Does One Size Fit All? Why Our Genes Show the Need for Tailor-Made Solutions

JACK HAISMAN[†]

Since the human genome was first sequenced in 2003, millions of consumers and medical professionals have swarmed the field of medical genetics, seeking to peer into the crystal ball and see what their own, or their patients', futures may hold. Also rushing in are direct-to-consumer genetic testing companies like 23andMe and AncestryDNA, which can circumvent medical privacy laws by offering genetic testing without a medical provider.

Medical privacy regulations, such as the Health Information Portability and Accountability Act of 1996 (HIPAA), the Genetic Information Discrimination Act of 2008 (GINA), and those promulgated by the Federal Trade Commission, do not regulate these companies adequately for a litany of reasons. These loopholes and shortcomings in regulation leave American consumers substantially less protected, less medically informed, and in some instances can jeopardize national security.

This Note proposes that Congress should enact legislation overhauling the current regulatory regime in at least three ways: (1) the "covered entity" approach should be abandoned and replaced with a data-driven model; (2) the Safe Harbor provision of HIPAA should explicitly exclude genomic data; and (3) consumers should be given a "right to be forgotten" and compel companies to delete their data. These reforms would significantly strengthen consumers' genetic privacy and give them an escape hatch to safeguard the core of their identity.

[†] J.D., University of California, Hastings College of the Law; Senior Production Editor, *Hastings Law Journal*. I would first like to thank my family and friends for their unwavering support. I am also incredibly grateful to Professor Chimène Keitner for her guidance and encouragement. I would also like to thank Dr. Gregory Idos and Christine Hong for their mentorship and for planting the seeds of this Note. Lastly, this Note would not have been possible without the editors of the *Hastings Law Journal* and their hard work.

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INTRODUCTION

When you decide to test for 'future risk,' you are also, inevitably, asking yourself, what kind of future am I willing to risk?

— Siddhartha Mukherjee[1]

The human genome was first sequenced in 2003.[2] Since then, consumers and medical professionals alike have swarmed the field of medical genetics, seeking to peer into the crystal ball and see what their own, or their patients', futures may hold. Rushing in on this hot field of scientific advancement are companies that seek to circumvent medical practitioners and sell this crystal ball themselves. These are, of course, direct-to-consumer genetic testing companies such as 23andMe and Ancestry.com—nearly ubiquitous names.[3] However, in circumventing licensed professionals who have taken an oath to do no harm to their patients, these companies avoid federal privacy laws regarding medical recordkeeping. The result? American consumers are substantially less protected and less medically informed, and in some instances, may jeopardize national security. In fact, both the Food and Drug Administration and the Center for Disease Control explicitly refuse to recommend direct-to-consumer genetic tests as a suitable alternative to a traditional evaluation by an individual's healthcare provider.[4] Moreover, the Federal Trade Commission (FTC) explicitly warns consumers of the privacy implications of direct-to-consumer genetic testing.[5] Furthermore, the United States Department of Defense has expressly warned service members of the privacy harms surrounding this method of testing.[6] In a memorandum, Joseph Kernan, the Undersecretary of Defense for Intelligence, warned:

> These DTC [direct-to-consumer] genetic tests are largely unregulated and could expose personal and genetic information, and potentially create unintended security consequences . . . . Moreover, there is increased concern in the scientific community that outside parties are exploiting the use of

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[1] SIDDHARTHA MUKHERJEE, THE GENE: AN INTIMATE HISTORY 438 (2016).

[2] *Human Genome Project Information Archive 1990–2003*, U.S. DEP'T OF ENERGY, http://www.ornl.gov/sci/techresources/Human_Genome/project/whydoe.shtml (last modified Mar. 26, 2019).

[3] This Note will treat 23andMe and the other top four direct-to-consumer companies as a proxy for the entire industry, as they command a sizable majority of the market and are the pioneers of the business model.

[4] *Direct-to-Consumer Genetic Tests*, FED. TRADE COMM'N: CONSUMER INFO. (Feb. 2018), https://www.consumer.ftc.gov/articles/0166-direct-consumer-genetic-tests [https://web.archive.org/web/20210323011005/https://www.consumer.ftc.gov/articles/0166-direct-consumer-genetic-tests].

[5] Lesley Fair, *DNA Test Kits: Consider the Privacy Implications*, FED. TRADE COMM'N: CONSUMER INFO. (Dec. 12, 2017), https://www.consumer.ftc.gov/blog/2017/12/dna-test-kits-consider-privacy-implications [https://web.archive.org/web/20210702090536/https://www.consumer.ftc.gov/blog/2017/12/dna-test-kits-consider-privacy-implications].

[6] Shawn Snow, *Pentagon Advises Troops to Not Use Consumer DNA Kits, Citing Security Risks*, MIL. TIMES (Dec. 24, 2019), https://www.militarytimes.com/2019/12/24/pentagon-advises-troops-to-not-use-consumer-dna-kits-citing-security-risks/.

> genetic data for questionable purposes, including mass surveillance and the ability to track individuals without their authorization or awareness.[7]

This Note examines the deficiencies in our current federal regulatory regime for genetic privacy and proposes ways to improve consumer privacy without sacrificing scientific advancement. Part I surveys the background of genetic privacy, including: the scientific basis of genetics, why sharing genetic information is important for innovation, how and what direct-to-consumer companies test for, and why those companies raise novel issues in the privacy and regulatory spaces. Part II describes the current regulatory background—which includes the Health Information Portability and Accountability Act (HIPAA), the Genetic Information Discrimination Act of 2008 (GINA), and the FTC rules—and their shortcomings. Finally, Part III proposes ideas for overcoming the current shortcomings in regulation and strengthening individual privacy rights. These solutions include overhauling HIPAA's current "covered entity" approach by abandoning the fallacy that what makes us fundamentally unique can be de-identified, and enacting a right to be forgotten. These reforms would greatly increase consumer genetic privacy through a top-down approach directly regulating direct-to-consumer genetic testing companies and would empower consumers in the face of unforeseeable risks.

I. BACKGROUND

A. GENETICS DECODED: FROM PEA PLANTS TO BESPOKE MEDICINE

In the mid-nineteenth century, an Austrian monk named Gregor Mendel cultivated a pea garden in an abbey that became the genesis for modern genetics.[8] In this garden, Mendel experimented with how different traits—such as flower color, pod shape, flower position, and stem length—are passed from one generation to the next.[9] The prevailing theory of the time was a blending theory, wherein inheritable material from both parents is mixed, similar to how blue and yellow paint mix to make green.[10] Mendel disproved that theory and instead proffered a particulate theory, wherein hereditary factors—now commonly known as genes—are shuffled like a deck of cards and passed from generation to generation undiluted.[11] This idea forms the basis for the modern understanding of genetics, and interest in heritable traits has since grown exponentially.

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[7] Memorandum from Joseph D. Kernan, Under Sec'y of Def. for Intel. & James N. Stewart, Assistant Sec'y of Def. for Manpower & Rsrv. Affs. (Dec. 20, 2019) (on file with author).

[8] LISA A. URRY, MICHAEL L. CAIN, STEVEN A. WASSERMAN, PETER V. MINORSKY & JANE B. REECE, CAMPBELL BIOLOGY 269–70 (Beth N. Winickoff et al. eds., 11th ed. 2016).

[9] *Id.* at 269–72.

[10] *Id.* at 269.

[11] *Id.*

Today, our understanding of the basis for inheritable traits has come very far from Mendel's hereditary factors. We now know that the hereditary factors we pass on are twenty-three pairs of chromosomes, one from each parent.[12] Each chromosome is made up of anywhere from hundreds to thousands of genes.[13] Humans are composed of 30,000 genes, which are long sequences of deoxyribonucleic acid, or DNA.[14] DNA is a double helical polymer comprised of four different types of nucleotide bases: adenine (A), thymine (T), guanine (G), and cytosine (C).[15] The specific sequence of these nucleotides is what allows for the incredible variety of genes, and the entirety of the sequence of all three billion nucleotide bases is what constitutes the human genome.[16]

However, DNA and genes are more than just a random sequence of nucleotide bases; they provide the blueprint and instructions for how to synthesize all proteins, controlling everything from our metabolism to our skin color, and even our risk of developing cancer.[17] The manifestation of the genetic code is called *gene expression* and can be divided into the genotype, or genetic makeup, and its phenotype, or physical manifestation.[18] Additionally, traits can be classified as single gene (such as a Widow's Peak hairline and influenced by only one gene), or polygenic (such as eye color and influenced by multiple genes).[19]

This distinction between underlying genes and their resulting phenotype is important because there is an immense amount of genetic variation, or polymorphisms, between individuals.[20] No two humans, besides identical twins (and triplets, quadruplets, etc.), will ever be genetically identical.[21] However, any two humans' DNA differs by about one in a thousand nucleotides, which means there is a 99.9% similarity of DNA from person to person.[22] Not all polymorphisms, also called mutations, lead to obvious downstream effects (e.g., silent mutations).[23] But some can cause serious genetic illnesses like

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[12] *Id.* at 235–36.

[13] *Human Genome Project FAQ*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/human-genome-project/Completion-FAQ [hereinafter *Human Genome Project*] (last updated Feb. 24, 2020).

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *DNA Sequencing Fact Sheet*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/about-genomics/fact-sheets/DNA-Sequencing-Fact-Sheet (last updated Aug. 16, 2020).

[18] URRY ET AL., *supra* note 8, at 274.

[19] NAT'L INSTS. OF HEALTH, *Understanding Human Genetic Variation: How Much Genetic Variation Exists Among Humans?*, *in* NIH CURRICULUM SUPPLEMENT SERIES (2007) (ebook), http://www.ncbi.nlm.nih.gov/books/NBK20363/ [hereinafter *Understanding Human Genetic Variation*].

[20] *Id.*

[21] *Id.*

[22] Jennifer Cacchio, *What You Don't Know Can Hurt You: The Legal Risk of Peering into the Gene Pool with Direct-to-Consumer Genetic Testing*, 87 UMKC L. REV. 219, 221 (2018).

[23] *Understanding Human Genetic Variation*, *supra* note 19.

Huntington's Disease, while others can confer protection against infectious diseases, like a mutation in the *CCR5* gene that confers protection against the Human Immunodeficiency Virus (HIV) retrovirus.[24]

Understanding genetic variation is important because it is arguably one of the most prescient indicators for fighting disease. Nearly every human disease has a genetic component, from cystic fibrosis to diabetes, heart disease and cancer.[25] Cancer, the second leading cause of death in the United States, is caused by an accumulation of genetic polymorphisms in a cell.[26] Additionally, there are some germline genetic mutations that can greatly increase an individual's risk of developing cancer.[27] For example, only 13% of women in the general population will develop breast cancer, but 55–72% of women with *BRCA1* mutations will develop breast cancer by age seventy or eighty.[28]

Outside of genetic status, an important distinction in the field of medical genetics is whether a mutation is somatic, germline, or de novo. Somatic mutations are those that occur after birth but are not present in any germ cells—such as egg cells or sperm.[29] Germline mutations are those present in reproductive cells that are inherited from generation to generation and are incorporated into every cell of the individual.[30] De novo mutations, meaning "from the beginning" in Latin, are those that occur during gametogenesis—the process in which females and males make eggs and sperm—and thus are present in the child but not the parent.[31] These critical distinctions determine whether a potentially deleterious (i.e., pathogenic) mutation is inheritable and thus affects an entire family or only the individual tested. Such distinctions also mean that your genetic test results reflect not only your own genetic makeup, but also those of your mother, father, sibling, cousins, and even more distant relatives. In addition to deleterious mutations, there are also variants of unknown significance (VUS), wherein the mutation's effect on clinical disposition is unknown, and silent mutations, wherein there is no discernible impact on clinical

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[24] *Id.*

[25] *Id.*

[26] Leif W. Ellisen & Daniel A. Haber, *Basics Principles of Cancer Genetics*, *in* PRINCIPLES OF CLINICAL CANCER GENETICS: A HANDBOOK FROM THE MASSACHUSETTS GENERAL HOSPITAL 1, 1 (Daniel C. Chung & Daniel A. Haber eds., 2010).

[27] *See generally id.*

[28] *BRCA Gene Mutations: Cancer Risk and Genetic Testing*, NAT'L CANCER INST., https://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet (last updated Nov. 19, 2020).

[29] *Somatic Variant*, NAT'L CANCER INST., https://www.cancer.gov/publications/dictionaries/genetics-dictionary/def/somatic-variant (last visited July 31, 2022).

[30] *Germline Mutation*, NAT'L CANCER INST., https://www.cancer.gov/publications/dictionaries/genetics-dictionary/def/germline-mutation (last visited July 31, 2022).

[31] *De Novo Mutation*, NAT'L CANCER INST., https://www.cancer.gov/publications/dictionaries/genetics-dictionary/def/de-novo-mutation (last visited July 31, 2022).

disposition.[32] This scientific theory and terminology is the backdrop for understanding the clinical impact of genetic tests.

1. Genetic Testing in Action: Angelina Jolie's Story

Our genes can be described in a variety of metaphors, such as the blueprint for protein formation or alternatively, as the user manual for our construction and operation.[33] If our genes are a manual, a genetic test represents the Rosetta Stone for reading our genetic code.[34] To illustrate this, let's look to the *BRCA1* gene, which encodes a protein involved in repairing DNA after it has been damaged (such as after a sunburn).[35] Because cancer is merely an accumulation of genetic mutations over time that result in cellular dysfunction (i.e., tumors),[36] a failure for adequate DNA repair (e.g., due to a dysfunctional mutation in *BRCA1*) can result in an 80% lifetime risk of developing breast cancer.[37] Additionally, *BRCA1* mutations are typically germline mutations that are passed from parent to child.[38] Because of this hereditability and heightened risk, families with a *BRCA1* mutation typically have numerous members that have battled cancer.[39]

Angelina Jolie is one such example.[40] Her mother had died at fifty-six from breast cancer, and Jolie's children would ask if the same could happen to her.[41] In fact, Jolie received a genetic test for *BRCA1* because of her heightened risk for developing cancer.[42] The *BRCA1* test came back with a deleterious mutation.[43] Her doctors estimated Jolie had an eighty-seven percent risk for developing breast cancer and a fifty percent risk for developing ovarian cancer.[44] Because of this astronomical risk, her medical team, who also administered the genetic test, recommended that she embark on a three-month surgical journey to

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[32] *See* Romy L.S. Mesman, Fabienne M.G.R. Calléja, Giel Hendriks, Bruno Morolli, Branislav Misovic, Peter Devilee, Christi J. van Asperen, Harry Vrieling & Maaike P.G. Vreeswijk, *The Functional Impact of Variants of Uncertain Significance in BRCA2*, 21 GENETICS MED. 293, 293 (2019).

[33] Adrian Woolfson, *A Genetic Pandora's Box*, WALL ST. J. (Mar. 10, 2017, 1:41 PM), https://www.wsj.com/articles/a-genetic-pandoras-box-1489171299.

[34] *See id.*

[35] Simon N. Powell & Lisa A. Kachnic, *Roles of BRCA1 and BRCA2 in Homologous Recombination, DNA Replication Fidelity and the Cellular Response to Ionizing Radiation*, 22 ONCOGENE 5784, 5784 (2003).

[36] Ellisen & Haber, *supra* note 26.

[37] Powell & Kachnic, *supra* note 35.

[38] *Id.* The exception are de novo mutations, wherein the deleterious mutation occurs during gametogenesis and thus is only present in the next generation. NAT'L CANCER INST., *supra* note 29.

[39] *See* Powell & Kachnic, *supra* note 35.

[40] *See generally* Angelina Jolie, Opinion, *My Medical Choice*, N.Y. TIMES (May 14, 2013), https://www.nytimes.com/2013/05/14/opinion/my-medical-choice.html.

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *Id.*

undergo a preventative double mastectomy removing all breast tissue.[45] This procedure reduced her risk of breast cancer to five percent.[46]

Unfortunately, Angelina Jolie's story is not a one-off. Hereditary cancers (i.e., those driven by germline mutations) represent approximately 10% of the estimated 19.3 million worldwide cancer cases in 2020.[47] For many people, obtaining genetic testing is a way to safeguard their health by evaluating their risk of future illness.

B. THE SHARING PARADOX: KNOWING MORE BY HAVING MORE

In order for genetic test results to hold any meaning, scientists and researchers must know each gene's function. There are over 30,000 genes composed of more than three billion base pairs in every human genome.[48] By compiling large amounts of genetic data, scientists can study genetic correlations between a mutation's presence and disease progression.[49]

The cost of human genome sequencing has significantly decreased since its inception. In 2003, sequencing an entire genome cost $2.7 billion.[50] Now it is less than $1,000.[51] Sequencing can even be performed overnight.[52] Thus, the field of genetics has become more accessible because of this rapid drop in cost. This accessibility has evolved from the realm of research scientists to the realm of everyday consumers—through both direct-to-consumer offerings and testing through medical providers. Increased access has consequently led to the evaluation of over twelve million genomes.[53] With such a substantial rise in

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[45] *Id.* She would later go on to have a bilateral salpingo-oophorectomy (i.e., removal of both ovaries and fallopian tubes) to reduce her risk of ovarian cancer. Alice Park, *Why Angelina Jolie Chose to Have Her Ovaries Removed*, TIME (Mar. 24, 2015, 6:30 PM), https://time.com/3756167/angelina-jolie-ovaries-removed-cancer/.

[46] Jolie, *supra* note 40.

[47] Hyuna Sung, Jacques Ferlay, Rebecca L. Siegel, Matthieu Laversanne, Isabelle Soerjomataram, Ahmedin Jemal & Freddie Bray, *Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries*, 71 CA: CANCER J. FOR CLINICIANS 209, 209 (2021) (discussing the worldwide prevalence of cancer in 2021); Fawz S. AlHarthi, Alya Qari, Alaa Edress & Malak Abedalthagafi, *Familial/Inherited Cancer Syndrome: A Focus on the Highly Consanguineous Arab Population*, 3 NPJ GENOMIC MED. 1, 1 (2020) (describing the prevalence of hereditary cancer syndromes both worldwide and in particular populations).

[48] *See Human Genome Project*, *supra* note 13.

[49] *See generally* Jeroen R. Huyghe et al., *Discovery of Common and Rare Genetic Risk Variants for Colorectal Cancer*, 51 NATURE GENETICS 76 (2019).

[50] U.S. DEP'T OF ENERGY, *supra* note 2; *The Cost of Sequencing a Human Genome*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/about-genomics/fact-sheets/Sequencing-Human-Genome-cost [hereinafter *The Cost of Sequencing a Human Genome*] (last updated Nov. 1, 2021).

[51] U.S. DEP'T OF ENERGY, *supra* note 2; *The Cost of Sequencing a Human Genome*, *supra* note 50.

[52] Jon Gertner, *Unlocking the Covid Code*, N.Y. TIMES (Mar. 25, 2021), https://www.nytimes.com/interactive/2021/03/25/magazine/genome-sequencing-covid-variants.html?searchResultPosition=1.

[53] *See* Mwenza Blell & M.A. Hunter, *Direct-to-Consumer Testing's Red Herring: "Genetic Ancestry" and Personalized Medicine*, 6 FRONTIERS MED. 1, 1 (2019).

testing, there is a corresponding rapid increase in the amount of data that exists, leaving scientists with the evolving issue of how to analyze that data.

A solution to this problem is using computer algorithms and analytics.[54] Looking back to the previous Subpart, there are generally three types of polymorphisms in the realm of genetic counseling (i.e., using genomic information to counsel medical decision-making):[55] deleterious mutations (i.e., those that increase the risk of genetic illness), variants of unknown significance (i.e., variants whose clinical outcomes are unknown), and silent mutations (i.e., those whose clinical outcomes are negligible).[56]

To simplify an incredibly complex sector of computer science, algorithms and analytics use large amounts of data to find correlations between polymorphisms (i.e., genetic variations between individuals) and disease outcomes.[57] To illustrate this, a recent study in *Nature Genetics* identified forty new "associations" between variants and an increased genetic risk of colorectal cancer.[58] But researchers needed to analyze 31.8 million genetic variations in order to identify those new associations.[59] It is important to note that this study was looking specifically for rare and low-frequency variations, but the lesson is nonetheless the same; in order to continue making novel discoveries about the role our genetics play in disease association and progression, a large amount of information needs to be compiled and subsequently analyzed.[60]

The easiest and best way to learn more about the genome is to analyze more data. The only way to acquire more genomic data is to sequence more individuals' genes and, potentially, their entire genome. This means that any potential regulation regarding genetic information must necessarily balance the competing interests in sharing and adequately protecting the consumer from unauthorized use and disclosure. On this balancing act, Eric Green, director of the U.S. National Human Genome Research Institute said, "[o]ne value is to make the data as widely available and unencumbered as possible, but then you're trading that off against concerns about how data is being used, and maintaining privacy and confidentiality . . . . We're constantly exploring models that put us between those two extremes."[61] This presents a significant paradox for the field

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[54] *See* Shital Shah & Andrew Kusiak, *Cancer Gene Search with Data-Mining and Genetic Algorithms*, 37 COMPUTS. BIOLOGY & MED. 251, 253 (2007).

[55] *See supra* Part I.A.

[56] *See supra* Part I.A.

[57] *See generally* Shah & Kusiak, *supra* note 54. For an in-depth look at another method of genomic data analysis, see generally Jae K. Lee, Paul D. Williams & Sooyoung Cheon, *Data Mining in Genomics*, 28 CLINICS LAB'Y MED. 145 (2008).

[58] Huyghe et al., *supra* note 49.

[59] *Id.*

[60] *See generally id.*; *see also* Shah & Kusiak, *supra* note 54.

[61] Erika Check Hayden, *The Genome Hacker*, 497 NATURE 172, 174 (2013).

of genetics: the only way to learn more about the genome is to have more data, amplifying privacy and confidentiality concerns.

C. GENETIC TESTING, FROM TRAINED PROFESSIONALS TO CONSUMERS: DEMOCRATIZATION OR EXPLOITATION?

1. Direct-to-Consumer Testing Offers an Alternative to Testing Through Genetic Counselors

Following the genomic revolution (i.e., the sequencing of the human), our understanding of genetic illness has increased greatly.[62] This increased knowledge has led to an increased interest in medical genetics—the science of human biological variation as it relates to health and disease—and an integration of genetics into healthcare decision-making.[63] If an individual or their supervising healthcare practitioner is concerned about potential genetic illness, their physician would refer them to a genetic counselor and/or a geneticist.[64]

A genetic counselor is a trained healthcare professional with at least a master's degree and is certified by the American Board of Genetic Counseling (ABGC) to help a patient understand, cope with, and diagnose genetic illnesses.[65] A geneticist is a physician, meaning that they have completed medical school and residency, that is board-certified by the American Board of Medical Genetics and Genomics (ABMGG) and specializing in medicine involving the interactions between genes and health.[66] In total, an ABGC-certified genetic counselor has at least six years of post-secondary education (four years of undergraduate education and two years of graduate education), whereas an ABMGG board-certified geneticist has at least eleven years of post-secondary education (four years of undergraduate education, four years of medical school, and three years of genetic residency).[67] This advanced education is important, because genetically informed decision-making affects incredibly harmful illnesses such as breast and colorectal cancer.[68]

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[62] *See generally* Charles J. Epstein, *Medical Genetics in the Genomic Medicine of the 21st Century*, 79 AM. J. HUM. GENETICS 434 (2006).

[63] *Id.*

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

[65] *Becoming a Genetic Counselor*, NAT'L SOC'Y OF GENETIC COUNS., https://www.nsgc.org/About/Becoming-a-Genetic-Counselor (last visited July 31, 2022).

[66] *Medical Genetics and Genomics*, AM. BD. OF MED. SPECIALTIES, https://www.abms.org/board/american-board-of-medical-genetics-and-genomics/ (last visited July 31, 2022).

[67] *See* NAT'L SOC'Y OF GENETIC COUNS., *supra* note 65 (describing the requirements of a genetic counselor); *see also* AM. BD. OF MED. SPECIALTIES, *supra* note 66 (describing the requirements of a board-certified geneticist).

[68] *See generally* Mesman et al., *supra* note 32 (breast cancer); *see also* Huyghe et al., *supra* note 49 (colorectal cancer).

Direct-to-consumer genetic testing companies seek to circumvent these specialized practitioners by selling genetic tests directly to patients, regardless of whether they have a medical team in place to deal with the fallout.[69] As this Note will describe at length, direct-to-consumer genetic testing companies largely evade federal regulations and are not covered by HIPAA. This presents numerous regulatory challenges and results in unique harms. To understand these challenges and harms, it is important to first understand the direct-to-consumer genetic testing industry.

2. *The Direct-to-Consumer Business Model: Is It Big Tech in a Lab Coat?*

In 2016, 246 different companies offered some form of online DNA test and served over twelve million individuals users.[70] By 2019, more than twenty-six million individuals had used the top four direct-to-consumer testing companies: 23andMe, AncestryDNA (Ancestry.com), FamilyTreeDNA, and MyHeritage.[71] In the two decades this industry has existed, these ventures have been incredibly lucrative.[72] By 2028, the direct-to-consumer genetic testing market is estimated to exceed $3.4 billion.[73]

The business model of these companies varies greatly from those of medical genetics companies.[74] First, direct-to-consumer companies have two main revenue sources: the sales of the tests to consumers and then selling consumers' data to secondary companies.[75] Second, some companies offer subscription services wherein consumers pay a yearly fee to have their samples reanalyzed as new deleterious mutations are identified.[76] This business model is in stark contrast with the medical model, wherein the product price is tied to the healthcare payment model (i.e., insurance), and any secondary use is mostly limited to healthcare research purposes.[77] The medical model is possible because

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[69] *See* Blell & Hunter, *supra* note 53.

[70] *See id.*

[71] Antonio Regalado, *More than 26 Million People Have Taken an At-Home Ancestry Test*, MIT TECH. REV. (Feb. 11, 2019), https://www.technologyreview.com/2019/02/11/103446/more-than-26-million-people-have-taken-an-at-home-ancestry-test/.

[72] Sumant Ugalmugle & Rupali Swain, *DTC Genetic Testing Market to Exceed US $3.4 Bn by 2028*, GLOB. MKT. INSIGHTS (Feb. 28, 2020), https://www.gminsights.com/pressrelease/direct-to-consumer-dtc-genetic-testing-market [https://web.archive.org/web/20210615124651/https://www.gminsights.com/pressrelease/direct-to-consumer-dtc-genetic-testing-market].

[73] *Id.*

[74] *See* Megan Allyse, David Robinson, Matthew Ferber & Richard Sharp, *Direct-to-Consumer Testing 2.0: Emerging Models of Direct-to-Consumer Genetic Testing*, 93 MAYO CLINIC PROC. 113, 120 (2018).

[75] *Id.* at 115.

[76] *See, e.g.*, *Compare 23andMe DNA Test Kits*, 23ANDME, https://www.23andme.com/compare-dna-tests/?gnav=gv1 (last visited July 31, 2022).

[77] Allyse et al., *supra* note 74, at 115.

the HIPAA largely prevents the commercialization of patient health data.[78] The implications of these two revenue streams will occur in turn.

The first revenue stream is selling the genetic tests to the consumer. These tests are simple: a consumer buys a test online, receives a kit in the mail, collects the DNA sample in their home and mails it back.[79] These tests are as low as $99.[80] The company then analyzes the consumer's DNA and sends the consumer individualized results.[81] From a business perspective, this revenue stream is straightforward and similar to any other product-driven business model.

The second revenue stream, selling access to data, is more complicated. In general, DNA associations are made by associating particular polymorphisms with a particular outcome.[82] In the medical context, particular polymorphisms are associated with particular disease outcomes. In the ancestral context, particular polymorphisms are associated with particular ethnic groups with strong geographic ties and little migration.[83]

As was necessary in the colorectal cancer association study analyzing 31.8 million polymorphisms, these companies need to amass an incredible amount of data in order to deliver on their promises to consumers.[84] 23andMe has amassed a repository of over two million individual genomes, and Ancestry.com, a company that started as a genealogy magazine, has amassed over five million DNA profiles.[85] By January 2019, the top four direct-to-consumer genetic testing companies—23andMe, AncestryDNA, FamilyTreeDNA, and MyHeritage—amassed more than twenty-six million individuals' genetic profiles.[86]

Notably, it is not just the companies that administer genetic testing that have amassed large repositories of genetic profiles; companies that merely find associations (i.e., finding links between individuals' various polymorphisms) also exist.[87] One such company, GEDmatch, created a product that allows

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[78] 45 C.F.R. §§ 164.501, 164.508(a)(3) (2020); *see also Marketing*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Apr. 3, 2003), https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/marketing/index.html [hereinafter *Marketing*].

[79] Andelka M. Phillips, *'Only a Click Away — DTC Genetics for Ancestry, Health, Love . . . and More: A View of the Business and Regulatory Landscape'*, 8 APPLIED & TRANSLATIONAL GENOMICS 16, 16 (2016).

[80] 23ANDME, *supra* note 76.

[81] *How it Works*, 23ANDME, https://www.23andme.com/howitworks/?gnav=gv1 (last visited July 31, 2022).

[82] *See* Shah & Kusiak, *supra* note 54, at 251.

[83] *Id.* at 1 (discussing the medical outcome association); Blell & Hunter, *supra* note 53, at 2 (discussing ancestral association).

[84] *See* Huyghe et al., *supra* note 49, at 76, 82.

[85] Catherine Arcabascio, *A Genetic Surveillance State: Are We One Buccal Swab Away from a Total Loss of Genetic Privacy?*, 63 HOW. L.J. 117, 123 (2020).

[86] *Id.*; Regalado, *supra* note 71.

[87] Arcabascio, *supra* note 85; *see also* Heather Murphy, *What You're Unwrapping When You Get a DNA Test for Christmas*, N.Y. TIMES (Dec. 23, 2019), https://www.nytimes.com/2019/12/22/science/dna-testing-kit-present.html.

individuals to upload their genetic information procured from other genetic testing companies like 23andMe and Ancestry.com to potentially find new relatives.[88] GEDmatch was able to amass over 1.3 million genetic profiles before the company's shutdown due to a data breach that leaked users' genetic information to law enforcement.[89]

Not only is the aggregated genomic data important for making decisions regarding the status and phenotype of certain polymorphisms, but selling access to that underlying data is also incredibly valuable.[90] In February 2015, 23andMe sold access to its aggregate genomic information to Genentech for $60,000,000.[91] 23andMe has also signed deals with Pfizer and twelve other entities for an undisclosed price.[92] In 2018, the company announced that GlaxoSmithKline, one of the world's largest pharmaceutical companies, will invest $300,000,000 into 23andMe and gain exclusive rights to mine customer data for potential drug targets.[93] These are just a few examples from a single company, and not even the company with the largest aggregated database (AncestryDNA). It should be noted that AncestryDNA, through its privacy agreement, has a "perpetual, royalty-free, worldwide, transferable license to use [a consumer's] DNA."[94] This industry is expanding exponentially in both the amount of data created and the money being made.

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[88] Murphy, *supra* note 87.

[89] *Id.* It should be noted that given the free nature of the upload, law enforcement already had near unfettered access to the company's database and had utilized it numerous times to find the relatives of DNA samples in criminal cases, most notably in the 2018 Golden State Killer. Zach Whittaker, *GEDmatch Confirms Data Breach After Users' DNA Profile Data Made Available to Police*, TECH CRUNCH (July 22, 2020, 10:01 AM), https://techcrunch.com/2020/07/22/gedmatch-investigating-dna-profile-law-enforcement/.

[90] *See* Ifeoma Ajunwa, Opinion, *There's No Guarantee of Anonymity*, N.Y. TIMES (Mar. 4, 2015), https://www.nytimes.com/roomfordebate/2015/03/02/23andme-and-the-promise-of-anonymous-genetic-testing-10/theres-no-guarantee-of-anonymity.

[91] *Id.*; *see also* Matthew Herper, *Surprise! With $60 Million Genentech Deal, 23andMe Has a Business Plan*, FORBES (Jan. 6, 2015, 9:58 AM), https://www.forbes.com/sites/matthewherper/2015/01/06/surprise-with-60-million-genentech-deal-23andme-has-a-business-plan/?sh=3e4696a32be9 [hereinafter Herper, *Surprise!*].

[92] Mark Sullivan, *23andMe Has Signed 12 Other Genetic Data Partnerships Beyond Pfizer and Genentech*, VENTUREBEAT (Jan. 14, 2015, 7:00 PM), https://venturebeat.com/2015/01/14/23andme-has-signed-12-other-genetic-data-partnerships-beyond-pfizer-and-genentech/; Caroline Chen, *23andMe Turns Spit into Dollars in Deal with Pfizer*, BLOOMBERG (Jan. 12, 2015, 3:29 PM), https://www.bloomberg.com/news/articles/2015-01-12/23andme-gives-pfizer-dna-data-as-startup-seeks-growth.

[93] Megan Molteni, *23andMe's Pharma Deals Have Been the Plan All Along*, WIRED (Aug. 3, 2018, 3:28 PM), https://www.wired.com/story/23andme-glaxosmithkline-pharma-deal/; *GSK and 23andMe Sign Agreement to Leverage Genetic Insights for the Development of Novel Medicines*, GLAXOSMITHKLINE (July 25, 2018), https://www.gsk.com/en-gb/media/press-releases/gsk-and-23andme-sign-agreement-to-leverage-genetic-insights-for-the-development-of-novel-medicines/.

[94] Deborah C. Peel, *Opinion*, *The Hidden Danger of Do-It-Yourself Genetic Tests*, NEWSWEEK (Dec. 16, 2017, 7:20 AM), https://www.newsweek.com/hidden-danger-do-it-yourself-genetic-tests-749475?utm_source=email&utm_medium=morning_brief&utm_campaign=newsletter&utm_content=read_more&spMailingID=2668187&spUserID=MzQ4OTU1MjQzODUS1&spJobID=930723861&spReportId=OTMwNzIzODYxS0.

But enticing customers to a product and then turning around to sell customer data to third parties is not new. Facebook and Google have implemented similar business models.[95] In fact, those companies' ties run deeper than just their similar business models. Google was a substantial initial backer of 23andMe, and the company was founded by Anne Wojcicki, the ex-wife of Google co-founder Sergey Brin.[96] Additionally, Facebook billionaire Yuri Milner was an early backer of 23andMe.[97] Amnesty International has called both Facebook's and Google's business practices an "assault on privacy."[98] Moreover, expanding this business model to the context of health data collection by private companies raises unique privacy and regulatory concerns.

D. DIRECT-TO-CONSUMER TESTING RAISES UNIQUE PRIVACY AND REGULATORY CONCERNS

Genetic testing has the potential to radically change disease progression, because our genetics play a role in nearly every illness.[99] While the direct-to-consumer companies may be off to the races and out of the gates, this is neither the Kentucky Derby nor a spectacle for all to benefit from. This Triple Crown presents significant privacy and regulatory concerns, unraised through by other types of medical data.

This Subpart examines two issues raised by genetic testing. First, it examines whether consumers are getting a one-time medical metric, or, as the *Sharing Paradox* teaches, opening Pandora's box because with more data comes more information and the underlying analyte of genetic testing is always the same—the consumer's DNA.[100] Second, DNA is an immutable characteristic and generally remains unchanged throughout an entire individual's life, unlike most other health metrics like blood pressure or lifestyle choices.[101] Moreover, DNA is what makes each individual fundamentally unique, with no two people sharing the same genome.[102] Current regulation freely allows the sharing of de-identified information; but that begs the question of whether an immutable and

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[95] Molteni, *supra* note 93.

[96] *See generally* Google, Inc., Current Report (Form 8-K) (May 22, 2007).

[97] Matthew Herper, *23andMe Nabs Billionaire Yuri Milner as Investor, Cuts Price to $99*, FORBES (Dec. 11, 2012, 11:56 AM), https://www.forbes.com/sites/matthewherper/2012/12/11/23andme-nabs-billionaire-yuri-milner-as-investor-cuts-price-to-99/?sh=6b4f8d1137c5.

[98] Zoe Schiffer, *Facebook and Google Surveillance Is an 'Assault on Privacy,' Says Amnesty International*, THE VERGE (Nov. 20, 2019, 7:13 PM), https://www.theverge.com/2019/11/20/20974832/facebook-google-surveillance-data-assault-privacy-amnesty-international.

[99] *Understanding Human Genetic Variation*, *supra* note 19, at 11.

[100] *See infra* Part I.D.*1*.

[101] *See generally* URRY ET AL., *supra* note 8, at 269–465 (describing human genetics from its foundational history to genomic engineering and manipulation).

[102] This excludes identical twins and other polyzygotic siblings. *Understanding Human Genetic Variation*, *supra* note 19.

highly individualized characteristic can ever be truly divorced from that individual?[103]

1. *Are Consumers Conjuring a Crystal Ball or Opening Pandora's Box?*

Direct-to-consumer genetic testing companies currently offer a variety of tests, including: ancestry, future athletic ability, paternity, relatedness, health-related tests (e.g., propensity for genetically influenced disease), and even tests for child talent, matchmaking, and "proving infidelity."[104] One of the largest direct-to-consumer genetic testing companies, 23andMe, offers over 150 personalized reports ranging from ancestry, breast cancer risk, and whether an individual is capable of matching a musical pitch.[105]

However, despite the range of results and tests from these companies, the underlying analyte (i.e., the substance that was identified, measured, and/or analyzed) is always the same; it is the individual's DNA sequence.[106] No matter which segment of DNA is being analyzed for that particular trait, an individual's DNA sequence remains the same. To illustrate this, imagine holding a soccer ball. You may be paying attention only to the black pentagons on the ball or perhaps counting how many stitches are on it, but you are still holding the same soccer ball with the same number of stitches. Consequently, no amount of selective looking can negate the fact that when a company peers into the genome, they have access to *all* of the person's genes.

This is why numerous direct-to-consumer companies warn that a risk of genetic testing is learning about information that an individual was not initially looking for.[107] 23andMe takes the opposite approach and embraces this unknown by offering a subscription service that allows a consumer's data to be continuously reanalyzed as newer tests are implemented.[108] Additionally, the company offers a *BRCA* test that is not comprehensive and "should not be used to make medical decisions."[109] However, "should a consumer choose to forgo a *BRCA* test on the first run, 23andMe is committed to guiding the consumer through the landscape of BRCA, regardless of whether or not you choose to access this report."[110] FamilyTreeDNA, an ancestry website that does not offer any clinical or diagnostic testing, fully discloses on their website that there is

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[103] *See infra* Part I.D.*2*.

[104] Phillips, *supra* note 79.

[105] *Health + Ancestry Service*, 23andMe, https://www.23andme.com/dna-health-ancestry (last visited July 31, 2022).

[106] *See generally* Phillips, *supra* note 79.

[107] *AncestryDNA Informed Consent*, Ancestry, https://www.ancestry.com/dna/lp/informedconsent-v4-en#8 (effective July 24, 2018).

[108] 23andMe, *supra* note 76.

[109] *See BRCA Genes*, 23andMe, https://www.23andme.com/brca/ (last visited July 31, 2022).

[110] *Id.*

"no assurance that the raw data of any tests of any kind" can be decoupled from other types of genetic data when analyzed by a "qualified person."[111]

Thus, there is a concern of whether direct-to-consumer companies are potentially trafficking in medical testing, despite conducting testing for nonmedical purposes. The U.S. FDA has shared this concern and in 2010 intervened in 23andMe and other direct-to-consumer genetic companies' practices.[112] The FDA intervened because of the belief that the direct-to-consumer genetic tests should be characterized as medical devices, as their results might be used in clinical decision making.[113] In 2017, 23andMe became the first FDA-approved direct-to-consumer company after receiving approval for ten of its over 150 tests.[114] Therefore, genomic data should be considered as medical data because the same underlying data is used for all tests, regardless of FDA approval.

Because genetic data is necessarily medical data, its possession by nonmedical entities raises questions when it comes to data privacy. Direct-to-consumer genetic testing companies have accrued large amounts of individual medical data, irrespective of the manner of testing. Accordingly, direct-to-consumer genetic testing companies may be prone to data breaches that can be catastrophic and unquantifiable in harm. In fact, these companies struggle with defining the harms associated with a genetic data breach in the informed consent section. For example, AncestryDNA—a company that does not offer medical or health testing—lists: the risk of being identified, the risk of having biological samples lost or stolen, and learning information about the consumer and their relatives that they do not expect or may make them uncomfortable, such as health risks.[115] Most importantly, the last line warns of additional risks that are currently unforeseeable.[116] 23andMe similarly warns that there are additional risks that are unforeseeable.[117]

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[111] *Common Questions*, FAMILYTREEDNA, https://learn.familytreedna.com/faq (last visited July 31, 2022).

[112] Andrew Pollack, *F.D.A. Faults Companies on Unapproved Genetic Tests*, N.Y. TIMES, June 12, 2010, at B2 [hereinafter Pollack, *F.D.A. Faults Companies*].

[113] *Id.*

[114] *See FDA News Release: FDA Allows Marketing of First Direct-to-Consumer Test That Provides Genetic Information for Certain Conditions*, U.S. FOOD & DRUG ADMIN. (Apr. 6, 2017), https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-direct-consumer-tests-provide-genetic-risk-information-certain-conditions. Additionally, as of December 20, 2019, the last time the FDA website on direct-to-consumer testing approvals was updated, 23andMe is the only direct-to-consumer genetic testing company to have FDA approval as a health diagnostic. *Direct-to-Consumer Tests*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/in-vitro-diagnostics/direct-consumer-tests (last updated Dec. 20, 2019).

[115] ANCESTRY, *supra* note 107.

[116] *Id.*

[117] *Research Consent Document*, 23ANDME, https://www.23andme.com/about/consent (last visited July 31, 2022).

The risks of a breach are unforeseeable because, as the *Sharing Paradox* teaches, with more data comes more information. When individuals take a genetic test, regardless of the purpose, they are exchanging medical data, the results of which can be constantly reinterpreted as more information comes to light. This begs one question: when a person takes a genetic test, are they peering into a crystal ball to learn about themselves, or are they opening Pandora's box?

2. *The De-Identification Paradox: Can Our Genes Be Unzipped from Us?*

Those who have watched an episode of *CSI, Law & Order*, or any law enforcement procedural know that DNA profiling is widely used in crime scene analytics from a mere few drops of blood.[118] Our blood, which contains our DNA, is useful because of DNA's inherently unique and immutable characteristics.[119] As will be discussed in more detail in Part III, current regulations allow medical data to be shared when it is de-identified, presumably meaning it will not be traced back to the originating patient.[120] However, this Subpart examines whether all identifying traits can truly be removed from an individual's DNA sequence.

Recall from Part I that all individuals' DNA differ by only about one in 1,000 nucleotides, or 0.1%.[121] Because of this relatively small amount of variability, genomic data is highly distinguishable, and thus identity confirmation can occur with as few as thirty to eighty single nucleotide polymorphisms (SNPs) (i.e., variations between individuals).[122] Typically, medical and biometric data is de-identified by removing personally identifiable information, such as name, location, certain demographic information, and anything else that can be traced back to the patient.[123]

Returning to the blood pressure analogy, a de-identified record ready for sharing may contain the blood pressure, height, weight, age and maybe demographic information such as smoking habits, alcohol intake, and geographic region. If that data were shared, it would be impossible to track those

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[118] *See* Barbara L. Ley, Natalie Jankowski & Paul R. Brewer, *Investigating* CSI*: Portrayals of DNA Testing on a Forensic Crime Show and Their Potential Effects*, 21 PUB. UNDERSTANDING SCI. 51, 52 (2010).

[119] *See* URRY ET AL., *supra* note 8, at 269–465.

[120] *Guidance Regarding Method for De-Identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html (last updated May 31, 2022) [hereinafter *Guidance Regarding Method for De-Identification*].

[121] *See supra* Part I; Cacchio, *supra* note 22.

[122] Fida K. Dankar, Andrey Ptitsyn & Samar K. Dankar, *The Development of Large-Scale De-Identified Biomedical Databases in the Age of Genomics—Principles and Challenges*, 12 HUM. GENOMICS 1, 2 (2018).

[123] Justin Banda, *Inherently Identifiable: Is It Possible to Anonymize Health and Genetic Data?*, INT'L ASS'N OF PRIV. PROS., https://iapp.org/news/a/inherently-identifiable-is-it-possible-to-anonymize-health-and-genetic-data (last visited July 31, 2022).

metrics back to any one individual, because those data points are secondary to the driver of those values (i.e., the individual patient). It is not that simple with genomic data because the driver of genomic variation is the genetic data itself. Unlike blood pressure, which is temporal and can change throughout the day depending on salt intake,[124] genomic data is incredibly stable and undergoes very little change throughout a patient's lifetime.[125] Moreover, genomic data is what makes an individual fundamentally and molecularly unique.[126]

For example, in 2013, a researcher at Whitehead Institute, a world-renowned biomedical research institute, tracked down five randomly selected individuals from a database that contained only their DNA, age, and state of residence.[127] The researcher was able to not only identify each person, but also nearly fifty of their relatives.[128]

In another example, Yaniv Erlich—a computer science professor at Columbia University and Chief Science Officer of MyHeritage, one of the largest direct-to-consumer genetic testing companies—discovered in a now famous study that a genetic database needs to cover only 2% of a target population in order to provide at least a third-cousin match to nearly every person in the population and a second cousin match for nearly 65%.[129] For individuals of Northern European ancestry in the United States, one of the most tested groups, this database needs to reach only approximately three million individuals, a result Erlich found not only foreseeable, but imminent.[130]

Moreover, to test the risks of re-identification from supposedly de-identified genomic data, Erlich endeavored to identify an individual from the 1000 Genomes Project, a publicly accessible data repository that de-identified data in accordance with federal law.[131] To study the specific risks of direct-to-consumer genetic testing, the data file was reformatted to emualte direct-to-consumer companies.[132] Researchers knew only that the individual was a female Utah resident with Northern and Western European ancestry.[133] The file was uploaded to GEDmatch and, within an hour, an ancestor was directly identified

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[124] *See* Andrea Grillo, Lucia Salvi, Paolo Coruzzi, Paolo Salvi & Gianfranco Parati, *Sodium Intake and Hypertension*, NUTRIENTS, Aug. 21, 2019, at 1.

[125] Dankar et al., *supra* note 122.

[126] *Id.*

[127] Ajunwa, *supra* note 90.

[128] *Id.*

[129] Yaniv Erlich, Tal Shor, Itsik Pe'er & Shai Carmi, *Identity Inference of Genomic Data Using Long-Range Familial Searches*, 362 SCI. 690, 690 (2018).

[130] *See id.*

[131] *Id.* at 691.

[132] *Id.*

[133] *Id.*

using publicly available genealogical records.[134] Within a day, they had a name for the "de-identified" individual.[135]

The harms of a breach of genetic privacy cannot be overstated. DNA is one of the most stable identifying metrics in the natural world and is capable of identifying familial relationships after 3,000 years.[136] Individuals taking a genetic test without adequate safeguards are not only putting themselves at risk, but also their parents, relatives, and future offspring. For example, there are *founded* fears that if an individual were to gain unfettered access to a genetic database, they would be able to engineer a crime scene by planting synthesized genetic evidence.[137] Accordingly, because genomic data is unlike any other biometric data, it warrants heightened scrutiny and consideration under relevant privacy law.

II. CURRENT REGULATORY LANDSCAPE

The advancements in genetic sequencing and understanding should be lauded. However, as Senators James Jeffords and Tom Daschle observed at the start of the genomic era, "[w]ithout adequate safeguards, the genetic revolution could mean one step forward for science and two steps backwards for civil rights."[138] This Part examines the regulatory safeguards that are currently in place and their shortcomings. Notably, some states have tried to take action through stopgap measures, but with the extensive sharing of information between entities and national distribution of direct-to-consumer companies, it is widely believed that a federal solution should be in place.[139]

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[134] *Id.* at 692.

[135] *Id.*

[136] *See generally* Zahi Hawass, Yehia Z. Gad, Somaia Ismail, Rahab Khairat, Dina Fathalla, Naglaa Hasan, Amal Ahmed, Hisham Elleithy, Markus Ball, Fawzi Gaballah, Sally Wasef, Mohamed Fateen, Hany Amer, Paul Gostner, Ashraf Selim, Albert Zink & Carsten M. Pusch, *Ancestry and Pathology in King Tutankhamun's Family*, 303 J. AM. MED. ASS'N 638 (2010) (describing the genetic analysis of Ancient Egyptian pharaoh Tutankhamun and five generations of relatives who lived from 1550–1479 B.C.E.); Verena J. Schuenemann, Alexander Peltzer, Beatrix Welte, W. Paul van Pelt, Martyna Molak, Chuan-Chao Wang, Anja Furtwängler, Christian Urban, Ella Reiter, Kay Nieselt, Barbara Teßmann, Michael Francken, Katerina Harvati, Wolfgang Haak, Stephan Schiffels & Johannes Krause, *Ancient Egyptian Mummy Genomes Suggest an Increase of Sub-Saharan African Ancestry in Post-Roman Periods*, 8 NAT. COMM'NS 1 (2017) (using DNA to establish the familial and ancestral histories in mummies from the first millennia B.C.E.).

[137] Dan Frumkin, Adam Wasserstrom, Ariane Davidson & Arnon Grafit, *Authentication of Forensic DNA Samples*, 4 FORENSIC SCI. INT'L: GENETICS 95, 95 (2010); Andrew Pollack, *DNA Evidence Can Be Fabricated*, N.Y. TIMES (Aug. 17, 2009), https://www.nytimes.com/2009/08/18/science/18dna.html.

[138] James M. Jeffords & Tom Daschle, *Political Issues in the Genome Era,* 291 SCI. 1249, 1249–50 (2001).

[139] *See* Colin McFerrin, *DNA, Genetic Material, and a Look at Property Rights: Why You May Be Your Brother's Keeper*, 19 TEX. WESLEYAN L. REV. 967, 987–90 (2013) (detailing Alaska's Genetic Testing Statute and Massachusetts's Genetic Bill of Rights); *see also* Juan Pablo Sarmiento Rojas, *Direct-to-Consumer Genetic Testing: Rethinking Privacy Laws in the United States*, 14 HEALTH L. & POL'Y BRIEF 21, 34–35 (2020)

A. HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT OF 1996

The Health Information Portability and Accountability Act of 1996 is a federal regulation which advances a Privacy Rule to protect and maintain the confidentiality of a medical patient's individually identifiable health information.[140] In order to effectuate this goal, the law takes a "covered entity" approach. Under the law, covered entities are healthcare providers (e.g., doctors, clinics, psychologists, pharma, etc.), health plans (e.g., insurance companies), healthcare clearinghouses (i.e., an entity that processes healthcare information from one of the other covered entities), and any business associate who helps a covered entity carry out its healthcare activities and functions.[141] A HIPAA violation can result in civil or criminal liability and is only enforceable by state prosecutors and the Department of Health and Human Services.[142]

HIPAA's Privacy Rule sets restrictions on sharing patients' protected health information (PHI). PHI is any health care information that can be traced back to individual patients and there are limited circumstances regarding when and with whom it can be shared.[143] HIPAA did not explicitly designate genomic data as PHI until 2008.[144] PHI can be shared from one covered entity to another covered entity for activities defined as "health care operations." Even then, only the minimum information necessary for the operation at hand may be disclosed.[145] The definition of healthcare operations includes patient case management and contacting health professionals about treatment alternatives.[146] Additionally, the Privacy Rule bans a covered entity from selling PHI to any third party for that party's own use.[147] Any other disclosure requires patient authorization.[148]

HIPAA's Privacy Rule does not restrict the use or disclosure of de-identified data.[149] Under the statute, there are two methods by which PHI can be

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(discussing the Alaska Genetic Privacy Act, California Genetic Nondiscrimination Act (CalGINA) & California Consumer Privacy Act (CCPA)); Kristi Harbord, *Genetic Data Privacy Solutions in the GDPR*, 7 TEX. A&M L. REV. 269, 281 (2019) (advocating for a GDPR-style federal regulation).

[140] *Privacy in Genomics*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/about-genomics/policy-issues/Privacy (last updated Apr. 27, 2021) [hereinafter *Privacy in Genomics*].

[141] *Covered Entities and Business Associates*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html (last updated June 16, 2017) [hereinafter *Covered Entities and Business Associates*].

[142] 42 U.S.C. § 1320d-5 (2018).

[143] *Privacy in Genomics*, *supra* note 140.

[144] *Infra* Part II.B.

[145] 45 C.F.R. § 164.506(c)(4) (2020).

[146] *Id.* § 164.506(c)(5).

[147] *Id.* §§ 164.501, 164.508(a)(3); *see also Marketing*, *supra* note 78.

[148] *Understanding Some of HIPAA's Permitted Uses and Disclosures*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/permitted-uses/index.html (last visited July 31, 2022).

[149] *Privacy in Genomics*, *supra* note 140.

designated as de-identified: by expert determination or by the statute's "Safe Harbor" provision.[150] When de-identifying through expert determination, a qualified individual uses statistical and scientific principles to remove identifying features to the degree that any anticipated recipient of the information could not identify the individual.[151] The de-identification protocol under the Safe Harbor provision involves the removal of eighteen types of identifiers, supposedly resulting in no actual knowledge or residual information that can be used to identify the individual.[152]

HIPAA fails to provide adequate protection from direct-to-consumer genetic testing companies for two reasons. First, direct-to-consumer genetic testing companies are not covered entities, and thus are not subject to regulation under the law. Second, even if these companies were covered entities, the Safe Harbor provision allows DNA to be classified as "de-identified," contrary to biological possibility, and thus still escape regulation.

Direct-to-consumer companies are not covered entities because their relationship to their customers is not initiated by a healthcare provider. In fact, the protection of this status is one that 23andMe, the only company with an FDA approved medical test, goes to great lengths to preserve.[153] When a genetic counselor recommends a test for their patient, rather than ordering the test themselves—the routine practice for medical genetics evaluations—23andMe uses an affiliate link, so that the consumer is the one who "orders" the test.[154] This preserves the direct-to-consumer relationship and prevents the company from being required to comply with HIPAA.

Even if direct-to-consumer companies were considered covered entities, because of the Safe Harbor provision, genomic data can still be considered de-identified. As the *De-Identification Paradox* teaches, this de-identification is biologically impossible. Identity can be confirmed with as few as thirty to eighty singular polymorphisms.[155] Moreover, numerous studies have shown that "de-identified" genomic information can still be easily traced back to an individual.[156]

Because of the covered entity approach and the Safe Harbor provision, HIPAA does not provide adequate protection of genomic privacy in general, and especially from direct-to-consumer companies.

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[150] 45 C.F.R. §§ 164.514(b)(1), 164.514(b)(2) (expert determination and safe harbor, respectively).

[151] *Id.* § 164.514(b)(1); *see also Guidance Regarding Method for De-Identification*, *supra* note 120.

[152] 45 C.F.R. § 164.514(b)(2); *see also Guidance Regarding Method for De-Identification*, *supra* note 120.

[153] *See Getting Started.*, 23ANDME, https://medical.23andme.com/dna-kits/#getting-started (last visited July 31, 2022).

[154] *Id.*

[155] Dankar et al., *supra* note 122.

[156] *Supra* Part I.D.*2*.

B. GENETIC INFORMATION DISCRIMINATION ACT OF 2008

The first federal regulation to directly protect against discrimination based on genetic status is the Genetic Information Discrimination Act of 2008, commonly referred to as GINA.[157] When passed, Senator Ted Kennedy praised the law as "the first civil rights bill of the new century of the life sciences."[158] GINA protects individuals from discrimination by employers and health insurers when purchasing insurance.[159] Congress enacted GINA to alleviate concerns about the potential for genetic discrimination and to spur individual participation in genetic research and testing on the then new frontier.[160] Further, GINA amended HIPAA to explicitly define genetic information as health information.[161]

GINA uses a two-prong approach for regulation, with Title I containing the health-insurance provisions and Title II containing the employment provisions.[162] Title I is enforced by the Department of Health and Human Services (HHS), the Department of Labor, and the Department of the Treasury, whereas Title II is enforced by the Equal Employment Opportunity Commission (EEOC).[163] Notably, only Title II provides a private right of action and thus is limited to the employment discrimination context.[164]

Despite its initial acclaim, GINA confers minimal privacy protection to citizens due to significant limitations.[165] Besides being limited to the purchase of insurance and employment discrimination, GINA only applies to employers with more than fifteen employees; does not extend to life, long-term care, and disability insurances; and does not apply to the military and Indian Health Service.[166] Additionally, GINA does not apply if the individual is symptomatic for genetic illness.[167] Further, in a subsequent publication regarding the history

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[157] Genetic Information Nondiscrimination Act, Pub. L. 110-233, 122 Stat. 881 (2008). *See generally* Louise Slaughter, *Genetic Information Non-Discrimination Act*, 50 HARV. J. ON LEGIS. 41 (2013).

[158] Press Release, U.S. Senate Comm. on Health, Educ., Labor, & Pensions, Kennedy, Enzi, Snowe Celebrate Passage of Genetic Information Nondiscrimination Act (Apr. 24, 2008), https://www.help.senate.gov/ranking/newsroom/press/kennedy-enzi-snowe-celebrate-passage-of-genetic-information-nondiscrimination-act (quoting Senator Kennedy (D. Mass.)).

[159] 42 U.S.C. § 300gg-53.

[160] Slaughter, *supra* note 157, at 56.

[161] *Genetic Discrimination*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/about-genomics/policy-issues/Genetic-Discrimination (last visited July 31, 2022).

[162] Slaughter, *supra* note 157, at 56–57.

[163] *Genetic Information Discrimination*, EQUAL EMP. OPPORTUNITY COMM'N, https://www.eeoc.gov/genetic-information-discrimination (last visited July 31, 2022).

[164] 29 C.F.R. § 16351.1(a) (2021).

[165] Slaughter, *supra* note 157, at 56.

[166] *Id.* at 57, 59.

[167] *See* Adam Rogers, *The House Health Plan Makes Your Genes a Preexisting Condition*, WIRED (May 4, 2017, 7:55 PM), https://www.wired.com/2017/05/house-health-plan-makes-genes-preexisting-condition/. However, this limitation is blunted in the insurance arena due to the Affordable Care Act (ACA); Harbord, *supra*

and passage of GINA, former representative Louise Slaughter acknowledged that direct-to-consumer genetic testing presents a challenge to GINA that legislators could not have foreseen at the time of passage.[168] Former Representative Slaughter also defended GINA's shortcomings by declaring that "[j]ust as access to all civil rights developed in stages, a first step was taken with the passage of GINA, but it was only the first step. Clearly more work is needed to protect the American people."[169] Unfortunately, Congress has not taken the additional steps needed to protect Americans.

C. FEDERAL TRADE COMMISSION

The FTC regulates direct-to-consumer genetics testing only insofar as it runs afoul of section 5 of the Federal Trade Commission Act.[170] Section 5 of the FTCA concerns unfair or deceptive trade practices.[171] Under section 5, an act or practice is unfair if it "causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition."[172] Additionally, the FTC interprets section 5 to prohibit false or misleading claims about companies' privacy or security protections, and that a failure to employ reasonable security measures likely causes substantial consumer injury.[173]

A notable example of this interpretation is an action against Genelink, Inc. and Foru International Corp. for marketing skincare products and nutritional supplements purportedly based on the consumer's genetic profile while failing to take adequate precautions for consumer privacy. Among other claims, the company marketed its products as capable of overcoming a consumer's genetics to treat diabetes, heart disease, and insomnia.[174] More than that, the FTC also alleged deceptive and unfair security practices when the company, despite claiming reasonable and appropriate security measures, failed to use readily available security measures to even limit wireless access to their network.[175] This led to genetic information, social security numbers, bank account

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note 139, at 284; *see also* Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (codified as amended in scattered sections of 26 and 42 U.S.C.).

[168] Slaughter, *supra* note 157, at 64.

[169] *Id.* at 59.

[170] *Regulation of Genetic Tests*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/about-genomics/policy-issues/Regulation-of-Genetic-Tests [hereinafter *Regulation of Genetic Tests*] (last visited July 31, 2022).

[171] *Id.*

[172] 15 U.S.C. § 45 (2018).

[173] *Regulation of Genetic Tests*, *supra* note 170.

[174] *Companies Pitching Genetically Customized Nutritional Supplements Will Drop Misleading Disease Claims: GeneLink, Inc. and Former Subsidiary Also Agree to Improved Safeguards of Consumers' Sensitive Medical Information*, FED. TRADE COMM'N (Jan. 7, 2014), https://www.ftc.gov/news-events/press-releases/2014/01/companies-pitching-genetically-customized-nutritional-supplements.

[175] *Id.*

information, and credit card numbers being susceptible to attack.[176] When discussing the case, Jessica Rich, Director of the FTC's Bureau of Consumer Protection, said, "[i]t doesn't matter whether the claims deal with the benefits of direct-to-consumer genetic testing or the privacy of personal information. It's against the law to deceive people about your product and to make promises you don't keep."[177] This quote is prescient, because it illustrates that FTC enforcement and regulation can only reach the direct-to-consumer genetic testing sphere when the company misrepresents its products and the benefits they may confer.

Unfortunately, the FTC has to catch companies in a lie.[178] This represents a significant limitation on the FTC's enforcement capabilities, especially considering that companies can just be vague in revealing their privacy policies or may bury them in lengthy terms and conditions hoping no one will read them.[179] On this predicament, Rebecca Lipman, a privacy expert and senior counsel for the New York City Law Department wrote, "[i]f users do not do their homework on what information [companies] are collect[ing] about them, and the [companies] are not foolish enough to outright lie about what they are doing, the FTC's ability to control how companies share our data is very limited."[180] Looking specifically at 23andMe, Kayte Spector-Bagdady, a lawyer and bioethicist at the University of Michigan said, "[i]f you read the documents carefully, all the information is there. They really do disclose it all. The challenge is people don't read it."[181]

Simply burying the risks in the terms of service is insufficient to protect the consumer. It is widely known that most people do not read a company's privacy policies, despite agreeing to them.[182] In fact, this phenomenon has been coined "[t]he Biggest Lie on the Internet."[183] A 2016 study found that 74% of users skip reading a privacy policy entirely and simply accept it.[184] The study additionally found that 97% of users agreed to privacy policies after scanning it over for only thirty seconds.[185]

While this study focused on social media companies, direct-to-consumer companies also employ the same use of clickwrap and browse-wrap

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[176] *Id.*

[177] FED. TRADE COMM'N, *supra* note 174.

[178] Rebecca Lipman, *Online Privacy and the Invisible Market for Our Data*, 120 PENN ST. L. REV. 777, 789–90 (2016).

[179] *Id.* at 790.

[180] *Id.*

[181] Molteni, *supra* note 93.

[182] Jonathan A. Obar & Anne Oeldorf-Hirsh, *The Biggest Lie on the Internet: Ignoring the Privacy Policies and Terms of Service Policies of Social Networking Services*, 23 INFO. COMMS. & SOC'Y 128, 129 (2018).

[183] *Id.*

[184] *Id.* at 135.

[185] *Id.* at 141.

agreements.[186] Moreover, the terms of service are usually written at college reading levels—beyond the scope of the average consumer.[187] Experts have questioned whether consumers can "fully or partially understand DTC-GT [direct-to-consumer genetic testing] compan[ies'] consumer policies and agreements even when consumers take time to read them,"[188] especially when those terms regard the complicated underlying science of genomics. This means that companies do not have to lie; they can simply bury the truth in their terms of service and know that customers will either not read or understand it. Because of this, FTC regulation and enforcement are inadequate in protecting the American consumer.

III. PROPOSED REGULATORY SOLUTIONS

Congresswoman Slaughter said that GINA was only the first step; this Part proposes the next steps the Federal Government should take to ensure that American consumers' genetic privacy remains intact.

A. THE "COVERED ENTITY" APPROACH SHOULD BE OVERHAULED, AND A COVERED INFORMATION APPROACH INCLUSIVE OF ALL MEDICAL-RELATED PHI SHOULD BE ENACTED

The first step in protecting consumers' genetic privacy is amending HIPAA's covered entity approach, extending the statute's coverage to entities transacting in personally identifiable health-related data. As described in this Subpart, due to the nature of the covered entity approach, direct-to-consumer genetic testing companies fall outside the scope of healthcare privacy regulation.[189] This proposed amendment would bring direct-to-consumer genetic testing companies within the purview of HIPAA, the law that regulates privacy for medical records.

This proposition is intuitive, because the genetic data derived from a genetic counselor and the genetic data derived from a direct-to-consumer company are the exact same: the patient-consumer's DNA. Additionally, this approach makes sense, because direct-to-consumer genetic testing companies are carefully watched by the FDA, as evidenced by its intervention in 2010.[190] Moreover, the FDA actively regulates 23andMe—the direct-to-consumer company with the most diverse product offerings—because it is a *medical diagnostic* company.[191] Because of the covered entity approach, 23andMe does

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[186] Rachele M. Hendricks-Sturrup & Christine Y. Lu, *Direct-to-Consumer Genetic Testing Data Privacy: Key Concerns and Recommendations Based on Consumer Perspectives*, 9 J. PERSONALIZED MED. 25, 27 (2019).

[187] *Id.*

[188] *Id.*

[189] *See Covered Entities and Business Associates*, *supra* note 141.

[190] Pollack, *F.D.A. Faults Companies*, *supra* note 112, at B2.

[191] *Id.*

not need to protect their consumer's records at the same standards as medical genetics companies. This is a loophole that must be closed.

This approach has been implemented elsewhere by the European Union's General Data Privacy Regulation (GDPR).[192] The GDPR covers the collection, processing, and sharing of any personally identifiable data of any nature.[193] The GDPR is an incredibly broad regulation that is outside the scope of this Note.

However, this Note is not advocating for the wholesale import of the GDPR or the regulation of a specific type of actor. Rather, this Note is advocating for only the adoption of the GDPR's approach of regulating a specific type of data. This approach should also be limited to the regulation of *health* data in the United States.

The exact definition of health data is left to Congress but should at least include genomic data. The danger of this approach is that an overly broad definition of health data additionally sweeps up fitness apps and other companies that transact in certain health metrics, such as blood pressure machines in local pharmacies or heart-rate fitness monitors. Thus, the definition of health data should be carefully drafted with such potential consequences in mind.

If the covered entity approach is abandoned and replaced with a health data standard, companies will be unable to avoid medical data privacy laws solely because of a direct-to-consumer relationship. This is important, because a direct-to-consumer relationship with a provider ultimately should not be discouraged. The direct-to-consumer model may promote the democratization of healthcare, but there must be adequate safeguards for patient privacy. This is the right first step.

B. SAFE HARBOR OR FALSE FLAG: WHY THE SAFE HARBOR PROVISION SHOULD EXPLICITLY EXCLUDE GENOMIC DATA

The second step to increasing consumer protection is to specifically exempt DNA and genetic data from HIPAA's Safe Harbor provision. This step is the simplest of potential reforms. As the *De-Identification Paradox* shows, it is biologically impossible to de-identify genetic data.[194] Because of this biological impossibility, entities should not be able to follow a set list of steps for de-identification, snap their fingers, and pretend the data is anonymized. The science is unambiguous.[195] Genomic data that has been de-identified can still be imputed back to the source. Moreover, the Erlich study found this identification

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[192] Matt Burgess, *What Is GDPR? The Summary Guide to GDPR Compliance in the UK*, WIRED (Mar. 24, 2020, 4:30 PM), https://www.wired.co.uk/article/what-is-gdpr-uk-eu-legislation-compliance-summary-fines-2018.

[193] *Id.*

[194] *See supra* Part I.D.*2*.

[195] *See* Erlich et al., *supra* note 129, at 692; *see also* Ajunwa, *supra* note 90.

can occur in a day's work.[196] Erlich—the Chief Science Officer of MyHeritage, one of the top four direct-to-consumer genetic testing companies—has called for increased data privacy regulations regarding the sharing of genomic data because of the ability to reidentify so easily.[197] Excluding genomic data from the Safe Harbor provision is the simplest way to strengthen genetic privacy.

C. GIVE THE LITTLE PERSON A SWORD: HOW GIVING CONSUMERS OWNERSHIP OVER THEIR DATA AND THE RIGHT TO BE FORGOTTEN CAN EMPOWER CONSUMERS AND ALLAY PRIVACY CONCERNS ON AN INDIVIDUAL LEVEL

The third step is to empower consumers with a right to be forgotten. Simply declaring genomic data as identifiable is not enough, as there are still enhanced privacy issues surrounding the nature of this data, as well as unforeseeable risks. Congress should empower consumers to take ownership of their genomic data. Given the inextricable and permanent link between an individual and their genome, they should be given pseudo-ownership of the data and records that contain the information. One way to convey this pseudo-ownership would be to institute a right to be forgotten, a right to correct incorrect data, and a right to demand a list of anyone who has had access to the data. These various rights are not new in the spheres of privacy. The rights to be forgotten and to rectify incorrect information are already instituted in the European Union's GDPR and the California Consumer Privacy Act.[198] Moreover, the right to demand access to a list of all individuals who have accessed a patient's data is already present in HIPAA.[199] The Federal Government needs to make these rights undeniably clear and bring them under one roof.

A right to be forgotten means that a consumer could force a company to delete their data and, in the genetic testing context, destroy their biological sample. This would allow the consumer to get their test results and receive whatever knowledge they desired. If that were the end of the road for them, the consumer could print the report and exercise their right to be forgotten. This does more than just protect the consumer by giving them a powerful tool to protect against exploitation. This is important because the "biggest lie on the internet" is that consumers generally do not read the terms of service or privacy policies.[200] For direct-to-consumer genetic testing companies, those terms of service are typically written at higher reading levels than the average consumer

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[196] Erlich et al., *supra* note 129, at 692.

[197] *See id.*

[198] Burgess, *supra* note 192; CAL. CIV. CODE § 1798.105(c) (West 2020).

[199] *See Your Rights Under HIPAA*, U.S. DEP'T OF HEATH & HUM. SERVS., https://www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html (last visited July 31, 2022).

[200] Obar & Oeldorf-Hirsh, *supra* note 182, at 144.

on subject matter that is incredibly complicated.[201] Moreover, even the most educated geneticists admit there are risks to genetic testing that are currently unforeseeable. The risks are unforeseeable because of the *Sharing Paradox*: as more genomes are tested and researched, more associations will be made. Even if consumers read the terms of service, the full ramifications and risks of their actions may be unknown for years. Because of these unforeseeable risks, consumers deserve to have an emergency exit. At a minimum, a right to be forgotten will give consumers a way out if they were to ever decide the juice is not worth the squeeze.

The right to be forgotten would also act as a check on the direct-to-consumer genetic testing companies and incentivize increased privacy protections. Recall that direct-to-consumer testing companies have two significant sources of revenue: the sale of genetic tests and the sale of the genetic data to third parties.[202] Additionally, this secondary revenue source is extremely profitable: 23andMe has made at least $360,000,000 this way.[203] The scale of this secondary revenue stream is massive, and companies will likely enact many changes to protect it. If consumers had a right to be forgotten, they could place an incredible amount of pressure on companies to safely protect consumer data. Unlike the other reforms suggested—which rely on pressure from the government to guide company policies—a right to be forgotten empowers the individuals whose data is being exploited. It gives the consumers a sword.

The biggest issue with this reform is that it will disrupt the economic calculus of direct-to-consumer genetic testing by directly challenging the companies' business model. However, this argument is easily rebutted because the direct-to-consumer genetic testing companies are free to set their prices in a manner the market would support. Moreover, it is important to remember that HIPAA tightly restricts the sale of PHI and bans its sale to third parties for their own uses.[204] Therefore, it is likely this revenue stream is only possible because of the current loopholes in the United States' regulatory regime. Finally, HIPAA and other consumer protection laws do not exist to open the market to exploitation; they exist to protect patients and consumers from exploitation. Thus, any regulatory regime should center patient-consumer privacy and let the market work out a suitable price after.

A right to be forgotten would inevitably change the economic calculus for direct-to-consumer companies. However, economic considerations do not take the driver's seat when it comes to protecting patient privacy, and companies are

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[201] Hendricks-Sturrup & Lu, *supra* note 186, at 2.

[202] Allyse et al., *supra* note 74.

[203] Herper, *Surprise!*, *supra* note 91 ($60,000,000 from Genetech); Molteni, *supra* note 93 ($300,000,000 from GlaxoSmithKline).

[204] 45 C.F.R. §§ 164.501(a)(1), 164.508(a)(3)(i)(B)(ii) (2020).

always free to raise their prices. A right to be forgotten would give consumers a check on a secondary revenue stream that exploits their own data, allowing them to protect themselves from unforeseeable future risks.

CONCLUSION

There are legitimate concerns surrounding genetic privacy and the uneven patchwork of its regulation. Genomic data is inextricably linked to an individual and their relatives, and thus can never be divorced from the individual's identity. In fact, genomic data can even be traced back several generations past a mortal life.[205] Currently, federal regulations allow the sharing of de-identified data and consider genomic data as being capable of de-identification despite that biological impossibility. Moreover, some of the most prolific genetic testing companies—those that offer the services without a relationship to a patient-consumer's healthcare practitioner—are able to dodge the privacy regulations regarding identifiable data protections. Even the most educated actors in the field admit that the potential risks involved with genetic privacy are unforeseeable. An overhaul needs to occur, and it is long overdue. The clock is ticking, and action must be taken before it is too late.

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[205] Erlich et al., *supra* note 129, at 692.

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