Olopade, *supra* note 360, at 2197.

378. In this context, a patient may expect follow-up care as part of treatment. However, principles of medical malpractice govern the analysis above. One can also conceptualize the failure to update as a breach of informed consent principles. *See* Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir. 1972) (discussing the doctrine of informed consent and the physician's duty to disclose). In that case, the patient's expectations become important, as opposed to the

hypothetical case could find that, as compared to the geneticist, the oncologist must make more of an effort to recontact the patient based on the nature and expectations of the treatment relationship.

3. Family Doctor

For the last hypothetical case study, imagine that the patient's family doctor orders the test herself after reviewing the patient's family medical history. Suppose that the physician has a solo practice in a rural area and treats the majority of the community members there. The doctor sees the patient for routine checkups, as well as for minor illnesses and injuries. When the laboratory calls regarding the reclassification, the patient is already planning to come in for her annual physical.

Here, the question of a treatment relationship is relatively straightforward. Keeping patients informed of their medical risks is part of a family doctor's job. As with the preceding case studies, courts will likely focus on the question of reasonableness.[379] Among our three doctors, the family doctor is least likely to understand the clinical relevance of the variant reclassification. Thus, a court might hold her to a lower standard than the geneticist or the oncologist, who are more likely to appreciate the importance of the update. At a minimum, the court would expect the hypothetical patient's doctor to review her records in light of the variant reclassification.[380]

Resources might be particularly relevant to the reasonableness analysis in this case. What is reasonable for a rural family doctor will be different from what is reasonable for a specialist working in a large medical center, who has both ample resources and a narrower patient pool.[381] Courts may not want to overwhelm providers who are already working with limited resources. Thus, courts may require less for the rural family doctor to fulfill her obligations to the patient. That said, the nature of the family doctor's practice may

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reasonableness of the doctor's actions. *See* Rothstein & Siegal, *supra* note 362, at 123 (finding that some jurisdictions use the reasonable patient standard in the informed consent context).

379. *See supra* Part I.B.1.

380. *See supra* Part II.B.2.

381. *See supra* Part I.B.2.

make it easier for her to get in touch with the patient than for either the geneticist or oncologist.

* * *

Failing to inform patients when labs reclassify a VUS could deny them access to clinically actionable information. However, doctors may not know when reclassification occurs, and labs may lack direct access to patients.[382] We therefore propose that courts place the duty to reinterpret on the lab and the duty to recontact on the ordering physician. While not a perfect solution, we believe that allocating the legal responsibilities in this way plays to the strengths of both kinds of potential defendants. However, the facts of the individual case will inevitably affect whether a given defendant has breached those duties.[383] Thus, as in all kinds of tort cases, what is reasonable for one class of defendants may not be reasonable for other kinds of defendants.

CONCLUSION

Fully realizing the potential for genetic medicine requires giving patients access to up-to-date risk information. As we develop better knowledge of the genome and faster techniques for analysis, the need for genetic duties will only increase. In this Article, we argue that reclassifying a VUS should trigger legal duties on the part of the clinical laboratory and the ordering physician and propose a framework for liability.[384] Thankfully, advances in science and technology will also address many of the practical challenges to updating patients by making the processes of reclassification, reinterpretation, and recontacting more streamlined. Yet in the meantime, laboratories and doctors should begin developing policies to address these issues.

Importantly, our proposal is by no means a guarantee of liability for labs and doctors. As discussed in Part III, deciding if a breach occurred can be very fact intensive. For example, for the boutique

382. *See supra* note 285 and accompanying text.
383. *See supra* Part I.B.2.
384. *See supra* Parts II.B, III.

lab—which does targeted testing for a small group of providers—the duty to reinterpret might require the lab to share updated results with each affected ordering physician and to ensure that the provider actually receives that information in an understandable form.[385] By contrast, the high-volume lab might only need to send a single email.[386] Thus, what might constitute a breach of the duty to reinterpret for the boutique lab might not be a breach for the high-volume lab. Similar questions arise in the context of the physicians' duty to recontact. How many times must the doctor reach out to the patient to share the updated results? If the patient has died, should the physician attempt to locate her family members? And what may constitute a reasonable effort to recontact on the part of the rural family doctor may well be a breach for the clinical geneticist, or vice versa.[387] Further, while outside the scope of this Article, the plaintiff must also establish that the breach caused a legally cognizable injury.[388]

Establishing genetic duties is therefore only the beginning. Courts dealing with torts cases related to variant reclassification will undoubtedly have to grapple with these and many other issues. Although important legal questions certainly remain, creating clearly recognized genetic duties—and placing them on the parties best situated to bear those responsibilities—is a vital first step to ensuring access to the most accurate genetic information currently available.

385. *See supra* Part III.B.1.
386. *See supra* Part III.B.2.
387. *See supra* Part III.C.
388. *See supra* note 111 and accompanying text.