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Genetic Villains

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GENETIC VILLAINS

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When a little boy's doctors relied on his genetic test results to guide their choice of treatment, they opted for medicines that eventually killed him. The lab that generated the genetic test results knew, at the time of the report, that these results might have meant something other than what was communicated to the doctors. Had his doctors known what the lab knew, their course of treatment would have certainly changed. Whether we see the lab as this narrative's villain depends on our perspective. And though, of course, it is tempting to name a villain under these circumstances, doing so leaves the problem unsolved. This Article proposes that the best way to prevent outcomes like this in the future is not by punishing the lab's conduct but by properly incentivizing it to perform for the public good. Class action theory and economics help us think of clinical genetic laboratories as DNA aggregators, free to benefit from their work. And, with this framework in mind, incentivizing labs to reorganize as benefit corporations and adopt contracts and practices that protect their business will lead to the implementation of more effective reclassification and recontacting procedures.

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I. INTRODUCTION

Amy Williams gave birth to a healthy baby boy named Christian.[1] For the first few months of his life, Amy's infant son grew healthy and strong.[2] But Christian didn't live long.[3]

Beginning when he was four months old, Christian started having seizures.[4] At first, these were mild.[5] Then, the seizures worsened, and the treatments his doctors prescribed repeatedly failed.[6] His doctors suggested that Christian have genetic testing done to gather more information and figure out how to better treat Christian's now unmanageable condition.[7] With the prospect of a better outcome, Amy did what most parents in a similar situation would do: she had Christian tested.[8] Now, she is convinced it was the laboratory's test-running that killed her son.[9] And for good reason.

The lab that ran Christian's first tests reported nothing useful.[10] To make things simple, the lab said Christian's genes included a variant we'll call *X*.[11] The lab not only told Christian's doctors that he had variant *X* but also told

1. *See* Williams v. Quest Diagnostics, Inc., 353 F. Supp. 3d 432, 436 (D.S.C. 2018); *see also* Turna Ray, *In* Williams v Quest*, State Supreme Court Leaves Room for Plaintiff to Argue Ordinary Negligence*, GENOMEWEB (July 3, 2018), https://www.genomeweb.com/molecular-diagnostics/williams-v-quest-state-supreme-court-leaves-room-plaintiff-argue-ordinary#.YOtI2C9h3jA [https://perma.cc/R9QL-BCGE].

2. Amended Complaint at 5, Williams v. Quest Diagnostics, Inc., No. 3:16-CV-00972-MBS (D.S.C. 2016), ECF No. 24 [hereinafter Williams Complaint].

3. *See Williams*, 353 F. Supp. 3d at 436–37.

4. *Id.* at 436.

5. *See* Williams Complaint, *supra* note 2, at 5.

6. *See id.*; *see also Williams*, 353 F. Supp. 3d at 437, 442.

7. *Williams*, 353 F. Supp. 3d at 436.

8. *See id.*

9. In *Williams v. Quest Diagnostics*, *Inc.*, Amy Williams sued Athena Diagnostics on behalf of her deceased son for failing to correctly report the meaning of a genetic variant. *Id.* at 436–37.

10. *See id.*

11. For the curious reader, the genetic variant is *Sodium Voltage-Gated Channel Alpha Subunit 1* (SCNA1), a variant of a protein-coding gene associated with different types of epilepsy in humans. Rashmi Parihar & Subramaniam Ganesh, *The SCN1A Gene Variants and Epileptic Encephalopathies*, 58 J. HUM. GENETICS 573, 573 (2013).

them that variant *X* is a variant of unknown significance.[12] So Christian's treatment didn't change; the doctors kept prescribing the same medications.[13] What neither the doctors nor Amy Williams knew was that the lab—two years before they reported on Christian's results—had some information that *X* was associated with Dravet Syndrome.[14] In fact, the lab's chief compliance director, who signed off on Christian's test results, was an author of a publication linking *X* to Dravet Syndrome.[15] And treating patients with Dravet Syndrome using the medications, such as those prescribed to Christian, kills them.[16] Had his doctors known that Dravet Syndrome was likely as Christian's underlying condition, their course of treatment would have certainly changed.[17]

At this point, it's easy to see the lab as the villain. But, as with most things, it gets more complicated. First, we have to recognize that, even though we don't think of our DNA as something that changes,[18] the meaning of our genetic tests constantly does.[19] Because our understanding of the meaning of genetic test results changes as new data accumulates, the same genetic profile that once indicated to a doctor that, for example, breast cancer was certain to develop, can later be indicative of no risk at all.[20] Sometimes, the meaning of someone's results changes after that person has paid to have a prophylactic

12. *Williams*, 353 F. Supp. 3d at 436.

13. *See id.* at 442.

14. *See* Williams Complaint, *supra* note 2, at 10.

15. *Id.* at 10. Dravet Syndrome is a rare form of drug-resistant epilepsy. Charuta Joshi & Elaine Wirrell, *Dravet Syndrome*, EPILEPSY FOUND. (Aug. 2020), https://www.epilepsy.com/learn/types-epilepsy-syndromes/dravet-syndrome [https://perma.cc/P3T3-9LRL].

16. *See* Joshi & Wirrell, *supra* note 15.

17. *See id*.

18. Although, make no mistake, in a very technical sense, our DNA does change. *See* Adrian Bird, *Perceptions of Epigenetics*, 447 NATURE 396, 398 (2007). DNA stands for deoxyribonucleic acid. Epigenetic changes, or "changes in gene function that cannot be explained by changes in DNA sequence," are sometimes heritable. *Id.* at 396. Random mutations in our DNA happen all the time. *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/CG6V-R676].

19. *See* Agnar Helgason & Kári Stefánsson, *The Past, Present, and Future of Direct-to-Consumer Genetic Tests*, 12 DIALOGUES IN CLINICAL NEUROSCIENCE 61, 64–65 (2010).

20. *See* Beth Peshkin & Claudine Isaacs, *Patient Education: Genetic Testing for Hereditary Breast, Ovarian, Prostate, and Pancreatic Cancer (Beyond the Basics)*, UPTODATE, https://www.uptodate.com/contents/genetic-testing-for-hereditary-breast-ovarian-prostate-and-pancreatic-cancer-beyond-the-basics#H2 [https://perma.cc/AU76-WBX4].

double mastectomy.[21] Or, as in Christian's case, maybe the results go from meaning nothing to meaning the difference between life and death.[22]

Second, the labs have complicated decisions to make as they interpret and share their information.[23] Deciding when and how variants are reclassified is no simple task.[24] Perhaps, in Christian's case, the lab concluded that two publications were not enough to decide that variant *X* now had some reportable significance.[25] To make matters even more complicated, the reclassification process is not standardized across labs, and labs don't always have an incentive to share information with either their competition or the doctors with whom they work.[26] At bottom, labs function as businesses, protecting their information, investments, and property rights in a competitive market;[27] in turn, a young boy dies, and people carry through with unnecessary surgeries.

Whether we see the labs as villains, however, depends on our perspective. The conversation in this area has focused on whether genetics labs have a duty to update the meaning of genetic results—a duty to reclassify variants.[28] The perspective offered is usually that of the patient harmed or the uninformed doctor, and the doctor's consequent duties should they learn of the new

21. Sometimes, the odds change after that person—based on their changing test results—encourages *seven* of their family members to do the same. Amy Dockser Marcus, *A Genetic Test Led Seven Women in One Family to Have a Major Surgery. Then the Odds Changed.*, WALL ST. J. (Dec. 20, 2019), https://www.wsj.com/articles/seven-women-in-a-family-chose-surgery-after-a-genetic-test-then-the-results-changed-11576860210 [https://perma.cc/97TZ-AC4F].

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

23. *See, e.g.*, Bird, *supra* note 18, at 397.

24. *See generally* Yvonne A. Stevens et al., *Physicians' Duty to Recontact and Update Genetic Advice*, 14 PERSONALIZED MED. 367, 367 (2017) (discussing whether physicians have a duty to recontact patients and update them on clinical advice based on a new or changed understanding of genomic information).

25. As we'll explore below, variant reclassification is quite complicated. *See infra* notes 37–67. To make things even more complicated, just because a lab designates a variant as one that is clinically actionable does not mean that avaliable medical literature will necessarily conclude that the variant has a certain link to genetic disease. There are important threshold issues about when a variant is declared pathogenic, none of which is within the scope of this Article.

26. *See generally* Jessica L. Roberts & Alexandra L. Foulkes, *Genetic Duties*, 62 WM. & MARY L. REV. 143 (2020) [hereinafter *Genetic Duties*] (explaining that the law does not recognize a duty owed by laboratories in this context and explaining the economics of reclassification and recontacting).

27. *See Quest Diagnostics, Inc.*, BAMSEC, https://www.bamsec.com/companies/1022079/quest-diagnostics-inc-1/articles-of-incorporation [https://perma.cc/Q6XR-2JBH] (noting Quest Diagnostics's share value and linking the company's Articles of Incorporation).

28. *See generally* Paul S. Appelbaum et al., *Is There a Duty to Reinterpret Genetic Data? The Ethical Dimensions*, 22 GENETICS MED. 633 (2020); Sue Richards et al., *Standards and Guidelines for the Interpretation of Sequence Variants: A Joint Consensus Recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology*, 17 GENETICS MED. 405, 420 (2015).

information.[29] When we think of labs amidst conversations of the fiduciary duties that doctors owe to patients and the ethical considerations entwined in doctor-patient relationships, a lab that doesn't share potentially life-changing information undoubtedly seems villainous.

But a lab doesn't owe the same duties that a doctor might.[30] So, perhaps, conceptualizing labs as the businesses that they are[31] would guide the development of more effective legal and ethical policy. Once we see labs as aggregators seeking to profit from their business endeavors—not as doctors or fiduciaries—we can promote more effective incentives for them to share information and play their proper role in reclassifying genetic data. This framing, underscoring the labs' role as an aggregator in the reclassification and recontacting saga, undercuts the prospect of casting labs as the saga's villain. And although we may want to have a villain in stories like Christian's, we may well be better off adjusting our frame so that we can find meaningful solutions more clearly. It will only be with these solutions that other individuals will not suffer a similar fate.

This Article proceeds as follows. Part II describes the role of laboratories in the reclassification and recontacting context, with a focus on how labs have protected and released information on the meaning of genetic variants. Part III argues that the class action framework and the extensively developed policy supporting the mechanism helps us think of labs as aggregators, free to benefit from their work. We have precedent in our legal system, after all, for how to treat an individual property right of negligible monetary value, which, once aggregated and processed by specialists, turns into an enormous pay out—for the specialists alone. Part IV explains how labs might be best incentivized in the reclassification and recontacting context. It first turns to the prospect of reorganizing labs as benefit corporations as a way to align the interests of the labs, doctors, and patients when it comes to variant reclassification. And next, it proposes a way for genetics laboratories to protect their interests and contribute positively to the process of patient recontacting.

29. *See Genetic Duties*, *supra* note 26, at 146.

30. *See id.* at 200–10.

31. *See, e.g.*, *Genetic Testing Registry*, NCBI, https://www.ncbi.nlm.nih.gov/gtr/all/labs/?term=inc [perma.cc/ESM4-AZP8] (listing thirty-nine clinical genetics laboratories that are incorporated); *Genetic Testing Registry*, NCBI, https://www.ncbi.nlm.nih.gov/gtr/all/labs/?term=corp [perma.cc/523G-YHCS] (listing two laboratories that are corporations); *Genetic Testing Registry*, NCBI, https://www.ncbi.nlm.nih.gov/gtr/all/labs/?term=co [perma.cc/KA4H-H9JU] (listing twenty-two laboratories that are companies).

II. RECLASSIFICATION & RECONTACTING

Not long ago, scientists completed a rough draft of the human genome.[32] And once they did, it was only the start of a scientific revolution—we did not then, do not now, and perhaps never will fully appreciate the meaning of the code they uncovered.[33] Nonetheless, research scientists since have come to understand more about what our genetic code means.[34] In fact, scientists make claims of having discovered a new genetic link almost every day.[35] And these new discoveries sometimes wreak havoc on the information doctors use to diagnose their patients.[36] Before explaining why, and what clinical genetics laboratories have to do with this, we start with a brief science lesson.

A. Reclassification: A Changing Diagnosis

DNA is a blueprint—a set of plans—for building a body.[37] DNA is made up of building blocks we call nucleotides, and these nucleotides string together to form sequences that code for certain messages.[38] We call these message sequences genes.[39] Although most humans have an identical set of genes, sometimes our genes are made up of slightly different message sequences.[40] That is, while almost everyone has the same genes, some people

32. *See* Sarah Zhang, *The Human Genome is—Finally!—Complete*, ATLANTIC (June 11, 2021), https://www.theatlantic.com/science/archive/2021/06/the-human-genome-is-finally-complete/619172/ [https://perma.cc/J8ZM-9TU6].

33. JANEY LEVY, THE HUMAN GENOME PROJECT 28 (2018).

34. *See* Zhang, *supra* note 32.

35. *See generally Genes News*, SCIENCEDAILY, https://www.sciencedaily.com/news/health_medicine/genes/ (last visited Sept. 5, 2021) (publishing almost daily articles concerning new genetic links).

36. *See, e.g.*, Williams v. Quest Diagnostics, Inc., 353 F. Supp. 3d 432, 437, 442 (D.S.C. 2018) (litigating issues arising from variant reclassification and an ensuing diagnosis).

37. *See* RICHARD DAWKINS, THE SELFISH GENE: 40TH ANNIVERSARY EDITION 19–20 (2016).

38. *See id.*

39. *See* Alexandra L. Foulkes et al., *Legal and Ethical Implications of CRISPR Applications in Psychiatry*, 97 N.C. L. REV. 1359, 1363 (2019).

40. 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.").

have different versions of these genes, and these different versions code for different messages.[41] We call these versions "variants."[42]

Doctors use genetic variants to give patients information about their health.[43] Genetic tests can help diagnose health conditions, identify treatment options, predict health risks, understand reproductive health, and identify effective medications.[44] Doctors usually get information about a genetic variant's meaning from laboratories.[45]

Depending on how much information a lab has about a certain variant, it will classify the variant under one of several categories including benign, pathogenic, or uncertain significance.[46] If the lab finds no information that the variant is linked to a heightened risk of disease, then the lab will classify it as benign.[47] Conversely, if a lab uncovers information linking a variant to a heightened risk of developing disease, then the lab will classify the variant as pathogenic.[48] Easy enough—but benign and pathogenic aren't the only options.[49] Variants without a known risk profile are classified as variants of uncertain (or unknown) significance: a "VUS."[50] So, when a lab doesn't have enough information to fully understand the medical impact of a variant, the

41. *See What Effect Do Variants in Coding Regions Have?*, EMBL-EBI, https://www.ebi.ac.uk/training/online/courses/human-genetic-variation-introduction/what-is-genetic-variation/what-effect-do-variants-in-coding-regions-have/ [https://perma.cc/RPN7-24J2]; *What Are Variants, Alleles and Haplotypes?*, EMBL-EBI, https://www.ebi.ac.uk/training/online/courses/human-genetic-variation-introduction/what-is-genetic-variation/what-are-variants-alleles-and-haplotypes/ [https://perma.cc/C364-DSYQ].

42. *What Are Variants, Alleles and Haplotypes?*, *supra* note 41.

43. *Genetic Testing*, CTRS. DISEASE CONTROL & PREVENTION (Mar. 23, 2020), https://www.cdc.gov/genomics/gtesting/genetic_testing.htm [https://perma.cc/EGA8-8EVD].

44. *See* R.O. Mason & G.E. Tomlinson, *Genetic Research*, *in* THE CONCISE ENCYCLOPEDIA OF THE ETHICS OF NEW TECHNOLOGIES 165, 179 (Ruth Chadwick ed., 2000).

45. *See id.* at 177–78. Under the current system in place, in fact, doctors and labs share information on a totally ad hoc basis. Yvonne Bombard et al., *The Responsibility to Recontact Research Participants After Reinterpretation of Genetic and Genomic Research Results*, 104 AM. J. HUM. GENETICS 578, 581 (2019); Julianne 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, 879 (2016).

46. To be precise, the framework that exists recommends that variants be classified into one of five categories along a gradient, ranging pathogenic to benign. Within this framework, labs use their own internal protocols; for example, different labs might weigh a piece of evidence differently in their determination of a variant's classification, ultimately resulting in different classifications of the same variant. Cristi Radford & Michele Gabree, *Variants of Uncertain Significance—Frequently Asked Questions*, 11 ONCOLOGY NURSE, no. 3, July 2018, at 16–17.

47. Depending on how much information a lab has, variants may also be classified as likely pathogenic or likely benign. *See id.* at 16.

48. *See id.*

49. *See id.*

50. *Id.*

lab doesn't report back to the doctor any clinically actionable information.[51] A VUS simply indicates that the patient's version of the tested gene is different from the majority of the population's, but the lab doesn't know if the difference is neutral, good, or bad.[52] It is with a VUS classification that things can get especially murky.[53]

Most often, labs are responsible for collecting, aggregating, processing, and making sense of genetic information.[54] This information is constantly changing because the technologies that labs are using to understand the meaning of genetic variants, and the field of genetics itself, are quite new.[55] As new information about these variants is uncovered, their classification might change.[56] For example, a variant that a lab categorizes as a variant of unknown significance today—because of a series of scientific discoveries that better explain what the variation means—might come to be categorized as a pathogenic variant tomorrow.[57] The process by which a variant's label changes is known as reclassification.[58]

For all labs, reclassification is time-consuming, expensive, and usually unprofitable.[59] What makes reclassification exceptionally complicated, however, is that labs classify variants on their own terms.[60] One lab is free to classify a particular variant differently than other labs.[61] Each lab uses its own set of internal protocols for reclassifying variants, and each lab also uses its own sets of genetic reference data to make sense of new information.[62]

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51. Clinically actionable information is information that a doctor can use to direct the patient to some form of treatment. *See* Gabriel Lázaro-Muñoz et al., *Which Results to Return: Subjective Judgments in Selecting Medically Actionable Genes*, 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"). For example, if a genetic test finds that a variant is linked with a heightened risk of breast cancer, a doctor might recommend a prophylactic mastectomy to prevent cancer in the future. *Id.* at 189; Noralane M. Lindor et al., *BRCA1/2 Sequence Variants of Uncertain Significance: A Primer for Providers to Assist in Discussions and in Medical Management*, 18 ONCOLOGIST 518, 519 (2013).

52. *Genetic Duties*, *supra* note 26, at 146–47.

53. *See id.* at 147, 153–54.

54. *See* Appelbaum et al., *supra* note 28, at 634.

55. *See* LEVY, *supra* note 33, at 28.

56. *See* Steven M. Harrison et al., *Clinical Laboratories Collaborate to Resolve Differences in Variant Interpretations Submitted to ClinVar*, 19 GENETICS MED. 1096, 1096 (2017).

57. *See id.* It bears repeating here that simply because a lab reclassifies a variant as pathogenic or benign, this does not mean the medical community agrees that the variant is conclusively linked to disease. *See* Lázaro-Muñoz et al., *supra* note 51, at 185.

58. Radford & Gabree, *supra* note 46, at 16–17.

59. This often leads to lags of up to ten years. *Genetic Duties*, *supra* note 26, at 155.

60. *Id.*

61. *See* Harrison et al., *supra* note 56, at 1097.

62. *See id.*

Ultimately, labs are in control of the reclassification process,[63] which is critically important for accurate medical diagnoses.[64] There is no governing body telling labs when and how to reclassify variants.[65] Once a lab reclassifies a variant, this reclassification must be used to reupdate the patients' results.[66] There is also no standard procedure for how to communicate to patients that the meaning of their genetic tests has changed.[67]

B. Recontacting: Updating Patients

Once a lab reclassifies a variant, it is in possession of valuable—and sometimes clinically actionable—health information.[68] The patients that once were told by their doctors that they had variants of uncertain significance, however, will never know that their same variant now means something of importance.[69] For example, it could indicate that they now have a heightened risk of breast cancer.[70] Unless there is a mechanism in place for supplying the patient with this information, the patient will remain in the dark.[71] As of now, there is no consensus on what this mechanism should be.[72]

Whether the lab or the doctor should be responsible for recontacting the patient is unsettled.[73] In fact, at present, there are no recognized legal duties

63. The Clinical Laboratory Improvement Amendments, the relevant U.S. regulations, do not impose mandatory standards for reclassifications. In fact, all guidelines in place remain voluntary. Adrian Thorogood et al., *Public Variant Databases: Liability?*, 19 GENETICS MED. 838, 839 (2017).

64. *See id.* at 838.

65. *See* Julia El Mecky et al., *Reinterpretation, Reclassification, and its Downstream Effects: Challenges for Clinical Laboratory Geneticists*, 12 BMC MED. GENOMICS, 2019, at 1, 4.

66. *See id.* at 6.

67. As the American College of Medical Genetics ("ACMG") recognizes, "there is currently no consensus for when and how often laboratories should review the classification of a particular variant." Karen L. David et al., *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 ET AL., 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/6ZV8-AKDL]; Moriah Wright et al., *Factors Predicting Reclassification of Variants of Unknown Significance*, 216 AM. J. SURGERY 1148, 1153–54 (2018).

68. *See* El Mecky et al., *supra* note 65, at 1.

69. *See id.* at 2.

70. *See* Julie Boyle, *Database of BRCA1 and BRCA2 Sequence Variants that Have Been Clinically Reclassified Using a Quantitative Integrated Evaluation*, LEIDEN OPEN VARIATION DATABASE (July 29, 2009), http://hci-exlovd.hci.utah.edu/home.php?select_db=BRCA2 [https://perma.cc/52PP-A4QH].

71. *See* El Mecky et al., *supra* note 65, at 4.

72. *Id.* at 2.

73. *See Genetic Duties*, *supra* note 26, at 149.

either to reinterpret genetic variants or to recontact patients with new information.[74] And, of course, it is patients who stand to be harmed by the variant reclassification process.[75] VUSs can be unsettling, leading to mistrust of doctors and the healthcare system.[76] Patients may also take unnecessary medical action.[77] For example, a woman underwent a double mastectomy (and convinced seven of her family members to do the same) because her genetic tests revealed she was at heightened risk of breast cancer—only to find out that same genetic test later meant something different.[78] Conversely, patients could lose the opportunity to take potentially life-saving clinical action, as in the case of young Christian.[79]

The conversation around reclassification and recontacting, and the duties that courts might impose on labs in this context, has centered mainly on how patients might recover legally for these potential harms.[80] As ethics and policy guidelines develop, there is a glaring omission in how we think about labs amidst conversations of the fiduciary duties doctors owe to patients and the ethical considerations entwined in doctor-patient relationships: the framing of labs as businesses.

Perhaps duties, regulations, and lawsuits have some role to play in incentivizing labs to reclassify data in the most efficient and effective way. The scope of these hypothetical duties has been explored elsewhere.[81] But I argue here that this role is a limited one. In this context, we must consider both the carrot and the stick, and in identifying which incentives might work best, we simply must conceptualize labs as the businesses they are. Thus, I turn to the legal precedent justifying doing exactly that.

I look first to the value of DNA aggregation. Next, I address the benefits of small claimant class actions; a look to class action lawsuits serves as a helpful tool for justifying and understanding a system where the aggregator of property rights in genetic data stands to profit maximally, with no obligation to share the profits. Finally, I analogize the two mechanisms and conclude that legal and ethical policy should develop so that labs, as

74. *Id.* at 148.

75. *Id.* at 157.

76. *See* Allen D. Roses, *Pharmacogenetics and the Practice of Medicine*, 405 NATURE 857, 857 (2000); 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 [perma.cc/JXJ5-9LSZ] ("It was scary. There are times I regret ever having genetic testing.").

77. *See* Marcus, *supra* note 21.

78. *Id.*

79. *See* Williams v. Quest Diagnostics, Inc., 353 F. Supp. 3d 432, 437, 442 (D.S.C. 2018).

80. *See Genetic Duties*, *supra* note 26, at 161; *see also supra* note 28 and accompanying text.

81. *See, e.g.*, Gary Marchant et al., *From Genetics to Genomics: Facing the Liability Implications in Clinical Care*, 48 J.L. MED. & ETHICS 11, 12 (2020).

aggregators, can keep profitting from their business endeavors while also providing necessary information to patients.

III. DNA AGGREGATORS

Most of us perceive an individual's genetic information as something of intrinsically high value.[82] Our genome is a cipher of who we are.[83] It's the key to our family history and a predictor of our vulnerability to disease.[84] But at its core, this perception is misguided because it equates the value of the interpretation of an individual's genetic code with the value of the individual's genetic information itself.[85] With very few exceptions,[86] an individual's genetic data alone is neither useful nor valuable.[87] Before genetic data can be analyzed and applied, aggregation on a large scale must take place.[88] Samples from hundreds—if not thousands—of people must be collected.[89] This data must then be processed and interpreted by specialists.[90] And yet, the possibility that individual donors are somehow being shortchanged if they don't benefit from the lab's payout seems reasonable at first blush.[91]

Keep in mind, though, that we have precedent in our legal system for how to treat an individual property right of negligible monetary value, which once aggregated and processed by specialists turns into an enormous payout only

82. *See* Lidewij Henneman et al., *Public Experiences, Knowledge and Expectations About Medical Genetics and the Use of Genetic Information*, 7 CMTY. GENETICS 33, 42 (2004).

83. *See* DAWKINS, *supra* note 37, at 19–20.

84. Mason & Tomlinson, *supra* note 44, at 179.

85. *See id.* at 181.

86. *See* Christina Farr, *Should You Get Paid for Your DNA?*, FASTCOMPANY (Mar. 12, 2016), https://www.fastcompany.com/3057732/should-you-get-paid-for-your-dna [https://perma.cc/YE6N-8RGM].

87. *See* Ben Hirschler, *Cashing in on DNA: Race on to Unlock Value in Genetic Data*, THOMSON REUTERS (Aug. 3, 2018, 4:01 AM), https://www.reuters.com/article/us-health-dna/cashing-in-on-dna-race-on-to-unlock-value-in-genetic-data-idUSKBN1KO0XC [https://perma.cc/6NC6-RD3N]; Daniel H. Farkas & Carol A. Holland, *Direct-to-Consumer Genetic Testing: Two Sides of the Coin*, 11 J. MOLECULAR DIAGNOSTICS 263, 263–64 (2009).

88. *See* David W. Craig et al., *Assessing and Managing Risk when Sharing Aggregate Genetic Variant Data*, 12 NATURE REVS. GENETICS 730, 733 (2011).

89. *See* Maggie Fox, *What You're Giving Away with Those Home DNA Tests*, NBC NEWS (Nov. 18, 2018, 6:16 AM), https://www.nbcnews.com/health/health-news/what-you-re-giving-away-those-home-dna-tests-n824776 [https://perma.cc/DV58-UE24] ("A lot of times companies are looking for large sets of DNA samples to do research on, to find new genes or even validate genetic tests that they've developed.").

90. *See generally* Craig et al., *supra* note 88 (discussing population-based genetic studies and privacy risks for participants).

91. *See id.*

for the specialists.[92] For example, a class action lawsuit is classically characterized by the aggregation of a large number of property rights, which individually have a trivial monetary value.[93] Without aggregation, each claim is essentially worthless, as the cost of litigation would far surpass the underlying value of the claim.[94] Once a lawyer has successfully aggregated, processed, and litigated the claims, the legal system allows the lawyer to profit tremendously.[95] The individual claimants, meanwhile, get nothing more—and sometimes less—than the value of their original property right.[96]

A. Class Action Policy

Proponents of small claimant class actions will most commonly point toward the class action's use as a deterrence mechanism.[97] Class actions provide a way to sanction bad behavior that creates a considerable total cost diffused over a large number of victims.[98] The minimal damage to each victim guarantees that, alone, individuals will rarely bring suit.[99] Therefore, without the class action mechanism, the bad actor is free to violate the law so long as the negative effects are widely dispersed.[100] The value to society incurred

92. *See generally* David Marcus, *The History of the Modern Class Action, Part: II: Litigation and Legitimacy, 1981–1994*, 86 FORDHAM L. REV. 1785, 1796 (2018) (profiling the rise in popularity of the modern class action lawsuit).

93. *See id.* at 1824–25.

94. *See* Brian T. Fitzpatrick, *Do Class Action Lawyers Make Too Little?*, 158 U. PA. L. REV. 2043, 2059 (2010).

95. *See id.* at 2045–46.

96. Recent Case, *Fifth Circuit Decertifies Nationwide Tobacco Class* — Castano v. American Tobacco Co.*, 84 F.3d 734 (5th Cir. 1996)*, 110 HARV. L. REV. 977, 978 (1997) ("[W]hen individual plaintiffs stand to recover large sums . . . a class action is not needed to overcome the problem of 'negative value' suits, in which the small value of claims relative to litigation costs effectively prevents individual litigation."). I do not mean to suggest that these policy considerations are always raised in defense of the class action suit, nor that they are undisputed. And, of course, there are important differences between the mass aggregation of claims and the mass aggregation of individual genetic codes. But at bottom, there are more similarities than differences. Class actions help us think about the benefits that labs—as DNA aggregators—offer the public while still remaining faithful to their shareholders and corporate missions.

97. *See, e.g.*, Adam C. Pritchard, *Markets as Monitors: A Proposal to Replace Class Actions with Exchanges as Securities Fraud Enforcers*, 85 VA. L. REV. 925 (1999) (discussing "fraud on the market" suits and proposing to replace those suits with antifraud monitoring by securities exchanges).

98. *See* John A. Fleishman, *Collective Action as Helping Behavior: Effects of Responsibility Diffusion on Contributions to a Public Good*, 38 J. PERSONALITY & SOC. PSYCH. 629, 629–31 (1980).

99. *See id.*

100. *See* Deborah R. Hensler & Thomas D. Rowe, Jr., *Beyond "It Just Ain't Worth It": Alternative Strategies for Damage Class Action Reform*, 64 LAW & CONTEMP. PROBS., nos. 2-

from class action lawsuits comes not from making each plaintiff whole, but rather from the resultant regulation of private conduct in ways that would otherwise be lost.[101] As a consequence of class actions, class members receive—at most—their claim's market value.[102] The lawyers responsible for processing and aggregating claims are the only ones that profit in exchange for generating a net benefit to society.[103]

The class action mechanism also aids in avoiding regulatory capture.[104] Capture is reflected in a regulator's excess of passivity and reactivity and is the process by which policy begins to look more like what the regulated entity wants and less like what the public interest requires.[105] In addition, the decisions issued by courts have external effects on non-parties.[106] And a successful class action brought against a large corporation can set a policy agenda for generations.[107] But because most individual members of the general public who are negatively affected by the actions of regulated entities have very little at stake, a collective action problem prevents them from pooling together to deter capture.[108] Incentivizing lawyers to aggregate and bring class action suits solves the collective action problem by having a single interested party round up a large number of disinterested individuals.[109]

B. Labs as Aggregators

Much like a cause of action that is well-suited to class action treatment, an individual's genetic information is of no meaningful monetary value[110]—although recently, some states have passed legislation creating a legally

3, Spring/Summer 2001, at 137, 137 ("Class actions for damages can provide compensation for modest but non-trivial losses suffered by widely dispersed but similarly positioned persons as a result of the negligence or illegal behavior of others, allowing recovery for losses that cannot practically be achieved through individual litigation.").

101. *See generally* KEVIN M. LEWIS & WILSON C. FREEMAN, CLASS ACTION LAWSUITS: A LEGAL OVERVIEW FOR THE 115TH CONGRESS (Apr. 11, 2018) (explaining requirements for forming and litigating a class action and discussing the harms and benefits to each interested party).

102. *See* Pritchard, *supra* note 97, at 954.

103. *See* Fleishman, *supra* note 98, at 629–31.

104. *See* Scott Hempling, *"Regulatory Capture": Sources and Solutions*, 1 EMORY CORP. GOVERNANCE & ACCOUNTABILITY REV. 23, 31–32 (2014).

105. *See* David Freeman Engstrom, *Corralling Capture*, 36 HARV. J. L. & PUB. POL'Y 31, 31 (2013).

106. *See* Hempling, *supra* note 104, at 31.

107. *See id.*

108. *See* Engstrom, *supra* note 105, at 31–32.

109. *See* Hensler & Rowe, *supra* note 100, at 159.

110. To be sure, both property rights to a cause of action and property rights to genetic information may be valuable to individual owners because of reasons other than the money. The implications of this point are beyond the scope of this discussion.

cognizable property right in a person's DNA.[111] All legislation passed so far requires only that informed consent be obtained from the donor of genetic material prior to collection.[112] But in the wake of this movement, some have called for the regulation of aggregators' profits[113] and the imposition of some duty to share their work with competitors.[114] When it comes to reclassifying the meaning of genetic variants, laboratory databases that collect information from various sources are especially useful.[115] The parallels between the property rights to a cause of action (well suited for class action treatment) and genetic information help to understand and justify a system where the aggregator of property rights in genetic data stands to profit maximally.[116] These parallels can help us think of labs as the businesses that they are and then develop policy accordingly.

In class actions, lawyers who spearhead aggregation and processing efforts for a large number of small claims provide a benefit to society.[117] Without the lawyer looking to profit from their efforts, bad actors would be undeterred in causing dispersed but systematic widespread harm.[118] Likewise, the potential benefit to society stemming from vastly dispersed individual genetic codes can never be realized without aggregation.[119] To learn what genetic variation means for predicting propensity to disease, specialized parties must first collect genetic material from a large number of individuals.[120] The aggregator must then—at their expense—process the

111. *See* Elizabeth E. Joh, *DNA Theft: Recognizing the Crime of Nonconsensual Genetic Collection and Testing*, 91 B.U. L. REV. 665, 689 (2011).

112. *See* Kayte Spector-Bagdady et al., *Analysis of State Laws on Informed Consent for Clinical Genetic Testing in the Era of Genomic Sequencing*, 178 AM. J. MED. GENETICS 81, 83–84 (2018).

113. *See, e.g.*, Sara LaJeunesse, *More than Half of Americans Want Money, Control in Exchange for Genetic Data*, PENN STATE NEWS (Mar. 11, 2020), https://news.psu.edu/story/611073/2020/03/11/research/more-half-americans-want-money-control-exchange-genetic-data [https://perma.cc/K8E5-U54M].

114. Dhikshitha Balaji & Sharon F. Terry, *Benefits and Risks of Sharing Genomic Information*, 19 GENETIC TESTING & MOLECULAR BIOMARKERS 648, 648 (2015) ("It is widely believed that 'big' data will propel research forward. No single organization or laboratory will collect sets of data that will be large enough to truly accelerate the science that is critical to understand the genome. This is largely due to practical and financial barriers."). *See also Precision Medicine Initiative (PMI) Working Group*, NAT'L INSTS. HEALTH (Mar. 16, 2018), https://acd.od.nih.gov/working-groups/pmi.html [https://perma.cc/GJG4-85PW].

115. *See* Thorogood et al., *supra* note 63, at 839.

116. *See id.* at 838.

117. *See* Fitzpatrick, *supra* note 94, at 2057–59.

118. *See id.* at 2062.

119. *See, e.g.*, Balaji & Terry, *supra* note 114, at 648.

120. *See id.* ("[L]arge-scale sharing of genomic information and associated clinical information is essential to accelerate biomedical research.").

samples and interpret the results.[121] We can test an individual's genetic material and deduce certain findings about predisposition to disease only because large databases against which to compare the individual's material exist.[122]

The benefit to society from genetic material is incurred at the expense of the aggregator, given the aggregator's investment of effort, time, and resources into developing useful databases and identifying meaningful genetic mutations within a population.[123] The individual holder of genetic property is unable to make use of his property alone, just like the individual who holds the right to a small value claim is unlikely to bring suit.[124] Like the lawyer who invests their own resources into recruiting clients, processing their claims, and championing the litigation, the aggregator of genetic material should profit maximally in return for their investment, which is ultimately responsible for generating an important societal benefit.

Aggregators of genetic information also help solve another collective action problem. Under the current rules, owners of genetic information relinquish their property rights by signing informed consent.[125] The aggregator then uses the collected samples to run a variety of tests and build a number of databases.[126] The aggregator is typically also free (and often incentivized, although, certainly not obligated) to share the databases with other groups, who then might run different tests for investigating different conditions.[127] All areas of research that benefit from the current aggregation process would likely receive less attention if individual property owners had to seek out the different causes independently and negotiate compensation for their individual genetic data in exchange for participation in the research.[128] Like the aggregator in a class action scenario—steering public policy to the

121. *Id.* ("Genetic tests can result in abundant data that must be managed, interpreted, and afforded the appropriate protections.").

122. *See* Amy L. McGuire et al., *Confidentiality, Privacy, and Security of Genetic and Genomic Test Information in Electronic Health Records: Points to Consider*, 10 GENETICS MED. 495, 495 (2008).

123. *See* Balaji & Terry, *supra* note 114, at 648.

124. *See id.*

125. *See* Carlo Petrini, *Ethical and Legal Considerations Regarding the Ownership and Commercial Use of Human Biological Materials and Their Derivatives*, 3 J. BLOOD MED. 87, 87 (2012).

126. *See* Marco D. Sorani et al., *Genetic Data Sharing and Privacy*, 13 NEUROINFORMATICS 1, 3 (2015).

127. *Id.* ("In the United States, biobanks in academia, government, and industry have implemented a range of sharing and security practices."). Note, however, that while industry labs are involved in sharing initiatives, these are usually driven by nonprofit academic or governmental institutions, although not always. *See* M.A. Franc et al., *Coding of DNA Samples and Data in the Pharmaceutical Industry: Current Practices and Future Directions—Perspective of the I-PWG*, 89 CLINICAL PHARMACOLOGY & THERAPEUTICS 537, 543 (2011).

128. *See* David et al., *supra* note 67, at 770.

benefit of society through their efforts—the aggregator of genetic information also solves problems that would result from passivity and reactivity.[129] The specialist in both cases sets in motion the mechanism by which aggregation affects third parties: the lawyer by establishing a new policy agenda through the litigation of a class action lawsuit against a large corporation, and the aggregator of genetic information by sharing the data and promoting discoveries in fields outside of the interests of the aggregator alone.[130]

In both the class action scenario and in the context of genetic information, the aggregators solve collective action problems to the benefit of society.[131] Make no mistake, however, in both cases, this consequence is secondary to (perhaps even dependent on) the success of the aggregator's business.[132] Like class action lawyers who are justified in benefitting maximally from their involvement in generating these societal benefits,[133] so are the institutions responsible for the aggregation of genetic information.

To be sure, the labs' role as an aggregator is only one of many aspects of their role in recontacting and reclassification.[134] But understanding the labs' incentives and how the law might value their role in the recontacting and reclassification scheme will be decisive in whether policy and ethical guidelines surrounding reclassification and recontacting ultimately cast the labs—seeking to profit maximally from their efforts—as genetic villains in this space. Arguably, the class action mechanism and the relevant policy that has developed in the class action context provide some guidance and justification for how legal and ethical policy should develop as it relates to labs as aggregators, seeking to profit from their business endeavors, in the reclassification and recontacting context.

Of course, I do not mean to suggest that we should let the market alone do the work of regulating labs in the space of reclassification and recontacting.[135] But I am suggesting that, if we think of labs as DNA aggregators, the ultimate impact of legal duties on the success of variant reclassification and patient recontacting will be limited. To be sure, the duties labs might owe in the reclassification and recontacting context have been

129. *See* Craig et al., *supra* note 88, at 735.

130. *See id.*

131. *Id.*

132. *See* Hirschler, *supra* note 87.

133. *See* Fitzpatrick, *supra* note 94, at 2044.

134. *See* David et al., *supra* note 67, at 770.

135. Indeed, clinical genetics labs are already regulated by a complicated network of agencies and regulatory bodies, and this regulation is often quite stringent and involved. *Regulatory Developments in Genetic Testing in the United States*, OCED, https://www.oecd.org/sti/emerging-tech/regulatorydevelopmentsingenetictestingintheunitedstates.htm [https://perma.cc/5JG5-W7KH].

thoroughly explored elsewhere.[136] And as of now, none has been conclusively established.[137] Any further discussion of these is beyond the scope of this Article. Having conceptualized labs as DNA aggregators, my focus here is on proposing solutions to the benefit of the reclassification and recontacting processes that might be attractive to these businesses. I first describe below how incentivizing labs to reorganize as benefit corporations would drive labs to reclassify variants more efficiently. I then turn to recontacting and explain how labs might take minimal action to protect their business and still contribute beneficially to the process.

IV. LABS, INC.

A. Benefit Corporations: Reclassification

Many, but not all, clinical genetics labs are currently organized as corporations.[138] The notion that labs have an ethical obligation to protect the public or the patients' interest in the reclassification context, though often posited in the reclassification and recontacting literature,[139] is arguably in tension with a labs' fiduciary duties as a corporation.[140] Recall that reclassifying genetic variants is time-consuming, expensive, and usually unprofitable for labs.[141] It often takes as long as ten years to reclassify variants once a lab has some indication that new information might be of consequence to a gene's classification.[142] So long as labs are beholden to shareholders, we can expect them to continue to act as players in a competitive market.[143]

136. *See, e.g.*, Marchant et al., *supra* note 81 (discussing the development of state and federal statutes, regulations, and common law surrounding genetic research).

137. *See Genetic Duties*, *supra* note 26, at 148.

138. *See supra* note 31 and accompanying text.

139. *See* Thomas P. Slavin et al., *The Effects of Genomic Germline Variant Reclassification on Clinical Cancer Care*, 10 ONCOTARGET, 417, 422 (2019).

140. *See* Dodge v. Ford Motor Co., 170 N.W. 668, 684 (Mich. 1919) ("A business corporation is organized and carried on primarily for the profit of the stockholders. The powers of the directors are to be employed for that end."); eBay Domestic Holdings, Inc. v. Newmark, 16 A.3d 1, 34 (Del. Ch. 2010).

141. *See supra* notes 37–67 and accompanying text.

142. *See* Jacqueline Mersch et al., *Prevalence of Variant Reclassification Following Hereditary Cancer Genetic Testing*, 320 JAMA 1266, Supp. Online Content Fig.1 (2018), https://jamanetwork.com/journals/jama/article-abstract/2703350 [https://perma.cc/NY2T-6HYY].

143. *See* William H. Clark, Jr. & Elizabeth K. Babson, *How Benefit Corporations are Redefining the Purpose of Business Corporations*, 38 WM. MITCHELL L. REV. 817, 825–28 (2012); *Genetic Duties*, *supra* note 26, at 189–90 (comparing laboratories' abilities to recontact patients with the feasibility of doing so). Certainly, some clinical genetics labs are affiliated with nonprofit institutions (namely, universities). The current divide shows how legislation has—

Independently of how clinical genetics laboratories are currently organized, it appears none has yet adopted a model which might align the labs' interests with those of the patient in the reclassification context: the benefit corporation.[144]

1. The Benefits of Benefit Corporations

The benefit corporation is a fairly recent, attractive development for labs in the role of DNA aggregators that are considering a broader focus on social responsibility.[145] The benefit corporation seeks to balance the competing and sometimes conflicting interests that arise when a business seeks to be both for-profit and mission-driven within a single entity.[146]

As of 2021, thirty-seven U.S. states have passed legislation making it possible for companies to incorporate as public benefit corporations.[147] A benefit corporation looks like a standard corporation in most respects.[148] Unlike other corporations, however, a benefit corporation is required to write its mission statement directly into its official charter and is not limited to shareholder wealth maximization.[149] Organized as benefit corporations, clinical genetic laboratories would be legally obligated to have a corporate

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until recently—focused on a binary approach to corporate structure. Organizations are thought of as either "for-profit" or "nonprofit." Benefit corporations offer a new alternative that could marry the pecuniary benefits of for-profit industry and the social benefit of nonprofit work. *See* Yaniv Heled et al., *Why Healthcare Companies Should Be(come) Benefit Corporations*, 60 B.C. L. REV. 73, 120–21 (2019).

144. *See* Heled et al., *supra* note 143, at 138–40. Some may argue that even for-profit labs already engage in altruistic behavior. *Id.* at 124. This may be so. But although for-profit corporations "can and do" sometimes engage in this type of behavior, "the law is clear that their overriding legal purpose must be to benefit shareholders, not third-party stakeholders." *Id.*

145. Arnold R. Eiser & Robert L. Field, *Can Benefit Corporations Redeem the Pharmaceutical Industry?*, 129 AM. J. MED. 651, 652 (2016); *see* Briana Cummings, *Benefit Corporations: How to Enforce a Mandate to Promote the Public Interest*, 112 COLUM. L. REV. 578, 578–79 (2012); Dana Brakman Reiser, *Benefit Corporations—A Sustainable Form of Organization?*, 46 WAKE FOREST L. REV. 591, 592 (2011).

146. *See* Heled et al., *supra* note 143, at 124, 127; Alicia E. Plerhoples, *Social Enterprise as Commitment: A Roadmap*, 48 WASH. U. J. L. & POL'Y 89, 89–91 (2015).

147. *State by State Status of Legislation*, BENEFIT CORP., https://benefitcorp.net/policymakers/state-by-state-status?state=south-carolina [https://perma.cc/AN8P-KD5S].

148. Heled et al., *supra* note 143, at 126 ("Just like regular corporations, these hybrid forms have private owners, can raise private capital, and can distribute profits to their investors."). *See, e.g.*, *Why is Benefit Corp Right for Me?*, BENEFIT CORP., https://benefitcorp.net/businesses/why-become-benefit-corp [https://perma.cc/5M2K-RPAQ] (explaining the differences between benefit corporations and standard corporations).

149. *See, e.g.*, MD. CODE ANN., CORPS. & ASS'NS § 5-6C-01(e) (LexisNexis 2012) (defining the role of third-party standard-setters); VT. STAT. ANN. tit. 11A, § 21.03(a)(8) (West 2012).

purpose that creates a positive impact on society.[150] Specifically, the labs' "fiduciary duties of directors are expanded to require consideration of nonfinancial and stakeholder interests beyond the economic interests of shareholders."[151] And labs would have to "periodically report on their overall social and environmental performance," which would then be assessed against a credible standard.[152]

As part of their mission statement, then, clinical genetics laboratories could include the prospect of reclassifying genetic variants in a timely and efficient way. That way, success in the reclassification context is aligned with the organization's success.[153] This would incentivize labs to do what ethicists and other do-gooders have wanted them to do all along, while protecting the labs' officers from fiduciary liability.[154]

2. Incentivizing Organization

Incentivizing clinical genetics labs to organize (or reorganize as the case may be) as benefit corporations might serve as a more efficient alternative to enforcing complicated legal duties and pursuing expensive lawsuits, which may or may not be successful. Doctors could select the labs they use based on whether they are organized as benefit corporations. As an alternate incentive, regulatory bodies and ethics boards could condition the grant of certain benefits or permits on the labs' mission statement and compliance with the legal requirements of benefit corporations.

If labs opt to organize in this way, they would not be the first players in the medical field to do so.[155] Other areas of medicine have already considered shifting their mission and practices from a focus on creating public wealth to a focus on creating public good.[156] Groups of physicians and drug developers,

150. Doug Raymond, *Impact Investing in the Boardroom*, DIRECTORS & BOARDS, Oct. 27, 2016, at 8, https://www.faegredrinker.com/-/media/files/insights/raymond-directors-and-boards/2016dbq3_impactinvestingintheboardroom.pdf [https://perma.cc/X598-QVLA].

151. *Id.* Benefit corporations provide protection against shareholder primacy; before investors buy shares, they are aware of a company's social aims—clearly stated for them to read. Shareholders might then have a harder time suing the company for making good on its stated long-term aims at the expense of short-term profit. For the most part all other policies, such as employment law and tax rates, are exactly the same as for a regular corporation. *See* Heled et al., *supra* note 143, at 123–24, 127.

152. Raymond, *supra* note 150.

153. *See id.*

154. *See* Heled et al., *supra* note 143, at 129.

155. *See* Arran Frood, *Nature Medicine: Mission Control: Drug Developers Test the 'Benefit Corporation' Business Model*, MAPS (Oct. 17, 2017), https://maps.org/news/media/6896-nature-medicine-mission-control-drug-developers-test-the-'benefit-corporation'-business-model [https://perma.cc/LHR2-WDQF].

156. *See id.*

for example, have considered the new business structure of benefit corporations.[157] This would be a good way for DNA aggregators to prioritize both patients and profits and make reclassification a part of their mission to the benefit of all.

B. Updated Terms of Service: Recontacting

Although benefit corporations are a possible solution to the reclassification of genetic variants, they do not solve problems related to reupdating patient information. As noted above, once a genetic variant has been reclassified, a patient's information has to be reupdated.[158] Take, for example, the following scenario: first, a particular genetic variant in the lab's database goes from being labeled a VUS to pathogenic.[159] Then, the information in the database has to be applied to a patient's file to reupdate the variant's newly uncovered meaning to their results.[160] The patient then has to be informed of this change.[161] Again, whether duties will be imposed on labs in the recontacting context is uncertain.[162]

How these hypothetical duties are enforced will, in all likelihood, vary greatly depending on the size of the lab and the type of testing the labs conduct.[163] But while the literature has focused on how labs might be punished for not doing their part in the reclassification and recontacting context, little has been said about what might incentivize labs to proactively protect their interests.[164]

1. A Simple Contractual Solution

Before the courts get involved, proactive measures should serve as a primary safeguard from liability.[165] Like most other businesses, labs can, by way of contract, reduce their liability in the reupdating and recontacting context.[166]

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157. *See id.*; Stephanie Saral Taylor, *Physicians Should Become B-Corps*, OP-MED (Nov. 25, 2019), https://opmed.doximity.com/articles/physicians-should-become-b-corps?_csrf_attempted=yes [https://perma.cc/34YV-HGXW].

158. *See* El Mecky et al., *supra* note 65, at 6.

159. *See id.* at 5.

160. *See id.* at 6.

161. *See* David et al., *supra* note 67, at 770.

162. *See id.*

163. *See Genetic Duties*, *supra* note 26, at 200–05.

164. *See, e.g.*, *id.* at 200–05, 211–12 (discussing different types of labs and their potential for liability).

165. *Id.* at 194; Stevens et al., *supra* note 24, at 8–9.

166. *See, e.g.*, Marchant et al., *supra* note 81, at 31.

Any disputes arising out of the genetic tests performed by laboratories are usually governed by the labs' terms of service agreements.[167] What those terms say can limit a given lab's legal liability.[168] For example, some labs have clauses that determine the applicable law or compel arbitration.[169] Just like labs are free to limit their liability with respect to testing procedures,[170] they could likewise use their terms of service to outline the contours of their obligations to patients related to reclassification and recontacting.

From the start, when a patient's data is collected by a lab for analysis, the lab could introduce language into its terms explaining that a patient's genetic test results are subject to change and outlining how the laboratory will communicate any updates related to those changes.[171] In the terms of service, labs might require patients to maintain a current email address with the lab.

In the event of a reclassification, the laboratory would then email patients who have taken the relevant test to let them know of a potential change in their variant's classification. The reupdate message might have a clear subject line, indicating to the patient that the meaning of their results has changed.[172] The

167. *See Terms & Conditions*, AMBRY GENETICS (Apr. 10, 2018), https://www.ambrygen.com/legal/terms-and-conditions [https://perma.cc/R3PT-P24B] ("THESE TERMS AND CONDITIONS GOVERN YOUR RIGHTS AND RESPONSIBILITIES WITH REGARD TO [THE SERVICES]").

168. *See* Briceno v. Sprint Spectrum, L.P., 911 So. 2d 176, 180 (Fla. Dist. Ct. App. 2005) (holding that a customer who was informed of, but did not read, updates to terms and conditions that were found on Sprint's website, was bound by such updates).

169. *See, e.g.*, *Sema4 Terms of Service*, SEMA4 (Nov. 4, 2020), https://sema4.com/terms/ [https://perma.cc/96T8-EKG7] ("Any legal action or proceeding . . . will be governed exclusively by the laws of the State of New York, without regard to conflicts of laws principles."); *OneOme Terms of Service*, ONEOME (June 30, 2020), https://oneome.com/terms [https://perma.cc/VQ3A-PALR] ("Any Disputes shall be resolved by final and binding arbitration under the rules and auspices of the American Arbitration Association, to be held in Minneapolis, Minnesota.").

170. *See* sources cited *supra* note 169.

171. Certainly, there are limits on liability disclaimers in many jurisdictions. For example, it is often illegal to disclaim liability for recklessness or negligence. *See, e.g.*, City of Santa Barbara v. Superior Ct., 161 P.3d 1095 (Cal. 2007) (holding that release of liability did not extend to gross negligence); Tunkl v. Regents of the Univ. of Cal., 383 P.2d 441 (Cal. 1963). It may also be illegal to disclaim liability for negligence resulting in bodily harm. *See, e.g.*, Berlangieri v. Running Elk Corp., 48 P.3d 70 (N.M. Ct. App. 2002) (holding that a disclaimer was unenforceable). Perhaps including a term in the patient's initial consent that purports to release the lab of all liability should variants never be reclassified—or a patient never be recontacted—would be insufficient. But an affirmative contact from a lab, informing a patient specifically of a change, and giving patients an opportunity to decide whether they want the information or not is quite different from disclaiming liability for medical malpractice or gross negligence on the front end.

172. *See, e.g.*, Resorb Networks, Inc. v. YouNow.com, 51 Misc. 3d 975, 982 (N.Y. Sup. Ct. 2016) ("[O]nline agreements are enforceable on the ground that the users have notice of the agreement and 'an effective opportunity to access terms and conditions.'") (quoting Berkson v. Gogo LLC, 97 F. Supp. 3d 359, 400 (E.D.N.Y. 2015)).

body of the email might be something as simple as the following: "Dear [patient]: Our records indicate that you have taken a genetic test related to [relevant gene]. We have recently reclassified certain variants of [relevant gene]. We encourage you to follow up with your treating physician." Because the use of healthcare software[173] and modern technology has become routine, this email template could be autogenerated as soon as the relevant genetic variant is reclassified in the labs' database.[174]

And so, automated email messages would be a relatively cost-effective tool that would both limit a lab's liability and put the patient on notice of the reclassification. Once a patient is notified of a reclassification, the labs' terms of service might also clearly indicate that the patient has the subsequent responsibility to take action if they[175] want the lab to reinterpret their genetic data. In other words, the patient—not the laboratory—must initiate the reinterpretation process by talking to their doctor.

To be sure, using email and apps to provide updates regarding sensitive information is already a widespread practice in medicine and beyond.[176] A vast majority of patients with access to the technology would prefer to have their providers contact them via email.[177] The use of email has been linked to reduced costs and increased health outcomes.[178] The Food and Drug

173. *See* Barbara Evans & Pilar Ossorio, *The Challenge of Regulating Clinical Decision Support Software After 21st Century Cures*, 44 AM. J.L. & MED. 237, 238 (2018) (stating that the FDA defined software as a medical device in 2013, when "the use of software grew pervasive in health care").

174. This update might also be communicated via an app and a push notification. *See The 23andMe Mobile DNA Reports App*, 23ANDME, https://customercare.23andme.com/hc/en-us/articles/212193898-The-23andMe-Mobile-DNA-Reports-App [https://perma.cc/G48W-UXYB]. During the COVID-19 pandemic, for example, many labs used apps to communicate the results via healthcare apps. *See How to Get Your Test Results*, QUEST DIAGNOSTICS, https://www.questdiagnostics.com/home/patients/getting-results/how-to-get-results/ [https://perma.cc/F9XV-R9ZJ].

175. The singular "they" replaces all gendered pronouns throughout this Article, except for where the preferred pronoun of the person referenced is known.

176. *See* Joy L. Lee et al., *Patient Use of Email, Facebook, and Physician Websites to Communicate with Physicians: A National Online Survey of Retail Pharmacy Users*, 31 J. GEN. INTERNAL MED. 45, 45 (2015).

177. *Id.* ("[T]here is strong interest among patients in the use of email and Facebook to communicate with their physicians."); 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/52AE-KH2Y] ("Among individuals with Internet access, 90% want to communicate with their physician over email.").

178. *See* Mary Reed et al., *Patient-Initiated E-mails to Providers: Associations with Out-of-Pocket Visit Costs, and Impact on Care-Seeking and Health*, 21 AM. J. MANAGED CARE e632 (2015). *See also* Ken Abrams & Natasha Elsner, *What Can Health Systems Do to Encourage Physicians to Embrace Virtual Care?*, DELOITTE (July 18, 2018), https://www2.deloitte.com/insights/us/en/industry/health-care/virtual-health-care-health-consumer-and-physician-surveys.html [https://perma.cc/MDQ8-VETX].

Administration, along with other government agencies,[179] have also implemented email update systems to electronically alert consumers to recalls, market withdrawals, and safety alerts.[180] In the consumer genetics space—as opposed to the clinical genetics space—companies like AncestryDNA and 23andMe email their users regarding updates to their policies and changes to their results.[181] In fact, AncestryDNA recently changed how it classified users based on their geographic ancestry—a reclassification of sorts—and informed its customers via email.[182] Email updates are already a widely accepted method of mass communicating important and sometimes sensitive information.[183]

2. Benefits to Institutions & Courts

This strategy has the benefit of communicating potentially valuable information to the patient with a minimal burden on laboratories. The labs must, of course, collect and maintain patient contact information. The terms of service, however, can charge the individual patients with ensuring that their email addresses are up-to-date.[184] This process might be automated with the help of health information technology, reducing the burdens associated with reinterpreting and recontacting.[185] After all, personal electronic health records

179. *Recalls.gov Subscription List Sign-Up*, RECALLS.GOV, https://www.recalls.gov/list.html [https://perma.cc/CYM9-63YK].

180. *Recalls, Market Withdrawals, & Safety Alerts*, FDA, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts [https://perma.cc/L9EV-K4SK].

181. *See, e.g.*, *Privacy Highlights*, 23ANDME (Oct. 30, 2020), https://www.23andme.com/about/privacy/ [https://perma.cc/4TZB-QWK6] ("By creating a 23andMe account, you are agreeing that we may send you product and promotional emails or notifications about our Services, and offers on new products, services, promotions or contests.").

182. *See Ancestry Surpasses 15 Million DNA Customers*, ANCESTRY (May 31, 2019), https://blogs.ancestry.com/ancestry/2019/05/31/ancestry-surpasses-15-million-dna-customers/ [https://perma.cc/5B3M-TYYQ].

183. *See* Shafrin, *supra* note 177.

184. Labs may already have patient email addresses on file to provide other kinds of updates. *See, e.g.*, *Test Requisition Form*, COLOR, https://static.getcolor.com/pdfs/Color_Hereditary_Cancer_Test_Requisition_Form_Self_Pay.pdf [https://perma.cc/62H5-B4P8] (stating that the patient's email address is "required," and the patient will receive a direct email through which to purchase their test).

185. To be sure, there once was a time when providers considered reinterpretation and recontacting unfeasible. *See* Jennifer L. Fitzpatrick et al., *The Duty to Recontact: Attitudes of Genetics Service Providers*, 64 AM. J. HUM. GENETICS 852, 858 (1999). Technology has advanced such that this is now changing. Corrette Ploem et al., *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 are likely to have a bearing on this process, to the extent that they will reduce the burden of updating previous test results and

now facilitate the speedy review of patient health data.[186] Additionally, and, perhaps most importantly, the ability to simultaneously contact all patients with certain medical conditions via email is accessible.[187]

The courts, too, will find this approach desirable. Informing patients of reclassification and making them responsible for taking action offers a clean solution for the courts. Fulfilling the legal duty associated with reclassification will be as simple as sending an email. Courts will then have a relatively straightforward inquiry: Did the laboratory email the appropriate patients regarding the reclassification within an appropriate time frame? Did the lab's email clearly notify the patient of the change and the patient's subsequent responsibility? The courts will not otherwise have to grapple with whether the laboratories or the providers made a reasonable effort to contact the patient and ensure they understood the updated results.

3. Benefits to Patients

Make no mistake, patients also stand to benefit from this approach, particularly if courts are unwilling to impose more stringent duties on laboratories or providers. Of course, this is not a patient-centered solution, and certain barriers to access might make it less than ideal for some. But this approach likely provides a patient with more information than they would otherwise have had. And importantly, updates about reclassification give patients the opportunity to play a more active role in managing their health.[188]

Generally, medical treatment—including genetic testing—requires patient consent.[189] Simply reinterpreting genetic test results following reclassification without asking the patient whether they would like those

communicating new information, including to former patients."); Sara H. Katsanis & Nicholas Katsanis, *Molecular Genetic Testing and the Future of Clinical Genomics*, 14 NATURE REVS. GENETICS 415, 415 (2013) ("Genomic technologies are reaching the point of being able to detect genetic variation in patients at high accuracy and reduced cost.").

186. Mark A. Rothstein, *Reconsidering the Duty to Warn Genetically At-Risk Relatives*, 20 GENETICS MED. 285, 289 (2018) ("Electronic health records and technology that enables the simultaneous contacting of all patients with certain medical conditions make such warnings feasible.").

187. *Id.*

188. *See* Ploem et al., *supra* note 185, at 538; 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, 114 (2012) ("[T]he physician's duty to notify patients of new medical developments, is consistent with the language and intent of several important ethical principles and further serves to advance the modern conception of the physician-patient relationship.").

189. Amy L. McGuire & Laura M. Beskow, *Informed Consent in Genomics and Genetic Research*, 11 ANN. REV. GENOMICS & HUM. GENETICS 361, 362 (2010).

services is arguably unethical.[190] By contrast, informing patients of a relevant reclassification and allowing them to decide for themselves whether to seek reinterpretation preserves patient autonomy and privacy.[191] This approach, thus, keeps with the recent trend toward cooperative medicine.[192]

In some cases, unwanted reinterpretation could actually be harmful. Recall that receiving a VUS result may leave patients feeling frustrated and confused, even causing them to distrust their doctors.[193] Reinterpreting a patient's genetic data without their express consent may lead to further feelings of uncertainty and frustration. In cases where reinterpretation reveals previously unknown risk, the updated results could be devastating.[194]

Consequently, a contractual solution—where the lab updates its terms of service and then asks the patient to take further action—protects the lab from liability and places some responsibility on the patient. We allow corporations to protect themselves in this way routinely,[195] and there are few reasons to prevent DNA aggregators from doing the same. Further, this result, which is to the labs' clear benefit, also has demonstrable benefits for the patient, the healthcare system, and the courts.

V. CONCLUSION

When we think of labs as villains, it is easy to want to punish them with sticks. But in the reclassification and recontacting context, everyone is better off if policy focuses on how to make better use of the carrot. The best way to

190. *See* Reed E. Pyeritz, *The Coming Explosion in Genetic Testing—Is There a Duty to Recontact?*, 365 NEW ENG. J. MED. 1367, 1367–68 (2011).

191. *See id.*

192. *See* R. Kaba & P. Sooriakumaran, *The Evolution of the Doctor-Patient Relationship*, 5 INT'L J. SURGERY 57, 59 (2007).

193. *See id.* at 63.

194. Take, for example, people ordering at-home genetic testing kits for fun. When the results of those genetic tests end up revealing a health risk the unsuspecting customer was not anticipating, the experience can be devastating. *See What It's Like to Get 'Devastating' Health News from 23andMe*, ADVISORY BOARD (Aug. 9, 2019), https://www.advisory.com/daily-briefing/2019/08/09/23andme-bad-news [https://perma.cc/W3Y2-76GC] ("But rather than being fun, the results left her in 'tears,' . . . [and] she 'felt like [she] couldn't breathe anymore.'") (first brackets added). *See also* Ellen W. Clayton et al., *A Systematic Literature Review of Individuals' Perspectives on Privacy and Genetic Information in the United States*, 13 PLOS ONE e0204417 (2018), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0204417 [https://perma.cc/US3L-2M6B] ("Since decisions about genetic testing and data are not made in a vacuum, it is critical to ask respondents about what trade-offs they are willing to make and risks they are willing to accept for their own health, for advancing science, and for their interest and convenience."); Walter F. Baile et al., *SPIKES—A Six-Step Protocol for Delivering Bad News: Application to the Patient with Cancer*, 5 ONCOLOGIST 302, 304 (2000) ("How bad news is discussed can affect the patient's comprehension of information, satisfaction with medical care, level of hopefulness, and subsequent psychological adjustment.").

195. Marchant et al., *supra* note 81.

prevent outcomes like young Christian's in the future is not by punishing the labs' conduct by turning to the courts and asking them to impose complicated legal duties. Nor is the answer necessarily to ask the already heavily regulated clinical genetics laboratories to comply with more regulations. Rather, we ought to properly incentivize them to perform for the benefit of all. Class action theory and economics help us think of genetics labs as DNA aggregators that are free to benefit from their work. And, with this framework in mind, we should incentivize labs to reorganize as benefit corporations and adopt contracts and practices that protect their business. By incentiizing rather than penalizing labs, they are more likely to implement more effective reclassification and recontacting procedures.