BE CAREFUL WHERE YOU SPIT: DO HIPAA-COVERED GENETIC TESTS ACTUALLY PROVIDE GREATER PRIVACY PROTECTION TO CONSUMERS?

Emily B. Sklar*

*J.D. Candidate Class of 2020, Seton Hall University School of Law; B.A., 2015, Kalamazoo College.

I. INTRODUCTION

The issues revolving around the retention and continued testing of human donative materials, such as saliva, tissues, and blood are a longstanding bioethical concern. Whether considering the unauthorized and continued experimentation on Henrietta Lack's cancer cells[1] or the events that led to the capture of the Golden State Killer,[2] an important question remains: how can lawmakers ensure the protection of biotechnology consumers? With the rapid expansion of genetic technology, individuals can easily crack the code of their DNA, but this information comes at a cost. DNA is a powerful identifier and unique to each individual.[3] This comment will explore the shortcomings of privacy protections in genetic testing. Specifically, this comment will consider whether a consumer is afforded greater privacy protection depending on whether the individual chooses genetic analysis in a hospital or Direct to Consumer ("DTC") analytical services.[4] As technology and its access improve, regulation of genetic testing is necessary to protect the privacy of those considering genetic testing. Privacy laws must be enacted to

[1] *See* Rebecca Skloot, THE IMMORTAL LIFE OF HENRIETTA LACKS 57 (New York: Crown Publishers, 2010) (describing the collection and propagation of cervical cancer cells collected without Henrietta Lacks knowledge or consent. The cell line developed from her sample has become the oldest and most commonly used cell line in biological research).

[2] The Golden State Killer—a rapist and murderer—was captured after 44 years of police investigation. The capture was made possible through the use of crime scene DNA and relatives matched through genetic databases. *See* Justin Jouvenal, *To Find Alleged Golden State Killer Investigators First Found His Great-Great-Great-Grandparents*, WASH. POST, (Apr. 30, 2018), https://www.washingtonpost.com/local/public-safety/to-find-alleged-golden-state-killer-investigators-first-found-his-great-great-great-grandparents/2018/04/30/3c865fe7-dfcc-4a0e-b6b2-0bec548d501f_story.html?noredirect=on&utm_term=.48abb8e17547.

[3] *See supra* notes 27-30 (explaining identical twins are an exception and share identical DNA).

[4] While this note will consider the merits of choosing one service over another, consideration of test accuracy is outside the scope of this comment.

specifically address genetic information due to DNA's unique, identifiable nature.

II. BACKGROUND

Individuals may choose to analyze their DNA for a variety of reasons. This section will consider common reasons that consumers choose genetic analysis. This section will then overview the process of DNA analysis and explain why genetic privacy is concerning.

A. Why do individuals test their DNA?

When Watson and Crick discovered the double-helix of deoxyribonucleic acid ("DNA"), they most likely did not imagine a world in which consumers could unravel their personal DNA codes so easily.[5] Since Watson and Crick's landmark discovery, advancements in DNA science unlocked tools through which scientists can aid in the formulation of medical treatment plans for individuals through DNA analysis.[6] For example, DNA analysis has revolutionized how doctors treat breast cancer.[7] After careful analysis of an individual's DNA, a doctor can recommend different treatments based on the genetic risk of breast cancer development or recurrence simply from the results of the analysis.[8] Another example is the use of DNA DTC health tests where consumers learn about potential genetic health risks or the risk of passing a genetically heritable trait to an offspring through companies like 23andMe.[9]

DNA analysis has further led to ground-breaking testing outside of healthcare, such as connecting long-lost relatives to one another.[10] Consumers who wish to connect to lost relatives can do so by analyzing

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[5] Office of NIH History, *Identifying DNA*, NAT'L INST. OF HEALTH, https://history.nih.gov/exhibits/nirenberg/HS2_DNA.htm (last visited Nov. 14, 2019).

[6] *Id.*

[7] *See generally* Karen Lisa Smith, *BRCA Mutation Testing in Determining Breast Cancer Therapy*, CANCER J., (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3240813 (explaining that the BRCA gene is commonly tested in both those who have been previously diagnosed with breast cancer and those who have family histories of BRCA related cancers. After genetic screening, a doctor may recommend prophylactic treatments, such as mastectomies.).

[8] *Id.*

[9] National Human Genome Research Inst., *Genetic Testing FAQ*, NAT'L INST. OF HEALTH, https://www.genome.gov/19516567/faq-about-genetic-testing/ (last visited Nov. 14, 2019); *Getting Started*, 23ANDME, https://medical.23andme.com/dna-kits/#clia (last visited Nov. 14, 2019) (23andMe is a company that provides genetic testing for purposes of health, wellness, and research. The website sells test kits to consumers that are interested in DNA analysis).

[10] *See Finding Biological Family*, ANCESTRY, https://support.ancestry.com/s/article/US-AncestryDNA-for-Adoptees-Search-Strategies (last visited Nov. 14, 2019) (showing how adopted children may use the service to find their biological parents).

their DNA using services offered by companies with large genetic databases. [11] These databases have the ability to connect consumers with unknown or lost relatives through shared DNA.[12] While some individuals utilize these services out of pure curiosity, others use these tools to connect with unknown family members.[13] Many companies provide both relative matching and analytical services; however, some companies, like GEDmatch.com only offer post-analysis services.[14] This platform allows consumers to upload test results from another company and search for genetic relatives in the database.[15]

B. What happens when an Individual's DNA is analyzed?

When an individual provides a sample for genetic testing—most often a saliva sample—that sample is sent to a laboratory for analysis. Different types of laboratory analyses can be conducted, depending on the service provider's aim.[16] Most methods of genetic analysis used by the services described in this comment are classified as molecular analysis, which refers to the process of tagging individual DNA building blocks to assess abnormalities.[17] This molecular process involves sequencing all or part of a DNA.[18] For example, 23andMe offers to test for certain variations in the BRCA gene.[19] Because the variants of BRCA are known, researchers can test for the presence or absence of a specific mutation.[20] Ancestry tests

[11] *Id.*

[12] *Id.*

[13] *Id*.

[14] GEDmatch.com is a database that provides genealogical tools for researchers and amateurs alike. Most tools on GEDmatch.com are free. GEDMATCH, https://www.gedmatch.com (last visited Nov. 14, 2019).

[15] *See* Sarah Zhang, *How a Tiny Website Became the Police's Go-To Genealogy Database*, THE ATLANTIC, (June 1, 2018), https://www.theatlantic.com/science/archive/2018/06/gedmatch-police-genealogy-database/561695/.

[16] Amelia Chappelle et al., *Understanding Genetics: A New York, Mid-Atlantic Guide for Patients and Health Professionals*, GENETIC ALLIANCE, July 8, 2009, at 78 (Cytogenic tests look at abnormalities such as translocations and deletions of chromosomes. Biochemical tests look to analyze the efficacy of metabolic pathways, seeking to determine if abnormalities in protein outputs are present when cells read genetic material.)

[17] *Id.*

[18] *Id.*

[19] *Do You Speak BRCA?*, 23ANDME, https://www.23andme.com/brca// (last visited Nov. 14, 2019); National Cancer Institute, *BRCA Mutations: Cancer Risk and Genetic Testing*, NAT'L INST. OF HEALTH, https://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet#q1 (last visited Nov. 14, 2019) (explaining that BRCA1 and BRCA2 are tumor suppressor genes. Mutation in one of these genes indicates a heightened risk of developing breast or ovarian cancers).

[20] Amelia Chappelle et al., *Understanding Genetics*, *supra* note 20, at 78.

similarly employ molecular analysis.[21] In the process of analyzing the samples, researchers target sequences of interest and digitize the code.[22] Through this process, researchers can analyze the pattern of Guanine, Thymine, Cytosine, and Adenine proteins.[23] Researchers then take the digitized samples and input them into mass databases to compare various genetic data samples.[24]

C. Why should we care about genetic privacy?

First, DNA is the building block of human life.[25] DNA provides instructions to our cells to grow, reproduce, and function.[26] While human species share roughly 99% of their genome, an individual's genome is unique.[27] Not only is DNA unique, but it is also heritable.[28] On 23andMe's website, the company explains that siblings (other than identical twins or higher-order multiple births) will share 50% of their DNA and third cousins will share less than 1% of their DNA [29]; yet genetic analysis can nonetheless recognize third cousins with accuracy.[30]

Second, the robust size of most genetic databases is sufficient to match relatives and therefore identify a DNA sample. There are currently many genetic databases holding more than five million samples.[31]

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[21] *Frequently Asked Questions*, ANCESTRYDNA, https://www.ancestry.com/dna/en/legal/us/faq#about-3 (last visited Sept. 28, 2019); Rafi Letzter, *How Do DNA Ancestry Tests Really Work?,* LIVE SCIENCE, (June 4, 2018), https://www.livescience.com/62690-how-dna-ancestry-23andme-tests-work.html (explaining Ancestry DNA tests 700,000 locations on a DNA strand).

[22] Letzter, *supra* note 21.

[23] *Id.*

[24] *Id.*

[25] *See What is DNA?*, *Genetics Home Reference: Help Me Understand Genetics*, NAT'L INST. OF HEALTH (October 29, 2019) https://ghr.nlm.nih.gov/primer/basics/dna.

[26] Letzter, *supra* note 21.

[27] Letzter, *supra* note 21; *see also What is in your DNA Fingerprint?*, YOUR GENOME, (last updated Jun. 2, 2016) https://www.yourgenome.org/facts/what-is-a-dna-fingerprint (explaining 99% shared DNA is true except in the case of identical twins, that share the same DNA).

[28] *See* District of Columbia Department of Health, *Understanding Genetics: A District of Columbia Guide for Patients and Health Professionals*, GENETIC ALLIANCE, February 17, 2010, at 6.

[29] *DNA Relatives: The Basics*, 23ANDME, https://customercare.23andme.com/hc/en-us/articles/212170668-Average-percent-DNA-shared-between-relatives (last visited Nov. 14, 2019) (stating that relationships such as grandparents, aunts, uncles, and half-siblings will all share about 25% of DNA.).

[30] *Id.*; *see also* DNA Relatives, *supra* note 29.

[31] Leah Larkin, *Database Sizes—September 2018 Update*, THE DNA GEEK, (Sep. 3, 2018), http://thednageek.com/database-sizes-september-2018-update/ (demonstrating that approximate sample sizes among major testing companies as follows: AncestryDNA over ten million, 23andME over five million, and GEDMatch over one million.).

According to research by Elrich, any genetic database with roughly three million entries will likely provide a genetically matched cousin to any individual of northern European descent.[32] Specifically, there is a 99% chance of a third cousin match and a 65% chance of a second cousin match in most databases.[33] Both AncestryDNA and 23andMe boast a database of over five million samples, meeting this threshold.[34]

The practical implication of a large DNA database is that even if the identity of a DNA sample is unknown, by searching for DNA relatives, an individual's identity can be discovered. For example, police officers have the potential to collect crime scene DNA and discover the individual's identity, based upon genetic relatives.[35] Recently, law enforcement in California used this method to identify the Golden State Killer.[36] Officials ran the collected crime scene DNA through a fake profile on GEDmatch.com, where it was matched the sample to the Golden State Killer's brother.[37] While easily finding DNA matches for dangerous criminals is a positive advancement, these databases can be used to detect the identities of more than just those who have committed serious crimes, potentially invading an individual's privacy.[38] Even if the size of a genetic database is insufficient to match an individual's relative, the database can be used in conjunction with other readily accessible public records containing demographic information to identify an individual without their consent or knowledge.[39]

The Elrich study, mentioned above, suggests that even DNA deposited through a health care professional ("HCP"), which must be de-identified pursuant to Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), could be re-identified through a database.[40] Publicly

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[32] *See* Yevin Elrich et al., *Identity inference of genomic data using long-range familial searches,* SCIENCE, Oct. 2018, at 2 (describing that authors predict that the size of third-party websites such as GEDMatch will expand to this size in the near future.).

[33] *Id.*

[34] *See* Larkin, *supra* note 31; *Id.*

[35] *See e.g.,* Jamie Durcharme, *A DNA Site Helped Authorities Crack the Golden State Killer Case. Here's What You Should Know About Your Genetic Data Privacy*, TIME, (Apr. 27, 2018), http://time.com/5257474/golden-state-killer-genetic-privacy-concerns/.

[36] *Id.*; *see also* Matthias Gafini, *Here's the 'open-source' genealogy DNA website that helped crack the Golden State Killer case,* THE MERCURY NEWS, (Apr. 26, 2019), https://www.mercurynews.com/2018/04/26/ancestry-23andme-deny-assisting-law-enforcement-in-east-area-rapist-case//.

[37] Durcharme, *supra* note 35; Gafini, *supra* note 36.

[38] Gafini, *supra* note 36.

[39] *See* Elrich et al., *supra* note 32, at 2.

[40] *Id.* at 2-3; Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. 104-191, 110 Stat. 1936, 2029 (codified as amended in 18 U.S.C., 26 U.S.C., 29 U.S.C., & 42 U.S.C.);
see generally 45 C.F.R.164 (authorized by 42 U.S.C.S. § 1302).

accessible databases like the 1000 Genomes Project[41] provide public access to "de-identified" patient information such as raw genetic data and birth year of research participants.[42] The study found that samples deposited through HCPs could be re-identified just as the investigator did in the Golden State Killer Case.[43] To test the hypothesis, researchers began with known samples searching for ancestors in GEDmatch.[44] The researchers eventually re-identified the sample.[45] The researchers noted that, although medical research samples are collected through HIPAA protected entities and stripped of identifiable information, there remains a significant risk of exposure because DNA may be re-identified, rendering private information no longer private.[46]

III. LAWS AND REGULATION GOVERNING PRIVACY OF GENETIC INFORMATION

This section will consider current federal and state privacy laws that regulate genetic testing performed by either a healthcare provider or direct-to-consumer genetic testing company.

A. HIPAA

The Privacy Rule was promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which aims to protect Patient Health Information ("PHI").[47] The Privacy Rule applies to three types of entities and their business associates: health plans, health clearinghouses, and health care providers that transmit health information electronically.[48] PHI is defined as information that is created or received by a covered entity that "relates to the past, present, or future physical or mental health [. . .] of an individual," including care to an individual or the payment for health care.[49] The Privacy Rule has four aims: (1) "[e]nsure the confidentiality, integrity, and availability of all electronic protected

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[41] The 1000 Genomes Project is an international research consortium formed for the goal of sequencing 1000 genomes and providing a greater understanding of genetic data. After sequencing over 1000 genomes, the consortium created an open-access database with the information. *See generally,* Olivier Devuyst, *The 1000 Genomes Project: Welcome to a New World*, J. OF INT'L SOC'Y FOR PERITONEAL DIALYSIS (Dec. 2015).

[42] Elrich et al., *supra* note 32, at 2, 3.

[43] Elrich et al., *supra* note 32, at 2, 3.

[44] Elrich et al., *supra* note 32, at 2, 3.

[45] Elrich et al., *supra* note 32, at 2, 3.

[46] Elrich et al., *supra* note 32, at 2, 3.

[47] *See generally* The Privacy Rule, 45 C.F.R. § 160 (2003) (authorized by 42 U.S.C.S. § 1302 (2019)).

[48] 45 C.F.R. § 164.104.

[49] 45 C.F.R. § 160.103.

health information;" (2) protect from threats or hazards to PHI security; (3) "protect against any reasonably anticipated uses" of the PHI; and (4) ensure compliance with the privacy rule.[50] In effect, the rule allows for disclosure, collection, and storage of identifiable health information subject to specified conditions, among other things.

HIPAA only covers the identifiable information collected from patients of a covered entity.[51] Health care providers include, but are not limited to, "a hospital, critical access hospital, skilled nursing facility [. . .] or a fund."[52] Covered entities are also classified by the services provided. Medical services, defined in 42 U.S.C.S. § 1395x(s), include diagnostic services—but only those "furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital" and "ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study."[53] The rule covers diagnostic tests performed by a health care provider.[54] DTC companies are not considered health care providers,[55] and thus these companies are not required to comply with HIPAA.

Under the Privacy Rule, genetic data that is stripped from the patient's personal information (e.g., name and address) is considered de-identified information.[56] Under HIPPA, when the genetic data is no longer connected to personally identifiable information, it may be shared freely, without express patient consent.

B. Federal Trade Commission Oversight

The Federal Trade Commission ("FTC") aims to, among other things, protect individuals from deceptive advertising.[57] Presently, the FTC's scope is limited to ensuring truth in regulating commerce activities; however, the FTC's scope may soon expand to include privacy regulation.[58] The U.S. Senate Committee on Commerce, Science, and

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[50] 45 C.F.R. § 164.306.

[51] *See* 45 C.F.R. § 160.102.

[52] 45 C.F.R. § 160.103; 42 U.S.C.S. § 1395x(u).

[53] 42 U.S.C.S. § 1395x(s)(2)(c).

[54] *See generally* 45 C.F.R. § 160.

[55] DTC companies provide this information without necessarily involving a health care provider. *See What is direct to consumer genetic testing,* NAT'L INST. OF HEALTH, https://ghr.nlm.nih.gov/primer/dtcgenetictesting/directtoconsumer (last visited Nov. 14, 2019).

[56] United States Dep't of Health and Human Services, *Health Information Privacy*, (last updated Nov. 14, 2015), https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.

[57] *About the FTC*, FED. TRADE COMM'N, https://www.ftc.gov/about-ftc (last visited Nov. 14, 2019).

[58] *See* Federal Trade Commission Act, 15 U.S.C.S. § 45(a)(1) (2019); Press Release,

Transportation held multiple hearings to discuss expanding data privacy regulation by the FTC.[59] In opening remarks, Senator Thune stated the question surrounding data privacy "is no longer whether we need a federal law to protect consumers' privacy. The question is what shape it should take."[60] This action follows recent data breaches, as seen with the Equifax[61] and Facebook's Cambridge Analytica scandals.[62] As of 2019, the Senate committee continues to evaluate a response to the privacy laws enacted by the State of California[63] and the European Union.[64] The European Union enacted the General Data Protection Regulation ("GDPR"), which is geared towards protecting the privacy of consumers' information in this digital age, and classifies the privacy from unauthorized data processing as a fundamental right.[65] The Senate committee has indicated that the FTC best serves the purpose of regulating privacy because of its role in consumer protection.[66] The committee has not held further hearings on the topic since May 2019.[67]

U.S. Senate Comm. on Commerce, Sci., & Transp., Committee Announces Second Data Privacy Hearing (Oct. 4, 2018) (on file at https://www.commerce.senate.gov/public/index.cfm/pressreleases?ID=2E7C60ED-9D88-418B-B5E0-EE2C41941E8C).

[59] Press Release, *supra* note 58; *see also Consumer Data Privacy: Examining Lessons From the European Union's General Data Protection Regulation and the California Consumer Privacy Act: Hearing Before the Senate Comm. on Commerce, Science, & Transp., Committee*, 116th Cong. (Oct. 10, 2018) (on file at https://www.commerce.senate.gov/2018/10/consumer-data-privacy-examining-lessons-from-the-european-union-s-general-data-protection-regulation-and-the-california-consumer-privacy-act).

[60] Press Release, *supra* note 58.

[61] *The Equifax Data Breach*, FED. TRADE COMM'N, https://www.ftc.gov/equifax-data-breach (last visited Sept. 28, 2019).

[62] Kevin Granville, *Facebook and Cambridge Analytica: What You Need to Know as Fallout Widens*, THE NEW YORK TIMES, (March 19, 2018), https://www.nytimes.com/2018/03/19/technology/facebook-cambridge-analytica-explained.html.

[63] California Consumer Privacy Act of 2018, Cal. Civ. Code § 1798.100 (effective Jan. 2020).

[64] European Union General Data Protection Regulation (EU) 2016/679, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=en.

[65] *Id.*

[66] Press Release, *supra* note 58.

[67] U.S. Senate Comm. on Commerce, Science, & Transp., Committee, Consumer Perspectives: Policy Principles for a Federal Data Privacy Framework: *Hearing Before the Senate Comm. on Commerce, Science, & Transp., Committee*, 116th Cong. (May 1, 2019) (on file at https://www.commerce.senate.gov/public/index.cfm/hearings?ID=EC293594-BD9A-4F07-9B7D-B9EFE65E7DC4)

The FTC is responsible for regulation of nonprescription medical device advertising.[68] The FTC has actively regulated and challenged the advertising representations of DTC tests, including GeneLink, Inc. and Foru International Corporation.[69] The FTC was concerned with the validity of their recommendations.[70] The FTC ensures that a company will adhere to promises of privacy presented to consumers when using their products.[71] The FTC's present scope of privacy control is limited to enforcement of the company's privacy policies, discussed below.

C. Food and Drug Administration Regulations

The Food and Drug Administration (FDA) regulates both in-hospital genetic testing and DTC testing when used to provide health information.[72] Both are classified as medical devices and are considered genetic health risk (GHR) tests under the regulations.[73] Most GHR tests are classified as Class III Medical Devices that require pre-market review prior to sale because there is no predicate device on the market.[74] The FDA in the past practiced "enforcement discretion" over the DTC tests, meaning the FDA deferred regulation and allowed the tests to be sold without pre-review.[75] The FDA classified GHR tests as low-risk laboratory developed tests.[76] In 2013, after a growing concern over the accuracy of DTC tests, the FDA halted the marketing of all DTC tests that provided health information.[77] Later, in 2017, the FDA changed their stance after acknowledging the growing popularity and risk of GHR testing.[78]

The FDA ensures accuracy and consistency in GHR tests.[79] Notably, the FDA also requires that the risks of use and the results of these tests, when conveying medical information, be presented in a way that

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[68] Kayte Spector-Bagdady & Elizabeth Pike, *Consuming Genomics: Regulating Direct-To-Consumer Genetic and Genomic Information*, 92 NEB. L. REV. 677, 717 (2014).

[69] Complaint at 1-2, *In re GeneLink, Inc. & Foru Int'l Corp.*, No. 112-3095 (F.T.C. Jan. 7, 2014) (The companies recommended certain dietary supplements based upon genetic tests).

[70] *Id.*

[71] *Id.*

[72] Spector-Bagdady & Pike, *supra* note 68, at 686.

[73] *Id.*

[74] Spector-Bagdady & Pike, *supra* note 68, at 703; *Evaluation of Automatic Class III Designation (De Novo)*, FOOD AND DRUG ADM', https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/ucm462775.htm (last visited Nov. 15. 2019).

[75] Spector-Bagdady & Pike, *supra* note 68.

[76] Spector-Bagdady & Pike, *supra* note 68.

[77] Spector-Bagdady & Pike, *supra* note 68, at 705-6.

[78] Spector-Bagdady & Pike, *supra* note 68 (this acknowledgement was part of the 21st Century Cures Act).

[79] *Evaluation of Automatic Class III*, *supra* note 74.

consumers can understand and use.[80] The FDA requires warnings that include privacy risks and health results.

D. Clinical Laboratory Improvement Amendments (CLIA)

The Clinical Laboratory Improvement Amendments of 1988 ("CLIA") were enacted to improve the quality of clinical laboratories.[81] CLIA is administered by the Department of Health and Human Services through the Centers for Medicare & Medicaid Services ("CMS") in conjunction with the Food and Drug Administration and the Centers for Disease Control.[82] Clinical laboratories include those that examine "materials derived from the human body to provide information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings."[83] CLIA regulates genetic testing when genetic analysis is used for health information; both direct-to-consumer tests like 23andMe[84], Helix[85] and laboratories used by hospitals[86] must be CLIA certified because they provide health information.[87]

Conversely, laboratories like Ancestry.com do not test their samples in CLIA certified laboratories because their analysis is used only for genealogical analysis, not health information.[88] CLIA's purpose is to ensure the quality of laboratories.[89] CLIA does not expressly have a direct

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[80] Press Release, Food and Drug Administration, *FDA Allows Marketing Of First Direct-To-Consumer Tests That Provide Genetic Risk Information For Certain Conditions* (Apr. 6, 2017) (on file at https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm551185.htm).

[81] 42 U.S.C.S. § 263(a).

[82] *About CLIA*, CENTERS FOR DISEASE CONTROL, https://wwwn.cdc.gov/clia/About.aspx (last visited Nov. 15, 2019).

[83] 42 U.S.C.S. §§ 263a (a-b) (explaining that no person may accept and/or examine samples from human beings without a CLIA certificate).

[84] *Genetic Science,* 23ANDME, https://www.23andme.com/genetic-science/ (last visited Nov. 14, 2019).

[85] HELIX, https://www.helix.com/ (last visited Nov. 14, 2019).

[86] *CLIA Laboratory Certification*, INVITAE, https://support.invitae.com/hc/en-us/articles/115000002427-Is-Invitae-Clinical-Laboratory-Improvement-Amendments-CLIA-certified (last visited Nov. 14, 2019) (explaining the certifications status of Invitae, a laboratory that process samples sent from health care providers); *see also CLIA Laboratory Certification*, AMBRY GENETICS, https://www.ambrygen.com/file/material/view/759/CLIA_EXP_5.29.20.pdf (last visited Nov. 14, 2019) (demonstrating the certification of Ambry Genetics, a lab that processes samples from a health care provider for genetic testing).

[87] *See e.g.*, HELIX, *supra* note 85; INVITAE, *supra* note 86; AMBRY GENETICS, *supra* note 86.

[88] *See* 42 U.S.C.S. § 263a(a).

[89] *But see* Stephany Tandy-Connor et al., *False-Positive Results Released By Direct-to-Consumer Genetic Tests Highlight the Importance of Clinical Confirmation Testing for Appropriate Patient Care,* NATURE, (Mar. 22, 2018), https://www.nature.com/articles/gim201838 (demonstrating that not all results are accurate);

impact on an individual's privacy; however, the operation of the regulations may affect individual privacy.[90] While CLIA requires laboratories to retain data for at least two years, it does not restrict the use of stored data. [91] Laboratories operating under the scope of CLIA cannot delete consumer or patient information, even upon request of the individual.[92]

E. The Federal Common Rule

The Federal Common Rule regulates any institution conducting federally-funded research with human subjects.[93] Some DTC testing companies, like 23andMe, perform this kind of federally-funded research.[94] The Common Rule requires approval by an institutional review board (IRB) before beginning most research that involves a human subject.[95] Part of the IRB requirements include the documentation of the privacy standards that will be employed to protect the confidentiality of participants.[96] As outlined in the regulations, the individual department heads provide industry-specific guidance.[97] In addition to the requirements above, the Common Rule requires that researchers maintain their records for at least three years.[98]

The Common Rule also sets forth regulations for the standards of informed consent for participants in research projects.[99] The statement of informed consent must include a "concise and focused presentation of the key information."[100] Informed consent requires a statement of the purpose, risks or discomforts, benefits, alternatives, and confidentiality

see also Phil Rogers et al., *DNA Test Says it Will Implement New Controls After NBC 5 Report,* NBC NEWS CHICAGO, May 2, 2018, 4:41 PM, *https://www.nbcchicago.com/investigations/DNA-Test-Says-itt-Will-Take-Implement-New-Controls-After-NBC-5-Report-481551691.html* (explaining high false-positive rate in direct-to-consumer genetic testing).

90 *See* Kristen V. Brown, *Deleting Your Online DNA Data Is Brutally Difficult,* BLOOMBERG NEWS, (Jun. 15, 2018, 5:00 PM), https://www.bloomberg.com/news/articles/2018-06-15/deleting-your-online-dna-data-is-brutally-difficult; 42 C.F.R. § 493.1105(a)(6) (2019).

91 42 C.F.R. § 493.1105(a)(6).

92 *See* Brown, *supra* note 90; 42 C.F.R. § 493.1105(a)(6).

93 45 C.F.R. § 46.109(a).

94 *Privacy Policy*, 23ANDME, https://www.23andme.com/about/privacy/ (last visited Sept. 28, 2019).

95 45 C.F.R. § 46.115(a).

96 45 C.F.R. § 46.111(a)(7).

97 45 C.F.R. § 46.101(a).

98 45 C.F.R. § 46.115(b).

99 45 C.F.R. § 46.116(b)(1)-(8).

100 45 C.F.R. § 46.116(a)(5)(i).

protections.[101] The disclosure must include a statement that the researchers are collecting identifiable information and whether that information will be de-identified.[102] If the researchers plan to distribute de-identified information, for example to a third-party for analysis, the future use of even the de-identified material must be included in the informed consent.[103] Similar to HIPAA, the Common Rule exempts de-identified information.[104] Secondary testing of de-identified information may be carried out without IRB approval.[105]

F. Genetic Information Nondiscrimination Act

The Genetic Information Nondiscrimination Act ("GINA") was enacted in 2008 to prevent discrimination based upon genetic information.[106] While the Act provides some privacy protection, it is limited to protection from discrimination in purchasing health insurance and employment.[107] Because of this limitation,[108] the Act does not adequately protect consumers of genetic testing services.[109] While GINA provides some protections, its application is too narrow to ensure the privacy of genetic information for most consumers.

G. State Laws

Currently, no federal law covers the privacy of genetic information disclosed to DTC testing companies; however, many states have enacted their own genetic or general privacy laws.[110] States have approached genetic data protection in different ways. This section discusses some of the most notable approaches. Important questions addressed by these laws involve the retention of ownership over genetic data after deposit. Specifically, does the individual who submitted the sample or the company that analyzed the DNA own the data? Regardless of the data's owner, state laws recognize that DNA is sensitive information and requires consent

101 45 C.F.R. § 46.116(b)(1)-(5).

102 45 C.F.R. § 46.116(b)(9).

103 *Id.*

104 *Id.*

105 *See generally, Fed. Policy for the Protection of Human Subjects ('Common Rule')*, HEALTH AND HUMAN SERVICES, (last updated Mar. 18, 2016), https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html.

106 *See generally* Genetic Information Nondiscrimination Act, 110 P.L. 233, 122 Stat. 881 (2008).

107 *Id.*

108 *Id.*

109 GINA expanded HIPAA protections to include genetic information under the definition of patient health information under HIPAA. *Id.* § 1180(a).

110 *See e.g.*, Alaska Stat. §§ 18.13.010–100 (2004).

before sharing. Thus, the key issue of privacy law is consent.

Alaska's Genetic Privacy Act focuses on ownership, and states "a DNA sample and the results of a DNA analysis performed on the sample are the exclusive property of the person sampled or analyzed."[111] This law ensures that the individual maintains ownership of their sampled information even after the DNA is analyzed. The Act allows an exception for law enforcement or medical necessity.[112] Notably, the law requires informed and written consent that is specific to the analysis performed.[113] A general release for genetic analysis is insufficient.[114]

New York ("NY") takes a different approach to regulating the genetic testing market, especially DTC tests.[115] To market or sell DTC tests to consumers, the company must first register the product as an over-the-counter device with the FDA.[116] NY Civil Rights Laws also include heightened confidentiality requirements.[117] Under NY law, genetic testing is strictly confined to the tests for which consent was given.[118] The NY law differs, significantly, from the Alaska law in scope. NY's law is applicable only when considering genetic testing for the purpose of medical diagnostics.[119] NY's laws add heightened confidentiality protections, but do not provide the same degree of ownership afforded in Alaska.

While some states chose to regulate the privacy of genetic information, California enacted laws to protect data privacy on a broad scale.[120] California's Consumer Privacy Act, effective January of 2020, has three primary aims: (1) to give individuals ownership of their data; (2) to give individuals control over the information collected from them; and (3) to provide increased security for consumers.[121] In providing ownership and control of data, the law requires disclosures from companies about what information is collected[122] and also requires that companies delete any data

111 Alaska Stat. § 18.13.010(a)(2) (2004).

112 Alaska Stat. § 18.13.010(b) (2004).

113 Alaska Stat. § 18.13.010(c) (2004).

114 *Id.*

115 *See generally* N.Y. C.L.S. Civ. R., Art. 7, § 79-l (2002).

116 *See* Emily Mullin, *As Consumer DNA Testing Grows, Two States Resist*, MIT TECH. REV. (Sept. 28, 2017), https://www.technologyreview.com/s/608958/as-consumer-dna-testing-grows-two-states-resist/; *see also* N.Y. C.L.S. Civ. R., Art. 7, § 79-l (2002).

117 *See generally* N.Y. C.L.S. Civ. R., Art. 7, § 79-l (2002).

118 *Id.*

119 N.Y. C.L.S. Civ. R., Art. 7, § 79-l(1)(a) (2002); *cf.* Alaska Stat. §§ 18.13.010-100 (2004) (where Alaska's statute applies broadly to include paternity, law enforcement, and medicine, New York's statute is limited to tests performed for medical purposes).

120 *See About,* CA PRIVACY, https://www.caprivacy.org (last visited Nov. 15, 2019).

121 *Id.*

122 Cal. Civ. Code § 1798.100 (2018).

collected upon consumer request.[123] In ensuring the security of information, the law adds penalties for companies with data breaches.[124] In addition, the state has enacted its own expansion of GINA, CalGINA, which includes genetic information as a protected class under state laws.[125]

IV. PRIVACY POLICIES OF DTC GENETIC TESTING COMPANIES

The specific policies of each genetic testing company provide the most insight into consumer privacy protections. 23andMe's privacy policy outlines how the company ensures the protection of consumer data once the company receives it.[126] The company explains, "23andMe will not sell, lease, or rent your individual-level information to any third party or to a third party for research purposes without your explicit consent."[127] Later in the privacy policy, individual-level data is defined as information ". . . about a single individual's genotypes, diseases or other traits/ characteristics, but which is not necessarily tied to Registration Information."[128] 23andMe represents that consumer consent is a prerequisite to disclosure of genetic data or personally identifiable information to certain parties contained within the privacy statement.[129] The Privacy Policy further states that even if an individual does not consent to 23andMe research, ". . . Genetic Information and Self-Reported Information may still be used by us and shared with our third party service providers."[130] While 23andMe cannot lease, sell, or rent the data to a third-party without consent, it seems clear that the company reserves the right to disclose identifiable information to a third-party service provider for other purposes.[131] 23andMe limits *who* the company can share information to, but the company does not limit *what* information can be shared under the

[123] Cal. Civ. Code § 1798.105 (2018).

[124] Cal. Civ. Code § 1798.150-55 (2018).

[125] Senate Bill No. 559, (Sept. 6, 2011), http://www.leginfo.ca.gov/pub/11-12/bill/sen/sb_0551-0600/sb_559_bill_20110906_chaptered.pdf.

[126] *Privacy Policy*, 23ANDME, (last updated Sept. 30, 2019) https://www.23andme.com/about/privacy/.

[127] *Id.*

[128] *Id.*

[129] *Id.*

[130] *See Privacy Policy*, *supra* note 126. Genetic Information is defined as "Information regarding your genotype (e.g. the As, Ts, Cs, and Gs at particular locations in your genome)" and includes reported results. Self-reported Information is defined as "information you provide directly to us, including your disease conditions, other health-related information, personal traits, ethnicity, family history, and other information that you enter into surveys, forms, or features while signed in to your 23andMe account."

[131] *See Privacy Policy*, *supra* note 126. The 23andMe Privacy Policy uses third party to reference companies like Facebook and Twitter, along with laboratories and researchers. The privacy policy, however, does not specify the purposes for which the information may be used.

policy.[132]

V. ANALYSIS

Ensuring genetic privacy is tricky. The information that a consumer provides to a company when choosing genetic testing is unique and important.[133] The information should be handled with care. Currently, no federal law ensures consumer privacy of this vital genetic information used by DTC testing companies, and instead enforcement of privacy is left to the FTC.[134] The FTC promises to enforce good faith and fair dealing, but their power in regulating genetic testing is limited to enforcing the promises made in that company's confusing privacy policy.[135] While some states took action to ensure consumer privacy through the enactment of genetic privacy laws, the lack of uniformity created a patchwork of protection, furthering consumer confusion.[136] The question of who a consumer can trust to hold and analyze their DNA has no simple answer. This section explores some of the shortcomings of the current regulatory framework while considering what a consumer's best option may be for genetic privacy. This section then argues that the current lack of uniformity in DNA privacy law leaves consumers vulnerable and seriously compromised to receive information through analysis of their DNA.

A. Looking to Future Regulation: Different classifications, same test? Using the purpose of genetic analysis to determine whether a test falls under certain regulation leaves consumers vulnerable.

Genetic testing and genealogy testing are monitored and regulated differently; however, the differences should not compromise the consumer's privacy in the process of conducting analysis. Furthermore, these similar testing mechanisms should be regulated similarly for the sake of consistency and predictability in regulation. Although DNA may be sequenced in both instances, companies are not required to comply with FDA,[137] HHS,[138] or CLIA[139] regulations of laboratories in genealogy testing

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132 *See Privacy Policy*, *supra* note 126.

133 *Genetics Home Reference, supra* note 25.

134 *About the FTC*, *supra* note 57.

135 *About the FTC*, *supra* note 57.

136 *Genetic Discrimination and Other Laws*, NAT'L INSTITUTE OF HEALTH, (Apr. 17, 2017), https://www.genome.gov/27568503/genetic-discrimination-and-other-laws/.

137 *See generally, Evaluation of Automatic Class III*, *supra* note 74 (A kit used to sample saliva for genealogical testing does not require FDA approval as it is not a medical device).

138 *Federal Policy for the Protection of Human Subjects ('Common Rule')*, HEALTH AND HUMAN SERVICES, (last updated March 18, 2016) https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html (HHS Common Rule does not apply in

due to a loophole created by the fact that the companies do not produce health information.[140] In looking towards a data privacy plan, lawmakers should consider whether companies like 23andMe or Ancestry.com can be effectively regulated under a broad privacy law, or in the alternative, whether DNA data presents a unique problem that will require more scrutinized regulation. If lawmakers choose to regulate the field of genetic analysis to improve privacy under a federal law, lawmakers must consider several important questions: (1) should consumers be afforded "ownership" of their genetic data?; (2) is the distinction between health information and genetic ancestral information material?; and (3) will DNA regulation slow advancements in health care? This section will argue that due to the identifiable nature and unique quality of familial DNA, regulating this field requires more than a federal privacy law.

1. Data Privacy is Not Sufficient to Protect Consumers of Genetic Testing

When consumers or patients participate in genetic testing, the risk associated with allowing a company to digitize their DNA is unclear.[141] When a consumer deposits a DNA sample, the sample is retained for a significant period of time.[142] Science has yet to fully understand the use and importance of retained DNA samples.[143] Lawmakers must consider whether legislation should aim to ensure consumers own or control their DNA, even after analysis is performed.[144] This consideration must also account for and remain adaptable to scientific advancements of DNA use and development.

One journalist—after comparing multiple DTC companies—felt unsettled about how easily and freely her genetic material flowed.[145] The journalist wrote an article comparing the results of her genetic analysis from many of the major DTC and genealogical companies.[146] The journalist then attempted to delete her data from the companies that she

ancestry DNA testing).

139 *About CLIA*, *supra* note 82.

140 42 U.S.C.S. § 263(a); 21 C.F.R. § 600.3.

141 Spector-Bagdady & Pike, *supra* note 68, at 729.

142 *See* 42 C.F.R. 493.1105(a)(6).

143 Carrie Arnold and Mosaic, *The Uncertain Future of Genetic Testing*, THE ATLANTIC (Jul. 19, 2017).

144 *See generally*, Emily Mullin, *As Consumer DNA Testing Grows, Two States Resist,* MIT TECHN. REVIEW, Sept. 28, 2017, https://www.technologyreview.com/s/608958/as-consumer-dna-testing-grows-two-states-resist./.

145 *See* Brown, *supra* note 90.

146 *See* Brown, *supra* note 90.

used.[147] It became clear to the journalist that deleting DNA from these websites is far trickier than she expected.[148] In fact, the journalist was ultimately unable to remover her data from the website.[149] The privacy policies are long and confusing, and the companies' compliance with CLIA regulation requires them to retain her DNA sample for at least three years.[150]

The issue of DNA regulation is unique, because the data itself is unique.[151] Currently, no federal law provides ownership of data, especially not genetic data. However, in drafting new legislative enactments, lawmakers should consider whether the aim is to protect genetic data after it is generated or to provide consumers with control over the data. Practically, an individual may wish to control their genetic data to ensure its safety, to delete their data, or potentially to sell their data to another party. However, companies investing in the development of DNA analysis also have interests in aggregating and selling the data. Data aggregation has played a large role in the advancement of genetic analysis and may even be critical to further developments.[152] The answer is that lawmakers should seek a combination of structures: allow consumers additional control, ensure safety in data storage, but should not grant complete ownership to ensure privacy protections do not hamper further developments. In doing so, lawmakers can ensure they continue encouraging technological developments and consumer safety.

Reaching a uniform method of genetic privacy protection is a timely concern. The Senate Committee on Commerce, Science, and Transportation recently held hearings to address consumer privacy law on a federal scale.[153] While some states already acted, the resultant patchwork protection is ineffective for both consumer protection and company efficiency. In Alaska, lawmakers answered the question of genetic privacy by providing ownership of genetic data post-analysis.[154] Other states, like California, instead focused on data privacy and the right to delete data.[155] It is likely, if lawmakers use these laws as a model, that a new law would

147 *See* Brown, *supra* note 90.

148 *See* Brown, *supra* note 90.

149 *See* Brown, *supra* note 90.

150 *See* Brown, *supra* note 90.

151 *See generally,* Mullin, *supra* note 144.

152 *See generally,* Olivier Devuyst, *The 1000 Genomes Project: Welcome to a New World*, J. OF THE INT'L SOCIETY FOR PERITONEAL DIALYSIS (Dec. 2015); *see e.g.,* Aparna Vidyasagar, *What is CRISPR?,* LIVE SCIENCE (Apr. 20, 2018) (Explaining the use and advancement of CRISPR-Cas9 technology as a gene-editing tool).

153 *Policy Principles, supra* note 67.

154 *See e.g.,* Alaska Stat. § 18.13.010 (2013).

155 *See About,* CA PRIVACY, https://www.caprivacy.org (last visited Sept. 28, 2019).

favor data privacy and add a right to delete as well as a heightened requirement for informed consent, but not the right to retain ownership, because privacy-focused laws are more numerous than ownership-focused laws.[156] Lawmakers likely would not impose full ownership of data, because such regulation may stagnate further development in genetic science. Because the future of DNA research is uncertain and the power of DNA has yet to be fully realized, it is imperative that consumers retain an ability to delete their DNA.

The California Consumer Privacy Act focuses on ensuring consumer consent to data collection and retention.[157] While this is an excellent step towards ensuring consumer privacy, in the realm of genetics, consent is not sufficient. Individuals share a significant amount of their DNA with family members: siblings, parents, and cousins.[158] In the case of the Golden State Killer, the suspect did not consent to DNA testing, but his brother's DNA was publicly available on GEDmatch.com, providing an adequate identifiable link.[159] Consent does not ensure privacy because of the shared DNA between family members. When genetic privacy laws focus on consent alone, they overlook the crucial consideration that many individuals who do not participate in genetic testing are still affected by these laws. Due to the popularity and size of genetic databases, statistically, almost every individual has a genetic link in at least one database.[160] While consent is a step towards greater privacy, the regulation of genetic data is *sui generis,* and regulating DNA requires a fine-tuned approach that understands the familial connection.

Regulating consent in genetic testing is an impractical solution to genetic privacy. By regulating consent, privacy laws do not protect the genetic relatives of those offering their consent. Privacy is always important; however, in consideration of genetic privacy, it is even more important, because third parties cannot practically offer consent on behalf of another. The Golden State Killer did not consent when his relative used an ancestral database; yet, the Golden State Killer was still identified using a freely accessible database.[161] Like the GDPR, a genetic privacy law

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156 *See e.g.,* Alaska Stat. §18.13.010 (2018).

157 *Id.*

158 *Average Percent DNA Shared Between Relatives*, 23ANDME https://customercare.23andme.com/hc/en-us/articles/212170668-Average-percent-DNA-shared-between-relatives (last visited Sept. 28, 2019).

159 Durcharme, *supra* note 35.

160 *See District of Columbia Department of Health, supra* note 28; *see also supra* notes 31-35.

161 *See* Sarah Zhang, *How a Tiny Website Became the Police's Go-To Genealogy Database*, THE ATLANTIC, June 1, 2018, https://www.theatlantic.com/science/archive/2018/06/gedmatch-police-genealogy-

should aim to keep information private. GDPR focuses on safeguarding the information once it is collected,[162] but GDPR does not fully account for the unique quality of DNA. GDPR and the California Consumer Privacy Act provide starting points for drafting new law, but these laws do not fully protect consumers, as discussed below.

2. The Difference Between Health Information and Ancestry Analysis is Immaterial and Therefore Both Approaches Should be Regulated as Similar Tests

Presently, regulation distinguishes between genetic analysis aimed at providing health information and genetic analysis aimed at providing ancestral information.[163] This is likely because the health industry is highly regulated, and lawmakers have an interest in protecting patients and ensuring they receive adequate care. The risk of providing inaccurate information for health risks is much higher than that of ancestry because consumers can make medical decisions based upon genetic health risks.[164] Considering the disparity of risk in providing inaccurate information, this distinction seems appropriate. Whenever focusing on consumer privacy, this distinction makes less sense. In either event, an individual has enough information about their DNA analyzed and digitized to create an identifiable data sample.[165] For this reason, lawmakers must consider a legal approach specific to genetic privacy, not just data privacy.

To avoid liabilities and regulatory controls, DTC companies can and have bifurcated, splitting their companies and services to avoid regulation.[166] This means that companies might provide either sequencing or interpretation of DNA and rely upon a third party for the remaining service.[167] Other companies may instead require a physician intermediary to ensure compliance with testing regulations.[168] While companies can adapt to new regulations, the fact that genetic data is regulated as either a laboratory test or health information means that companies can split their

database/561695.

[162] *See generally,* European Union General Data Protection Regulation (EU) 2016/679, Art. 1, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=en.

[163] *See* 42 U.S.C.S. § 263(a) (2019); 21 C.F.R. 600.3 (2019) (Regulations such as FDA and CLIA only apply to laboratories that provide health information, not ancestry).

[164] Bob Curley, *Up to 40 Percent of At-Home Genetic Test Results May Be 'False Positives,'* HEALTHLINE, (Apr. 5, 2018), https://www.healthline.com/health-news/40-percent-at-home-genetic-test-results-false-positives.

[165] *Id.*

[166] Spector-Bagdady & Pike, *supra* note 68, at 729.

[167] Spector-Bagdady & Pike, *supra* note 68, at 730.

[168] Spector-Bagdady & Pike, *supra* note 68, at 728.

services into two separate companies to avoid regulation and liability.[169] However, if the goal of heightened oversight from the FDA and CLIA in DTC health tests is to ensure consumer protection, should those same protections not be afforded to consumers of ancestry tests?

Not only can companies avoid regulations, but consumers may also bypass these regulatory safeguards. Ancestral testing companies, like Ancestry.com, allow consumers to obtain their raw DNA data.[170] If a test is performed only to produce a raw DNA sequence it can avoid compliance with FDA and HHS regulations.[171] The output information can later be utilized to provide health information.[172] Under the current regulatory framework, the same genetic test is subject to materially different regulation depending on the purpose of the test.[173]

Lawmakers clearly understood the unique quality of genetic data when they enacted GINA. However, since the enactment of GINA, genetic data has become more accessible to consumers. GINA's protections must be expanded to ensure discrimination does not occur in contexts outside the rule's current scope. GINA, for example, does not protect from discrimination in some insurance contexts such as disability insurance, long-term care insurance, or life insurance.[174] It may be a necessary business policy to exclude individuals with genetic abnormalities from life insurance; however, it is unlikely consumers fully understand the downstream effects of testing their DNA when they reach for a DTC test. If an individual has a genetic condition covered under GINA, that same individual is likely in need of additional insurance plans like those listed above. By choosing to use a genetic test, that individual may render themselves unqualified for necessary insurance benefits without understanding this risk at the time of testing.

GINA's current scope is too narrow to protect consumers's use of genetic analysis effectively. By ensuring protections only in the realm of health insurance and employment, lawmakers are effectively masking the problem. GINA has a broad name that seems to offer a promise of wide-ranging protections, when in reality, the law is extremely limited in scope.

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169 Spector-Bagdady & Pike, *supra* note 68, at 728-30.

170 *Frequently Asked Questions, supra* note 21.

171 Spector-Bagdady & Pike, *supra* note 68, at 730.

172 Spector-Bagdady & Pike, *supra* note 68, at 730.

173 Spector-Bagdady & Pike, *supra* note 68, at 730-31.

174 *Can the results of direct-to-consumer genetic testing affect my ability to get insurance?*, NAT'L INST. OF HEALTH, https://ghr.nlm.nih.gov/primer/dtcgenetictesting/dtcinsurancerisk (last visited Sept. 28, 2019).

If the legislature enacts a new law to protect consumer privacy, the most effective regulator is the FTC. The FTC is presently the only regulatory agency with jurisdiction over all types of genetic analysis: health care provider, DTC testing, and genealogy.[175] Therefore, the FTC is a reasonable choice for such regulation. However, as argued above, it is necessary to enact a law specific to the unique problem of genetic testing, and if such an approach were taken, the FTC would not be the most appropriate regulator of the tests, because the scope of the FTC's regulatory power is too narrow. Instead, the legislature would need to expand the classification of health information to also include genealogy. These types of genetic analyses could be effectively regulated under the supervision of the FDA as those methods of analyses employ a device that is either used to produce health information or has the capacity to produce health information.

3. Regulation Must Encourage Further Advancements in DNA.

Free information sharing is important to the advancement of DNA technology. When data is shared freely, researchers learn from one another and advance more quickly. Stagnation in research often occurs when researchers cannot collaborate. Genetic research is still a growing field.[176] Many questions remain as to what can be learned from and manipulated in DNA.[177] Much of the existing advancement of genetic research is attributable to the free sharing of data.[178] While it is important to protect consumer privacy, these concerns must be balanced against the utility of collaborative science.[179]

With this in mind, it is important for lawmakers to consider and ensure that privacy protection does not limit the ability of scientists to further developments in genetic research. This problem, however, presents a simple solution. As it stands, many genetic databases, regardless if the information is collected through a HIPAA protected entity, can be accessed by any researcher, regardless of their credentials.[180] Individuals should be

[175] *See generally About the FTC, supra* note 57.

[176] *See* Carrie Arnold and Mosaic, *The Uncertain Future of Genetic Testing*, THE ATLANTIC, (July 19, 2019), https://www.theatlantic.com/science/archive/2017/07/the-uncertain-future-of-genetic-testing/534045/.

[177] *See*, *e.g.*, Aparna Vidyasagar, *What is CRISPR?*, LIVE SCIENCE, (Apr. 20, 2018) (explaining the use and advancement of CRISPR-Cas9 technology as a gene-editing tool).

[178] *See generally*, Olivier Devuyst, *The 1000 Genomes Project: Welcome to a New World*, JOURNAL OF THE INTERNATIONAL SOCIETY FOR PERITONEAL DIALYSIS (2015).

[179] Sejin Ahn, *Whose Genome Is It Anyway?: Re-identification and Privacy Protection in Public and Participatory Genomics*, 52 SAN DIEGO L. REV. 751, 802 (2015) (suggesting that if DNA databases are permitted to free source genetic information, further protections should restrict access).

[180] *See* Devuyst, *supra* note 178.

allowed to freely input their own data and retrieve information related to their own genetic analysis. However, privacy should ensure that not every researcher or layman can obtain access to listings of inputted genetic data. Licensing or training should be necessary to access this information. DNA is unique to an individual and because it can be re-identified, it should be handled with care. Licensing would provide a simple method to ensure appropriate safeguards to the development of science, while ensuring protection of consumers.

Presently, the issue of genetic privacy is approached from the wrong angle. DTC health testing will likely continue to appeal to the market as an easily accessible tool to learn about potential health risk.[181] The only way to ensure that consumers receive the same level of protection as in-hospital testing is to regulate it under a genetic privacy law.

B. Where should you send your spit?

With the regulatory framework explained above in mind, the question remains: when an individual look to analyze their DNA, which type of service will provide the greatest protection to their privacy? The following section will explore the privacy benefits and pitfalls of the four main frameworks: (1) in-hospital testing; (2) DTC genetic health testing; (3) DTC ancestry testing; and, (4) ancestral databases. The following will not consider the accuracy of genetic testing or other cost/benefits, but the privacy protections afforded by the different services.

1. In-Hospital Genetic Testing is Not as Safe as it Seems.

In-hospital genetic testing may offer greater accuracy, but privacy protections for these types of tests are lacking.[182] A consumer may think that this avenue would provide them with the greatest privacy, but that may not be the case. When a doctor orders genetic testing at a hospital, an individual is protected by the Privacy Rule of the Health Insurance Portability and Accountability Act.[183] While HIPAA protects individual privacy, it allows for the sharing of patient health information once the information is deemed de-identified.[184] It is important to note that "information inherent in DNA can be retrieved by relatively simple

[181] *See* Steven Salzberg, *NY Times, Why Are You So Worried About 23andMe's Genetic Tests*, FORBES, Feb. 4, 2019; *see also* Editorial Board, *Why You Should Be Careful About 23andMe's Health Test*, N.Y. TIMES, Feb. 1, 2019; Anne Wojcicki, *23andMe Responds: Empowering Consumers*, N.Y. TIMES, Feb. 5, 2019.

[182] *How can consumers be sure a genetic test is valid and useful?*, NAT'L INST. OF HEALTH, https://ghr.nlm.nih.gov/primer/testing/validtest (last visited Nov. 15, 2019).

[183] Health Insurance Portability and Accountability Act (HIPAA), *supra* note 40.

[184] Ahn, *supra* note 179, at 772-775.

processing," meaning that DNA can be re-identified.[185] HIPAA protection does not account for the re-identifiable nature of DNA.[186]

Not only does HIPAA allow the free sharing of "de-identified" patient information, but many databases exist that allow public access to genetic databases for genetic research. These include laboratory databases, the NIH database, and open source databases from data sharing campaigns.[187] "Free the Data!" is a grassroots movement to share sequenced data to advance genetic technologies.[188] Laboratories and hospitals that sequence and analyze patient genetic samples participate in grassroots data sharing campaigns.[189] Patient information, once analyzed and stripped of identifiers, is entered into free databases.[190] Database sharing exists for practical reasons.[191] Through the open sharing of data, hospitals can more accurately and efficiently diagnose and treat illnesses; thus, medical advancements come with a trade-off. [192] Medical information may be less protected, yet medical treatment may improve.[193] Researchers have, in fact, re-identified genetic information retrieved from a grassroots database.[194] The individual participated in a clinical trial, in which their data was entered into an open database.[195] Although that database did not include "identifiable information," researchers used a combination of open-source ancestry databases and public genealogy databases to re-identify the genetic sample.[196]

Patients that receive genetic analysis in hospitals will also have added protections of CLIA and HHS Common Rule if they participate in research, but as explained above these regulations do not provide *privacy* protection.[197] While in-hospital tests provide the additional benefit of heightened accuracy and a professional's opinion, privacy is not necessarily any greater. In this context, HIPAA is a false promise.

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185 Ahn, *supra* note 179, at 768; *see also* Elrich *supra* note 32 at 2.

186 Ahn, *supra* note 178 at 768-69.

187 *Privacy Practices,* INVIATE, (last visited Nov. 14, 2019) https://invitae.com/en/privacy/.

188 Katherine Lamberston & Sharon F. Terry, *Free the Data!,* 18 Genetics Testing and Molecular Biomarkers, 1 (Jan 1, 2014).

189 *Id.*; *Collaborations,* AMBRY GENETICS, https://www.ambrygen.com/research/collaborations (last visited Sept. 28, 2018).

190 Lamberston et al., *supra* note 188.

191 Lawrence O. Gostin, *Health Information Privacy*, 80 CORNELL L. REV. 451, 455 (1995).

192 *Id.* at 476-77.

193 *Id.*

194 Elrich, *supra* note 32.

195 Elrich, *supra* note 32.

196 Elrich, *supra* note 32.

197 *See supra* notes 81-92, 93-105.

2. DTC Genetic Testing: The Greater the Market Pressure, the Greater the Privacy

DTC companies like 23andMe and Helix are required to comply with Common Rule and CLIA regulations when conducting federally-funded research.[198] These requirements are also applicable to in-hospital testing and require the retention of testing information.[199] CLIA regulations require that laboratories conducting health information testing retain a certain level of data for each individual and test.[200] This includes the retention of patient information and the types of testing ordered for at least two years.[201] CLIA, however, imposes higher retention standards for test reports.[202] For example, pathology tests are required to be retained for ten years.[203] This means that genetic testing data must be retained by companies performing the testing to comply with CLIA. Consumers of both in-hospital testing and DTC testing do not have a right to delete their data.[204]

Consumers may be under the impression that they can delete their data.[205] However, consumers of products like 23andMe can only delete their individual-level information to an extent.[206] An individual can delete their account on the website and request their physical samples (deposited saliva) to be discarded, but cannot delete their genetic information or personal identifiers during a period required by CLIA and the contract for services.[207] While consumers may benefit from CLIA, because the regulations work to ensure accuracy in testing, the alternative consideration is that an individual loses the right to delete their data when sending their sample to a CLIA certified laboratory.[208]

Most privacy protections for DTC test consumers stem from the FTC assuring that companies are held to their promises.[209] The FTC can ensure that any representations in the companies's privacy policy are enforced.[210] Therefore, the privacy protections found in DTC testing stem only from the

198 42 U.S.C.S. § 263(a) (2019).
199 42 C.F.R. 493.1105(a)(6) (2019).
200 42 C.F.R. 493.1105.
201 42 C.F.R. 493.1105(a)(1)-(5).
202 42 C.F.R. 493.1105(a)(6).
203 *Id.*
204 *See id.*; *see also* Brown, *supra* 90.
205 *Id.*
206 *Privacy and Data Protection*, 23ANDME, https://www.23andme.com/about/privacy/ (last visited Nov. 15, 2019).
207 *Id.*
208 *Id.*
209 *About the FTC*, *supra* note 57.
210 *About the FTC*, *supra* note 57.

privacy policy represented in the contract for services. These privacy policies are non-negotiable and often overly complicated. Consumers have only one option to protect their privacy: an adhesion contract. This is an unfortunately unsatisfying answer when considering data as unique as DNA.

There are various models amongst DTC testing companies that depend partially upon the companies' resources. For example, 23andMe is considered one of the largest databases.[211] Other companies, with smaller pools of genetic information, may need to participate in data-sharing to a larger extent than 23andMe. The privacy policy, however, on 23andMe's website reserves the company's right to share consumers' genetic information and even individual level information with third party service providers in limited circumstances.[212] Data sharing exists in both in-hospital genetic testing and DTC tests like 23andMe, but the exposure of personal, identifiable health information may be greater in DTC tests, dependent on the size of the company.[213]

The fact that 23andMe owns a large private database creates a significant protection for consumer privacy. For example, as a result of their success, 23andMe has few incentives to allow other individuals or companies to access their databases. These market pressures caused DTC companies to increase privacy; however, these market pressures and FTC regulations remain the main incentives to protect the genetic information of their customers. While individuals are afforded privacy protection when they contract for the services of DTC tests, individuals deserve greater protection than the choice between adhesion contracts of different DTC companies. Because consumers are providing such important information, consumers should have an opportunity to materially bargain or should be afforded greater protection.

3. DTC Genealogy Testing Provides Little to No Privacy Protection

Services like Ancestry provide genetic analyses that do not provide health information.[214] These services instead analyze DNA and input the DNA into a database to find relatives or assess regional ethnicity.[215]

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[211] Henri-Corto Stoeklé et al., *23andMe: a new two-sided data-banking market model*, BMC MEDICAL ETHICS, 2006, at 4; *see also* Ducharme, *supra* note 35 (explaining that 23andMe has over five million users).

[212] *Law Enforcement Report*, ANCESTRY.COM, https://www.ancestry.com/cs/legal/privacystatement (last visited Nov. 15, 2019).

[213] *Id.*

[214] *Geographical DNA Tests*, ANCESTRY.COM, https://www.ancestry.com/dna/ (last visited Nov. 15, 2019).

[215] *Id.*

Because Ancestry does not provide health information or receive federal funding, it is not necessary for Ancestry to comply with CLIA, Common Rule, or FDA regulations. These three requirements apply to data utilized for health information. Since these tests are not required to comply with these regulations, there is no data retention requirement for genealogy testing companies.[216] Thus, if a consumer chooses genealogy testing over health information, the consumer retains an option to delete their data. Ancestry's privacy policy states that they will delete "all genetic information" within 30 days of a deletion request.[217] This additional ability to delete information mimics a progressive understanding of data ownership.

A comparison of DTC genealogy testing and DTC genetic testing is not a comparison of like outputs. One test provides health information and the other settles curiosities of family origin. Both tests begin with the same process: the analysis of DNA; however, one test is held to higher standards than the other. These tests are under-regulated for DNA privacy. In theory, an individual could sequence their DNA through an ancestry website and later use that same sequence to receive health information. Genealogy testing could allow a consumer to bypass any regulatory pathways already in place.

Ancestry must comply with valid requests from law enforcement to release personal information about their clients.[218] Ancestry provides the most clarity and transparency regarding which information and the frequency in which the company must share information with law enforcement. In addition, Ancestry publishes yearly reports that allow consumers to understand the frequency with which Ancestry releases information.[219] Not all requests necessarily involve the disclosure of genetic material or codes, but such an avenue exists if a valid request is submitted.[220]

Genealogy testing companies also must comply with FTC guidelines as DTC genetic testing companies do.[221] It is important to note that while the FTC does not provide failsafe protections for the consumer of genetic testing, it is the single federal regulatory agency with privacy jurisdiction over both DTC health and genealogy testing. The FTC regulation is

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[216] *Law Enforcement Report*, ANCESTRY.COM, https://www.ancestry.com/cs/legal/privacystatement (last visited Nov. 15, 2019).

[217] *Id.*

[218] *Id.*

[219] *Transparency Report*, ANCESTRY.COM, https://www.ancestry.com/cs/transparency (last visited Nov. 15, 2019).

[220] *Enforcement Report*, ANCESTRY.COM, https://www.ancestry.com/cs/legal/lawenforcement (last visited Nov. 15, 2019).

[221] *About the FTC*, *supra* note 57.

imperfect because it does not provide privacy protection per se; instead, it only enforces what has been promised by the company. The FTC will likely have the power to administer any federal privacy law that may come to fruition in the future.[222] Arguably, because DTC genealogy and health testing utilize the same sensitive re-identifiable information, the two services should be regulated under like pathways. A privacy law would not be effective if a such a bypass remains.

4. Publicly Accessible Genetic Databases Bypass Current Privacy Protections

It is worth considering a final type of consumer tool used in the analysis of DNA. Websites like GEDmatch.com allow consumers to upload already digitized DNA data.[223] GEDmatch.com recently came into the spotlight as the genetic database that led to the capture of the Golden State Killer.[224] The website allows individuals to upload their genetic data digitized from companies like Ancestry.com and share it through a free database to find relatives that may use another website.[225] GEDmatch.com offers the least privacy protections of any above groups, because testing was not performed on human samples but already digitized information.

Websites like GEDmatch.com allow individuals to quickly access vast amounts of data.[226] Their privacy policy boasts that the company takes care in striking the right balance between individual privacy and access to information.[227] While this application is especially helpful to individuals looking for long-lost relatives, DNA test consumers may be uploading highly sensitive information without fully understanding the significant risks. GEDmatch.com's greatest shortcoming is the accessibility of the database. Because the data is so freely available to anyone who wishes to find a relative, the privacy of an individual is minimal. However, an individual gives informed consent to this minimal privacy.[228]

5. Where Should you Spit?

There is no simple answer when considering where a consumer's data is most protected from the threat of privacy invasion. Practically, a consumer would choose to narrow the type of testing based on the accuracy

222 *See* Press Release, *supra* note 58.

223 Durcharme, *supra* note 35.

224 *Id.*

225 *Privacy Policy*, GEDMATCH.COM, https://www.gedmatch.com/tos.htm (last visited Sept. 28, 2018).

226 *Id.*

227 *Id.*

228 *Id.*

they require in output. Various studies questioned the accuracy of DTC testing, which in part prompted increased regulation from the FDA.[229] If an individual is interested in learning about their risk of disease, they should undoubtedly approach a healthcare professional. If a consumer is concerned only with a curiosity to unlock their genetic building blocks, the consumer must consider their privacy.

In a hospital setting, genetic data can be inputted into a publicly accessible database like the 1000 Genomes Project or "Free the Data!" In hospital and DTC health tests alike, consumers and patients do not have a right to delete their data. Ancestry tests, however, leave consumers only with the protections of the FTC and the contract entered into with the testing company. An open database leaves consumer with the least protection. Consumers must better inform themselves of the risk of inputting their genetic information into a database, such as GEDmatch.com. From this analysis, it is evident that privacy is lacking; whether legal protections take the form of federal or state laws, more is required to protect consumers.

VI. CONCLUSION

When lawmakers consider genetic privacy laws, they must consider them as such: issues of *genetic* privacy. The rapid growth and expansion of genetic analysis and the popularity of genetic testing amongst consumers have left consumers unprotected. Because this field continues to grow and develop, the laws must be adaptable, forward-looking, and specific to genetics. Consumers of either DTC or in-hospital testing either for genetic health analysis or genealogy must face serious compromise to receive the information held in their DNA. However, if one wants to test their DNA, where they should spit? The unfortunate and easiest answer is that you should not. Current privacy protection is a misnomer; it does not protect consumers. Future privacy regulation should specifically tackle the issues of genetic privacy. Finally, these issues should balance the free flow of data that allows for the development of genetic science with the rights of consumers to have their privacy protected.

229 Curley, *supra* note 164.