

Direct-to-Consumer Genetic Testing: The Law Must Protect Consumers' Genetic Privacy

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Executive Summary

Consumers that use direct-to-consumer (DTC) genetic testing generate highly sensitive data about themselves and their biological relatives. The regulatory gap around DTC genetic testing means there is no legal guarantee that this information will remain private. Rather, as the marketplace for health technology continues to evolve, existing health privacy protections leave consumers' sensitive data exposed. Lawmakers must step up and close the regulatory gap by making sure that genetic information remains confidential, with detailed requirements to allow for authorization to disclose the information to specific recipients but in a way crafted to protect the privacy of non-consenting related consumers.

Consumer Reports¹ developed this white paper to inform federal and state policymakers about the need to better protect consumers' genetic privacy due to gaps in the current law. This white paper will:

- explain what genetic testing is;
- what privacy concerns are raised by direct-to-consumer genetic testing;
- what security concerns are raised by direct-to-consumer genetic testing;
- demonstrate why such additional protections are needed to protect the privacy of consumers' genetic information; and
- recommend policy approach to protect the privacy of genetic data.

I. Introduction: What is Genetic Testing?

Genetic testing is a type of medical test that identifies changes in chromosomes, genes, or proteins.² The results of a genetic test can confirm or rule out a suspected genetic condition or help determine a person's chance of developing or passing on a genetic disorder.³ Over 1,000 genetic tests are currently in use, and more are being developed.⁴

Traditional genetic testing is administered through healthcare providers, once the provider determines and orders the appropriate test.⁵ Often, insurance companies cover part or all of the cost of testing.⁶ In contrast, direct-to-consumer (DTC) genetic testing is marketed directly to consumers who send their samples directly to the company.⁷ DTC genetic testing does not usually involve a healthcare provider, the primary difference from traditional genetic testing.⁸ DTC genetic testing can also be referred to as direct-access genetic testing, at home genetic

¹ Consumer Reports is the world's largest independent product-testing organization. It conducts its advocacy work in the areas of privacy, telecommunications, financial services, food and product safety, health care, among other areas. Using its dozens of labs, auto test center, and survey research department, the nonprofit organization rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 6 million members and publishes its magazine, website, and other publications.

² *What is Genetic Testing*, U.S. NAT'L LIBRARY OF MEDICINE, <https://ghr.nlm.nih.gov/primer/testing/genetic-testing> (last visited July 22, 2020).

³ *Id.*

⁴ *Id.*

⁵ *What is direct-to-consumer genetic testing*, U.S. NAT'L LIBRARY OF MEDICINE, <https://ghr.nlm.nih.gov/primer/dtcgenetic-testing/direct-to-consumer> (last visited July 22, 2020).

⁶ *Id.*

⁷ *Id.*

⁸ *Direct-to-Consumer Genetic Tests*, U.S. FED. DRUG ADMIN., <https://www.fda.gov/medical-devices/vitro-diagnostics/direct-consumer-tests> (last visited July 22, 2020).

testing, home DNA testing, and ancestry or genealogy testing.⁹ These transactions are generally governed by the same electronic agreements common to other e-commerce transactions.¹⁰ Direct-to-consumer genetic testing is becoming increasingly popular. Last year, millions of Amazon shoppers found discounted DTC testing kits for sale during Amazon Prime Day.¹¹

According to the FDA, not all DTC genetic tests are accurate, and varying degrees of support exist for their conclusions.¹² There is disagreement within the clinical community about the role of certain genes in determining whether a person may get a specific disease or condition.¹³ The results also vary from company to company, due to the many methods of testing,¹⁴ lending uncertainty to the results.

II. Direct-to-Consumer Genetic Testing Raises Privacy Concerns

With increasing developments of at-home healthcare solutions, testing, and products, it is important to assess how our laws are protecting consumers in the rapidly changing market. Currently, no federal law directly addresses consumer privacy issues resulting from DTC genetic testing; state-based privacy protections are few and far between. As a result, DTC genetic testing companies are largely in control of consumers' most personal information. This information can also affect the privacy of blood relatives, even if they choose not to take these tests. Importantly, blood relatives may be wholly unaware of their relatives' uses of these tests; consent from siblings, parents, children, cousins, nieces and nephews will be implied without notice.

Because of limited privacy laws in general, and the regulatory gap around health technology, companies have broad powers to govern their own practices and how they protect, disseminate, and use customer information. Discussed below in more detail, consumers are mostly¹⁵ protected by how a limited cohort of third parties, such as insurers and employers, use the information from their genetic tests. Still, DTC genetic testing providers have the autonomy to control what happens to a consumer's genetic information once it is received.¹⁶ Not only are companies in

⁹ *What is direct-to-consumer genetic testing?*, U.S. NATIONAL LABORATORY OF MEDICINE (Aug. 20, 2019), <https://ghr.nlm.nih.gov/primer/dtcgeneticstesting/directtoconsumer>.

¹⁰ Anelka M. Phillips, *Reading the Fine Print When Buying Your Genetic Self Online: Direct-to-Consumer Genetic Testing Terms and Conditions*, 36 NEW GENETICS & SOC'Y 273 (2017), available at <https://www.tandfonline.com/doi/full/10.1080/14636778.2017.1352468>.

¹¹ Prime Day is a two-day only online sale for Amazon Prime members. As of December 2019, 112 million people in the United States have Amazon Prime. J. Clement, *Number of U.S. Amazon Prime Subscribers 2013-2019*, STATISTA (Mar. 10, 2020), <https://www.statista.com/statistics/546894/number-of-amazon-prime-paying-members/>.

¹² *What is direct-to-consumer genetic testing?*, *supra* note 9.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ With one exception, the use of genetic information in long term care insurance is not protected by state or federal laws and will be discussed in further detail later.

¹⁶ This does not apply if the consumer decides to opt-out of agreements allowing their information to be disseminated.

control of genetic information, but consumers are often encouraged to provide sensitive information about themselves and their families to maximize the utility of the genetic tests being offered.¹⁷ State and federal laws only partially protect consumers from discrimination based off genetic information,¹⁸ and the current regulatory scheme allows too much self-governance in regards to an individual's, and their blood relatives', most personal information.

Already-existing law arguably limits the ways employers can use genetic information. Insurance and health providers also are significantly limited. Still, serious privacy concerns remain. Access to long-term care insurance can be impacted by the results of genetic testing. Genetic information gathered by DTC genetic companies can be sold to third parties and used internally to benefit the company, with limited information provided to the consumer. Companies view consumer information as an asset,¹⁹ and not as sensitive information that should be handled with special care. Proper limitations on how companies can use consumer information do not exist; this system of self-governance fails consumers.

In a survey of DTC genetic testing companies, 71 percent of companies used consumer information internally for purposes other than providing the results to consumers, with 62 percent of companies saying they use data for internal research and development.²⁰ Seventy-eight percent of companies had data sharing provisions that provided genetic information to third parties in de-identified or aggregate forms without additional consumer consent.²¹ Despite laws on discrimination and limited use of genetic information, an individual's most personal information is still being bought, sold, and traded without clear understanding or consent from the consumer. This major privacy violation has yet to be addressed through legislation, both federal and in most states.

III. Direct-to-Consumer Genetic Testing Raises Security Concerns

In addition to the privacy concerns raised by DTC genetic tests, consumers' use of these tests also raises data security issues. DTC companies are not regulated under the Health Insurance Portability and Accountability Act (HIPAA), the law that protects the privacy and security of health information shared with healthcare providers, health plans, healthcare clearinghouses, and the business associates of covered entities.²² As such, DTC companies are not bound by the

¹⁷ James W. Hazel & Christopher Slobogin, *Who Knows What, and When: A Survey of the Privacy Policies Proffered by U.S. Direct-to-Consumer Genetic Testing Companies*, 28 CORNELL J. L. & PUB. POL'Y 35, 43 (2018), available at <https://ssrn.com/abstract=3165765> [hereinafter *Who Knows What, and When*].

¹⁸ See Appendix for information on current legal protections.

¹⁹ *Who Knows What, and When*, *supra* note 17 at 56.

²⁰ *Id.* at 52.

²¹ *Id.* at 55.

²² Health Insurance Portability and Accountability Act of 1996, Centers for Disease Control and Prevention, <https://www.cdc.gov/phlp/publications/topic/hipaa.html> (last visited July 22, 2020).

HIPAA Security Rule, which ensures the confidentiality, integrity, and availability of all electronic protected health data. Although Section 5 of the Federal Trade Commission Act²³ requires some level of data protection, such protection is unclear and underenforced.

As there are few rules governing the collection, storage, and disposal of genetic data by DTC genetic-testing companies, consumers' genetic privacy and that of their relatives could be vulnerable to a data breach.²⁴ Unlike other breaches of sensitive or personal information, genetic data is immutable. Thus, any breach of DTC genetic testing data will adversely affect the consumer whose information is breached and that consumer's relatives. In 2018, MyHeritage, a direct-to-consumer genetic testing company, experienced a breach of 92 million users' email addresses and hashed (i.e., scrambled) passwords.²⁵ Although this breach did not involve personal genetic data, future data breaches could. Furthermore, as more and more people use DTC testing services, the databases of genetic information stored by these companies represent an increasingly valuable target to bad actors. For these reasons, any new law that works to protect consumers' genetic information that is shared with DTC testing companies should require reasonable security safeguards for the sensitive information they store.

IV. Consumer Reports Recommended Policy Approach to Protect the Privacy of Genetic Data

Lawmakers must create solid legal protections for consumers that use DTC genetic testing, and for their relatives. The optimal legislative solution is to make results from all genetic testing private as a default, with detailed and specific requirements to allow for authorized release of information, with added safeguards to ensure that an individual's choice to share their genetic information will not impute genetic data for blood relatives. The legislative solution should also require DTC companies to reasonably secure the consumers' private genetic information. The goal of this new law would be to protect an individual's genetic information because of its deeply personable and unalterable nature—regardless of the source of the test or its results. As the landscape of at-home healthcare evolves, the parameters for what is protected genetic information therefore must be broadly defined.

Lawmakers may borrow from examples already set in Illinois and Missouri law,²⁶ which both strictly limit whether and the extent to which direct-to-consumer genetic test results may be used. This policy stops DTC genetic testing providers from selling information unless the person to

²³ 15 U.S.C § 45.

²⁴ Rhys Dipshan, *Giving Away Your Genes: US Law's Blind Spot with DNA Data*, LAW.COM (Aug. 2, 2018), <https://www.law.com/legaltechnews/2018/08/02/giving-away-your-genes-u-s-laws-blind-spot-with-dna-data/>.

²⁵ Makena Kelly, *MyHeritage Breach Leaks Millions of Account Details*, THE VERGE (June 5, 2018), <https://www.theverge.com/2018/6/5/17430146/dna-myheritage-ancestry-accounts-compromised-hack-breach>.

²⁶ See Appendix for additional information on state approaches to legislating privacy.

whom the information is being released is specifically authorized by the individual. It also protects individuals from being unknowingly discriminated against by insurers because insurers would only have access to this information with specific authorization from the individual. Policymakers should broadly prohibit the use of genetic data in insurance underwriting, and prohibit insurers from discriminating against individuals who do not provide such information. Alternatively, policymakers could repurpose Illinois’s restriction that allows the use of genetic data in underwriting only “if the individual voluntarily submits the results and the results are favorable to the individual,” though such a policy could result in unfairly higher rates for individuals unwilling or unable to provide a “favorable” test.²⁷

A significant aspect of this approach is the written requirements for authorization to release the genetic information. These documents would need to be separate from other documents that are reviewed by the consumer. If a DTC genetic testing company would like to share consumer information with a third party, they must send a separate agreement for the consumer to review, not an authorization buried in other legal documents reviewed by the consumer. The Illinois act also specifies that “No person to whom the results of a test have been disclosed may disclose the test results to another person except as authorized under this Act.”²⁸ Written authorization would need to specify exactly to whom the results are going, and that the privileged and confidential nature of the information would transfer to the third party. In order to transfer the information to another party, the consumer would need to provide written authorization for this transfer. This burden on third parties who wish to gain genetic information would be appropriate and necessary to allow the consumer to have complete control over access to their most sensitive information, how it is shared, and why it is shared. If companies would like to access genetic information, they will need to overcome these necessary hurdles to ensure information is protected at a high standard. Where in state code genetic privacy could be protected will vary based on the state.

In addition to drafting a separate genetic data privacy act, lawmakers may consider amending the definition of “medical information,” or the relevant terms, to include results from DTC genetic testing in state-based medical privacy laws. If a DTC genetic test is considered “protected health information” (or “medical information”), testing companies may not be able to share consumers’ information without their express authorization. Expanding these definitions may at first glance appear to be a straightforward way to protect DTC genetic testing information, but making the definition too broad could have unintended consequences. As noted by the Federal Drug Administration (FDA),²⁹ the accuracy of some of these tests is questionable, and no consensus in the scientific community exists about their accuracy. Expanding the definition of medical information to include DTC genetic testing results could put these two types of information on

²⁷ 410 ILL. COMP. STAT. 513 § 20 (c).

²⁸ 410 ILL. COMP. STAT. 513/35.

²⁹ *Direct-to-Consumer Genetic Tests*, *supra* note 8.

the same plane, lending them unearned credibility.

This protection would have minimal meaning without strong enforcement power. Similar to the statutes in Alaska, Illinois, and Missouri, a private right of action should be authorized under this code as well as a civil fine. An individual should be able to collect reasonable attorney's fees and costs, as well as other appropriate relief such as an injunction. Nothing in the code should limit relief under other applicable law. This is modeled after the Illinois codes enforcement mechanisms.³⁰

V. Consumer Reports Warns Against Creating a Property Right in Genetic Data

Consumer Reports urges lawmakers against creating a property right for an individual's genetic information. There is already an opaque market for consumers' personal information and consumers are left out of the profit chain. But the solution is not to pay consumers to give up their privacy—they deserve privacy rights to shield their genetic information from being monitored and sold by data brokers. They do not need policy that ratifies a harmful data ecosystem.

Supporters of the property approach to data rights claim that it accommodates various opinions and preferences when it comes to personal data. To wit: some individuals have no problem sharing their personal data for either monetary gain or sense of societal obligation, while others feel a strong sense of protection over their information. The theory is that having a property interest in genetic information allows consumers to control their data and to benefit from their information being shared if they chose to share it.

Realistically, even if an individual wishes to sell their genetic information, complications would arise from the commodification of genetic information. First, an individual may be willing to sell or give their information to one party for a certain reason, but not to a second party for a different reason. When something is considered property, there are particular rules regarding the transferability of that information.³¹ Once the information is sold, its future destinations will most likely be out of the control of the consumer. Genetic information is not like a car or a piece of clothing resold after the original sale. As noted earlier, genetic information is deeply personal, and an individual might not be comfortable with their most personal information being used in ways they cannot foresee at the time of sale. Additionally, it is difficult for individuals to judge the risks of selling their personal information. While some of these risks can be mitigated, like putting strict limits of transferability, it is unusual to have a property right without a presumption

³⁰ 410 ILL. COMP. STAT. 513/40.

³¹ Pamela Samuelson, *Privacy as Intellectual Property*, 52 SAN. L. REV. 1125, 1139 (1999), available at http://people.ischool.berkeley.edu/~pam/papers/privasip_draft.pdf.

of the right to sell property from one owner to the next, otherwise known as alienability.³² This suggests that an interest in the information not rooted in property law may be a more efficient solution.³³

There is also a danger of low-income and marginalized communities being targeted to sell their information. For any individual, the task of fully analyzing the risk of releasing information is extremely difficult if not impossible. Such an analysis forces individuals to balance immediate monetary compensation against what may feel like theoretical future harms. The scales would be tipped for those with a significant and immediate need for cash.

We stand at a critical juncture for individual data rights. Any legislation that seeks to protect consumers' genetic information must not fortify a status quo that is eroding fairness and trust in the marketplace.

VI. Conclusion

Genetic data from DTC genetic testing lacks the legal privacy protections appropriate for such sensitive information. As the market adapts and technology developers sell directly to consumers, privacy protections for this extremely personal information must be elevated. Consumer Reports therefore urges lawmakers to resolve the regulatory gap by making genetic data, created via DTC genetic testing, privileged and confidential, and empowering consumers to control who has access to their genetic information.

For more information on Consumer Reports' genetic privacy legislation recommendations, please contact:

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³² *Id.* at 1145.

³³ *Id.*

Appendix – Relevant Federal and State Privacy Laws

I. Federal Law

Traditional and DTC genetic testing results and genetic information are protected by some federal laws and federal oversight. Although the Food and Drug Administration (FDA) has oversight over DTC genetic testing, their main concern is the validity, not the privacy of the results. The Federal Trade Commission (FTC) can control the marketing practices of the DTC genetic testing company, but they are not currently using their enforcement powers to protect the privacy of the information. Traditional genetic testing, i.e. testing done through a healthcare provider, is regulated under the Health Insurance Portability and Accountability Act (HIPAA) and the Genetic Information Nondiscrimination Act (GINA), but DTC genetic testing is only covered by GINA, not HIPAA. Though GINA provides substantial protections, it is limited in scope and focuses on discrimination based off information, not the protection of the information once it is in possession of the company.

A. FDA Oversight: The Food, Drug & Cosmetics Act (FDCA)

The Federal Food, Drug and Cosmetic Act (FDCA) charges the FDA with regulating medical devices, which are defined as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.”³⁴ Added to that, the 21st Century Cures Act amended the FDCA to exclude software that is intended “For maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.” The 21st Century Cures Act also excluded “clinical decision support” (CDS) software used by clinicians in clinical decision-making. The end result of these laws is that:

Applying these provisions to third-party genetic interpretation services, the FDA clearly lacks authority to regulate services that provide or facilitate interpretations of genetic data solely for the purposes of helping users understand their ancestors’ geographic origins or identify their genetic relatives, as such interpretations are not intended for use in disease diagnosis, prognosis, treatment, or prevention and do not affect any bodily function or structure. With respect to third-party genetic interpretation services that do provide health-related information, however, the regulatory picture is murky ... Finally, and as a more general matter, it is unsettled whether the FDA’s authority extends to software that is developed and

³⁴ 21 U.S.C. § 321(h)(2).

used by third-party genetic interpretation services but is not itself commercially distributed.”³⁵

Finally, as with CLIA, whether the FDCA applies to DTC genetic testing relates to the accuracy of the claims and the test results, not the nature and privacy of the information. However, keeping in mind FDA jurisdiction may be meaningful if drafting legislation.

B. FTC Oversight: The Federal Trade Commission Act (FTCA)

Under the Federal Trade Commission Act (FTCA), the FTC has the authority to protect consumers from unfair or deceptive business practices.³⁶ When it comes to DTC genetic testing, the FTCA gives the FTC the power to stop companies from making false claims about what their genetic testing products do. When it comes to privacy, the FTC has the authority to enforce the FTCA on DTC genetic testing companies that violate their own privacy policies. This means that a company can post lax or limited privacy policies and meet that low bar, and the FTC is without jurisdiction to demand better. Companies are prohibited from retroactively changing these privacy policies, which the FTC states “constitutes deceptive and unfair business practices.”³⁷

More engagement from the FTC could be helpful in making sure there are stricter transparency and disclosure rules to consumers about the sale of their information to third parties. Overall the ability of the FTC to act is limited, though they could be more aggressive with their existing powers. The primary actions taken by the FTC, thus far, are general warnings and advisories on their website regarding DTC genetic testing.³⁸ Despite being aware of the practices of the DTC genetic testing providers, the FTC has for the most part chosen not to use their enforcement power.³⁹ The FTC has brought one administrative action against a DTC genetic testing company for making false claims about their ability to prescribe skin care solutions and their practices regarding data security.⁴⁰ However, the primary focus of that case was on a lack of substantiation

³⁵ Christi J. Guerrini, et al., *Who’s on Third? Regulation of Third-Party Genetic Interpretation Services*, GENETICS IN MEDICINE (August 12, 2019) at 5, available at <https://doi.org/10.1038/s41436-019-0627-6> [hereinafter *Who’s on Third?*].

³⁶ 15 U.S.C. § 45(a)(1). Deceptive advertising is officially defined by the Federal Trade Commission (FTC) as “a representation, omission or practice that is likely to mislead the consumer” and “practices that have been found misleading or deceptive.” FTC Policy Statement on Deception, FED. TRADE COMM’N (1983), <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>.

³⁷ *Gateway Learning Corp., File No. 042-3047*, FED. TRADE COMM’N (Sept. 17, 2004) (complaint), <http://www.ftc.gov/os/caselist/0423047/040917comp0423047.pdf>.

³⁸ *Direct-to-Consumer Genetic Tests*, U.S. FED. TRADE COMM’N, <https://www.consumer.ftc.gov/articles/0166-direct-consumer-genetic-tests> (last updated Jan. 2014); *DNA Test Kits: Consider the Privacy Implications*, U.S. FED. TRADE COMM’N, (Dec. 12, 2017), <https://www.consumer.ftc.gov/blog/2017/12/dna-test-kits-consider-privacy-implications>.

³⁹ *Who Knows What, and When*, *supra* note 17 at 42.

⁴⁰ *In the Matter of Genelink., a corporation also d/b/a Genelink Biosciences, Inc., and Foru™ International Corporation formerly known as Genewize Life Sciences, Inc.*, FED. TRADE COMM’N (May 12, 2014), <https://www.ftc.gov/system/files/documents/cases/140512genelinkcmpt.pdf>.

for its claims about the efficacy of its products.⁴¹ Given the sensitivity of genetic testing data, the FTC could seek to use its unfairness authority to broadly limit secondary use and sharing of this information, but to date has not done so.⁴²

C. CMS Oversight: The Clinical Laboratory Improvement Amendments of 1988 (CLIA)

Any clinical laboratory that operates in, or returns test results to consumers in the United States, is regulated by Centers for Medicare and Medicaid Services (CMS)⁴³ under Pub. L. 100–578, the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and implementing regulations. Under this law, a *clinical laboratory* is a “facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.”⁴⁴ A lab that meets the CLIA definition of clinical laboratory must meet a certification standard, demonstrate compliance with regulations having to do with personnel and quality control (among other factors), and must be able to ensure tests results are analytically valid. Importantly, CLIA does not address the clinical validity or clinical utility of genetic tests.⁴⁵

Genetic testing, conducted through a DTC company, can be performed in-house or can be outsourced. A DTC genetic testing company that does not purport to provide health-related testing is not required to obtain CLIA certification. Similarly, depending on what claims they make, these DTC genetic testing companies can use an outside lab that is not CLIA certified. Further, they may use a CLIA-certified lab even though, technically, it is not necessary. Whether CLIA extends to labs that conduct genetic testing is unclear. In fact, in 2018 the Clinical Laboratory Improvement Advisory Committee (CLIAC) recommended the formation of a working group to consider “the need for optimal oversight by CLIA” of these nontraditional

⁴¹ *Id.*

⁴² 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.” 15 U.S.C. § 45(n). In other contexts, the Federal Trade Commission has alleged that the sharing of sensitive personal information for commercial purposes without clear consent constituted an unfair practice. *FTC v. Vizio*, FED. TRADE COMM’N (February 16, 2017), https://www.ftc.gov/system/files/documents/cases/170206_vizio_2017.02.06_complaint.pdf (alleging that the sharing of television viewing activity without permission was an unfair business practice under the FTC Act).

⁴³ The Division of Clinical Laboratory Improvement & Quality, within the Quality, Safety & Oversight Group, under the Center for Clinical Standards and Quality (CCSQ) has the responsibility for implementing the CLIA Program.

⁴⁴ 42 U.S.C § 263a.

⁴⁵ In some cases, the Food and Drug Administration (FDA) requires information about clinical validity for some genetic tests.

testing models.⁴⁶

Ultimately, CLIA is chiefly a law designed to ensure the quality and safety of clinical laboratories; it does not address consumer privacy, except to the extent that patients have the right to request (and receive) their laboratory test results directly from the lab rather than going through their healthcare provider. Therefore, in a conversation about whether consumer privacy protections are sufficient in the case of DTC genetic testing, whether-or-not the laboratory processing the genetic test is CLIA-certified is of little to no importance. However, it may be relevant in the context of definition setting in newly drafted laws and regulations.

D. OCR Oversight: The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule established a national standard for protecting personal health information and setting limits and conditions for the disclosure of this information.⁴⁷ HIPAA also has a Security Rule that protects electronic personal information.⁴⁸ The Office of the National Coordinator for Health Information Technology of CMS, known as OCR, is tasked with enforcing these rules. In 2013, the HIPAA Omnibus Rule amended HIPAA to include genetic information in the definition of “protected health information.”⁴⁹

Although consumers may rely on HIPAA to protect their health privacy, the results of DTC genetic testing are rarely protected under HIPAA because they must be maintained by a healthcare provider, health plan, or healthcare data clearinghouse.⁵⁰ Unless the result of DTC genetic testing is conveyed to one of those entities, and integrated into their records, which is not the norm, the test results will not fall under HIPAA privacy protections. Furthermore, even if a copy of the test results becomes HIPAA protected health information (PHI), the original records would remain outside of HIPAA controls.

E. Equal Employment Opportunity Commission Oversight: Genetic Information Nondiscrimination Act of 2008 (GINA)

⁴⁶ *Who’s on Third?*, *supra* note 35 citing *Summary Report*, CLINICAL LABORATORY IMPROVEMENT ADVISORY COMM., (Apr. 10–11, 2018),

https://ftp.cdc.gov/pub/CLIAAC_meeting_presentations/pdf/CLIAAC_Summary/cliac0418_summary.pdf.

⁴⁷ 45 C.F.R. §160; 45 C.F.R. §164(a) and (e).

⁴⁸ *Id.*

⁴⁹ *Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules*, 78 FR 5565 (Jan. 25, 2013) (revising 45 C.F.R. § 160 and 45 C.F.R. § 164).

⁵⁰ See 45 C.F.R §160.103; and, see 45 C.F.R § 164.501.

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that regulates employers’ and insurance providers’ ability to use genetic information.⁵¹ GINA defines “genetic information” as information about an individual’s genetic test, the genetic test of a family member, and the manifestation of a disease or disorder in family members of individuals.⁵² The term “genetic test” is defined as an analysis of human DNA, ribonucleic acid (RNA), chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.⁵³ Although DTC genetic testing is not referenced specifically in the law, a DTC genetic test would meet the definition of genetic test defined in the statute⁵⁴, and the results of the test are genetic information.

Under GINA, employers are prohibited from requesting, requiring, or purchasing genetic information. Additionally, it is unlawful for an employer to refuse to hire, discharge, or discriminate against an employee based on genetic information.⁵⁵ Health insurance providers also are prohibited from requesting, requiring, or using a person’s genetic information for underwriting purposes.⁵⁶ This protection does not cover life, disability, or long-term care insurance.⁵⁷ Although GINA significantly restricts the way employers and insurers can use genetic information, it does not establish any rules or standards for DTC genetic testing providers when they initially share genetic information with various third parties and does not include important forms of insurance.

II. State-based DTC Genetic Testing Privacy Protections

A. Florida

Florida recently enacted a law specifically targeting the use of genetic information in underwriting insurance policies, extending existing federal protections to cover other forms of insurance such as life, disability or long-term care coverage.⁵⁸ The bill prohibits these insurers from using genetic data to cancel, deny, limit, or set prices for insurance policies unless there has been a diagnosis of a medical condition.

⁵¹ *Genetic Information Non-Disclosure Act, H.R. 493*, 110TH CONG. §101, <https://www.govinfo.gov/content/pkg/BILLS-110hr493enr/pdf/BILLS-110hr493enr.pdf>.

⁵² 42 U.S.C. § 2000ff(4); *Id.*

⁵³ 42 U.S.C. § 2000ff(7); *Genetic Information Non-Disclosure Act, H.R. 493*, *supra* note 51.

⁵⁴ In *Lowe v. Atlast Regional Group Retail Services*, the court found the legislative intent for a broad definition of the term “genetic test.” In this case, fecal matter analyzed by an employer was considered a genetic test, and therefore the information derived from the analysis was genetic information that could not be used to fire an employee. 102 F.Supp.3d 1360 (N.D. Ga. 2015).

⁵⁵ 42 U.S.C. § 2000ff-1(a); 42 U.S.C. § 2000ff-1(b).

⁵⁶ *Genetic Information Non-Disclosure Act, H.R. 493*, *supra* note 51.

⁵⁷ *Id.*

⁵⁸ FLORIDA STAT. § 627.4301.

B. Alaska

In 2004 Alaska passed the Alaska Genetic Privacy Act, which requires written informed consent for the collection, analysis, retention, or disclosure of DNA samples and test results.⁵⁹ A DNA sample and the results of any genomic analysis under this act are the exclusive property of the person or sample analyzed.⁶⁰ Both civil and criminal fines exist for violating the statute, and a private right-of-action is authorized. This law is found in Alaska's Public Health and Safety Code.

C. Illinois

Under the Genetic Information Privacy Act, "genetic testing and information derived from genetic testing is confidential and privileged and may be released only to the individual tested and to persons specifically authorized...by that individual to receive the information."⁶¹ Direct-to-consumer genetic testing companies specifically are only permitted to share testing information or other personally identifiable information about a consumer with any health or life insurance company if they receive written consent to do so.⁶² In addition, insurers may only consider the results of genetic testing if both the individual voluntarily submits the information and that information is favorable to the individual.⁶³

The definition of genetic test under this law is "an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes."

⁶⁴ A person under this act has a private right-of-action, and significant fines can be levied for violation.⁶⁵ This law is found in the Illinois Public Health code.

D. Missouri

Under Missouri law, "any person who, in the ordinary course of business, practice of a profession or rendering of a service, creates, stores, receives or furnishes genetic information ... shall hold such information as confidential medical records and shall not disclose such genetic information except pursuant to written authorization of the person to whom such information

⁵⁹ ALASKA STAT. § 18.13.010.

⁶⁰ ALASKA STAT. § 18.13.010 (a)(2).

⁶¹ 410 ILL. COMP. STAT. 513/15 (a).

⁶² 410 ILL. COMP. STAT. 513 §. 20 (e).

⁶³ 410 ILL. COMP. STAT. 513 §. 20 (c).

⁶⁴ 410 ILL. COMP. STAT. 513/10; 45 C.F.R. § 160.103.

⁶⁵ 410 ILL. COMP. STAT. 513/40.

pertains or to that person's authorized representative.”⁶⁶ A genetic test is defined as “a laboratory test of human deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) used to identify the presence or absence of inherited alterations in the DNA or RNA which cause predisposition to disease or illness.”⁶⁷ Although this is under Missouri’s insurance code, it defines a person as “a natural or artificial entity, including, but not limited to, individuals, partnerships, associations, trusts or corporations.”⁶⁸

E. Nevada

Nevada law⁶⁹ requires consent from the individual prior to collection, retention, or disclosure of their genetic information. Additionally, the individual for whom the genetic information applies has the right to obtain and review their genetic records and they can require the genetic information destroyed. This law is enforced via private right of action as well as criminal penalties.

⁶⁶ MO. ANN. STAT. 375.1309 (1).

⁶⁷ MO. ANN. STAT. 375.1300 (4).

⁶⁸ MO. ANN. STAT. 375.1300 (6).

⁶⁹ NEV. REVISED STAT. 629.101 et. seq.