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DON'T SWAB ME!: LIMITATIONS OF THE GENETIC INFORMATION PRIVACY ACT IN THE MODERN GENETIC TESTING LANDSCAPE

Ibrahim Al-Gahmi[*]

ABSTRACT

In an age where consumers can easily obtain genetic tests by simply sending a saliva or cheek swab sample through the mail and learn more than ever about their DNA and its genetic makeup, it is imperative that measures are established to provide consumers with both control and protection to the privacy of their submitted biological sample and analyzed genetic data. Currently, the landscape of genetic testing, and the resulting genetic information, is regulated by one law in New Mexico. The Genetic Information Privacy Act (NM-GIPA or Act), enacted in 1998, provides general prohibitions on the collection of genetic information or samples for genetic analysis without an individual's informed consent. Because the Act's effectiveness is limited by its narrow definitions, inadequate consent requirements, and blanket exceptions, it leaves consumers susceptible to improper uses of their genetic data without their knowledge or consent. This is especially the case where genetic testing and analysis is obtained through private, direct-to-consumer genetic testing (DTC-GT) companies, which have significantly gained popularity over the last decade.

New Mexico has an opportunity to address the vulnerabilities posed by DTC-GT by amending NM-GIPA to protect consumers who use DTC-GT services to submit their biological samples for genetic testing and analysis or to upload their genetic data for interpretation. Strengthening the regulation of genetic testing and data provides consumers with personal autonomy over how their genetic data is used, helping to prevent improper usage, discrimination, or unauthorized exposure of the genetic data. Regardless of a consumer's motivations to explore their DNA, it should not come at the cost of compromising the consumer's personal autonomy or privacy of their genetic information.

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INTRODUCTION

In 1990, the Human Genome Project, an international scientific endeavor, undertook a mission to produce the first sequence of the human genome.[1] Thirteen years later and at a cost of roughly $3 billion, the project sequenced 92% of the human genome in 2003, a feat for the technology available at the time.[2] The need to generate the first sequence of the human genome required "development of high-throughput technologies for preparing, mapping and sequencing DNA."[3] The completion of the Human Genome Project ushered in a new era of genetic and medical research.[4]

Within the decades that followed, genome sequencing and genetic testing technology soared, significantly improving the speed, cost, and accuracy of sequencing DNA.[5] Amidst this scientific advancement emerged direct-to-consumer genetic testing (DTC-GT) services, which allowed consumers to learn more about their genetic makeup without the involvement of a health care provider.[6] Rather than sequencing the whole genome, most DTC-GT companies instead focus on select regions of the DNA where genetic variation has been reported to be linked to a trait or disease, known as SNP-chip genotyping.[7] Companies like 23andMe, Ancestry, and MyHeritage, among many others,[8] offer comparable genetic testing services that

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[1] *Human Genome Project Fact Sheet*, NAT'L HUM. GENOME RSCH. INST. (Aug. 24, 2022), https://www.genome.gov/about-genomics/educational-resources/fact-sheets/human-genome-project [https://perma.cc/5JSR-V8CP].

[2] *Id.*

[3] Leroy Hood & Lee Rowen, *The Human Genome Project: Big Science Transforms Biology and Medicine*, 5 GENOME MED., no. 79, Sept. 13, 2013, at 1, 2.

[4] *See id.* at 1.

[5] *See The Cost of Sequencing a Human Genome*, NAT'L HUM. GENOME RSCH. INST. (Nov. 1, 2021), https://www.genome.gov/about-genomics/fact-sheets/Sequencing-Human-Genome-cost [https://perma.cc/D7Q4-QGWR] (providing a breakdown of the cost of genome sequencing from when the Human Genome Project began its mission to sequence the human genome to today); *see also* M. Via, E. Ziv & E.G. Burchard, *Recent Advances of Genetic Ancestry Testing in Biomedical Research and Direct to Consumer Testing*, 76 CLINICAL GENETICS 225, 225–26 (2009).

[6] Megan A. Allyse, David H. Robinson, Matthew J. Ferber & Richard R. Sharp, *Direct-to-Consumer Testing 2.0: Emerging Models of Direct-to-Consumer Genetic Testing*, 93 MAYO CLINIC PROC. 113, 113–14 (2018).

[7] Rachel Horton, Gillian Crawford, Lindsey Freeman, Angela Fenwick, Caroline F. Wright & Anneke Lucassen, *Direct-to-Consumer Genetic Testing*, BMJ, no. 367, Oct. 16, 2019, at 1, 1. However, some DTC-GT companies have started to offer whole genome sequencing services as the cost of DNA sequencing continues to decrease and the "computational speed and data storage capacity" continues to rapidly grow. Joel C. Eissenberg, *Direct-to-Consumer Genomics: Harmful or Empowering?*, 114 MO. MED. 26, 28 (2017).

[8] A study conducted in 2016 identified 246 DTC-GT companies offering different genetic services, "rang[ing] from health and ancestry tests to those for child talent, paternity, and infidelity." Andelka M. Phillips, '*Only a Click Away — DTC Genetics for Ancestry, Health, Love . . . and More: A View of the Business and Regulatory Landscape*,' 8 APPLIED & TRANSLATIONAL GENOMICS 16, 16–17 (2016) [hereinafter Phillips, *DTC Genetics*].

provide consumers with reports of their ancestral background, susceptibility to health risks, and kinship to others with similar DNA, to name a few.[9]

In the short history that DTC-GT services have persisted, these services have not come without their fair share of concerns. For one, concerns have been raised regarding inaccuracies and false positives in the genetic analysis reports provided to consumers.[10] Moreover, law enforcement agencies have started using genetic information provided by DTC-GT companies in the course of their investigations and to identify perpetrators of past crimes.[11] And with the rise and use of DNA interpretation tools and databases that provide for additional analysis of genetic data, the probability of a consumer's genetic data being exposed is further increased as more of these companies host a consumer's genetic data.[12] However, these concerns, as well as others, have not forestalled the uses of DTC-GT services as they continue to grow exponentially. The American Medical Association estimates that by the end of 2021, upwards of one hundred million individuals have undergone genetic testing through DTC-GT companies.[13] Additionally, the global DTC-GT market surpassed $1.4 billion USD in 2021, with projections the market will exceed $4.4 billion by 2028.[14]

As DTC-GT companies continue to expand their businesses, lowering the cost of test kits, providing new reports as discoveries are made, and marketing to new consumers, little regulation is currently available within the United States or

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[9] *See 23andMe Compare DNA Tests*, 23ANDME, https://www.23andme.com/compare-dna-tests [https://perma.cc/P65B-RUFS]; *Ancestry DNA Test Kits*, ANCESTRY, https://www.ancestry.com/dna [https://perma.cc/S387-PQ38]; *MyHeritage DNA Test Kits*, MYHERITAGE, https://www.myheritage.com/dna [https://perma.cc/MDY6-U8QP]; *see also* Jessica DiGiacinto & Sarah Davis, *5 Best DNA Testing Kits Of 2023: Reviews and Costs*, FORBES (Sept. 21, 2023), https://www.forbes.com/health/body/best-dna-testing-kit [https://perma.cc/HFB7-A9HW] (providing a breakdown of the most popular direct-to-consumer genetic testing kits as of 2023, "consider[ing] factors such as cost, information security and how detailed matches actually get, among others.").

[10] *See e.g.*, Amanda Ewart Toland, *New Study Shows the Inaccuracy of At-Home Genetic Tests*, 43 ONCOLOGY TIMES 15, 15 (2021); Stephany Tandy-Connor, Jenna Guiltinan, Kate Krempely, Holly LaDuca, Patrick Reineke, Stephanie Gutierrez, Phillip Gray, & Brigette Tippin Davis, *False-Positive Results Released by Direct-to-Consumer Genetic Tests Highlight the Importance of Clinical Confirmation Testing for Appropriate Patient Care*, 20 GENETICS MED. 1515, 1519–20 (2018).

[11] *See e.g.*, Thomas Fuller, *How a Genealogy Site Led to the Front Door of the Golden State Killer Suspect*, N.Y. TIMES (Apr. 26, 2018), https://www.nytimes.com/2018/04/26/us/golden-state-killer.html [https://perma.cc/L8NY-D9BU]; Raehoon Jeong, *How Direct-to-Consumer Genetic Testing Services Led to the Capture of the Golden State Killer*, HARV. SITN (Sept. 2, 2018), https://sitn.hms.harvard.edu/flash/2018/direct-consumer-genetic-testing-services-led-capture-golden-state-killer [https://perma.cc/L8NY-D9BU].

[12] *See, e.g.*, Michael D. Edge & Graham Coop, *Attacks on Genetic Privacy Via Uploads to Genealogical Databases*, ELIFE, no. 9, Jan. 7, 2020, at 1, 2.

[13] Tanya Albert Henry, *Protect Sensitive Individual Data at Risk from DTC Genetic Tests*, AMA (Nov. 16, 2021), https://www.ama-assn.org/delivering-care/patient-support-advocacy/protect-sensitive-individual-data-risk-dtc-genetic-tests [https://perma.cc/FN7G-3RA2]; *see also* Antonio Regalado, *More than 26 Million People Have Taken an At-Home Ancestry Test*, MIT TECH. REV. (Feb. 11, 2019), https://www.technologyreview.com/2019/02/11/103446/more-than-26-million-people-have-taken-an-at-home-ancestry-test [https://perma.cc/5JDT-KTKP].

[14] *Direct-to-Consumer Genetic Testing Market*, GLOB. MKT. INSIGHTS (Apr. 2022), https://www.gminsights.com/industry-analysis/direct-to-consumer-dtc-genetic-testing-market [https://perma.cc/SL26-ZAS5].

New Mexico to control the collection, retention, transmission, usage, and destruction of genetic samples, as well as the personal and genetic data obtained and retained by DTC-GT companies. Federal legislation such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA)[15] fail to protect individuals from DTC-GT companies because no health care provider or insurer is involved in the purchasing of a test kit. And the federal Genetic Information Nondiscrimination Act of 2008 (GINA)[16] only prohibits health insurers or employers with fifteen or more employees from discriminating against an individual based on their genetic information; it does not, however, include disability, long-term care, or life insurance companies within its scope.

For consumers, use of DTC-GT services can promote awareness of their health and encourage proactive decision making in terms of lifestyle changes aimed at reducing health risks.[17] These services can also provide benefits to society, allowing us to learn more about our DNA, identify genetic variations, and intervene early for certain health risks.[18] However, use of DTC-GT services should not come at the cost of compromising a consumer's personal autonomy and control over their genetic data. Both elements can exist together mutually, promoting personal responsibility of a consumer's health and advancing breakthroughs in science and medicine that benefit society while also protecting individual autonomy and privacy. Several states have recently begun to enforce regulations on DTC-GT companies, balancing both social benefits and privacy protections.[19]

This Comment argues that New Mexico's Genetic Information Privacy Act (NM-GIPA or Act) fails to provide consumers with adequate protections for their genetic information that is collected and retained by DTC-GT companies. The Act's narrow definitions, inadequate consent requirements, and blanket exceptions leave DTC-GT companies largely unregulated and outside the scope of the Act. Unlike other types of information collected from consumers, such as a password or Social Security number, DNA is unique and identifiable to an individual and thus cannot be changed once compromised.[20] And while obtaining a genetic test is an individual

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[15] Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified in various titles of the U.S.C.).

[16] Pub. L. No. 110-233, 122 Stat. 881 (2008) (codified as amended in scattered sections of 29, 42 U.S.C.).

[17] Cinnamon S. Bloss, Burcu F. Darst, Eric J. Topol & Nicholas J. Schork, *Direct-to-Consumer Personalized Genomic Testing*, 20 HUM. MOLECULAR GENETICS R132, R133 (2011).

[18] *See* Pascal Su, *Direct-to-Consumer Genetic Testing: A Comprehensive View*, 86 YALE J. BIOLOGY MED. 359, 360–61 (2013); Jeffrey S. Bland, *In Defense of Direct-to-Consumer Genetic Testing*, 18 INTEGRATIVE MED. 8, 9 (2019).

[19] *See generally* Arizona's Genetic Information Privacy Act, ARIZ. REV. STAT. ANN. §§ 44-8001 to -8004 (effective Sept. 29, 2021); California's Genetic Information Privacy Act, CAL. CIV. CODE §§ 56.18 to .186 (West, effective Jan. 1, 2022); Kentucky's Genetic Information Privacy Act, KY. REV. STAT. ANN. § 311.705 (West, effective July 14, 2022); Maryland's Genetic Information Privacy Act, MD. CODE ANN., COM. LAW §§ 14-4401 to -4408 (West, effective Oct. 1, 2022); Utah's Genetic Information Privacy Act, UTAH CODE ANN. §§ 13-60-101 to -106 (West, effective May 5, 2021); Wyoming's Genetic Data Privacy Act, WYO. STAT. ANN. §§ 35-32-101 to -105 (West, effective July 1, 2022).

[20] Jennifer King, "*Becoming Part of Something Bigger": Direct to Consumer Genetic Testing, Privacy, and Personal Disclosure*, 3 PROC. ACM HUM.-COMPUT. INTERACTION, no. 158, Nov. 7, 2019, at 1, 3; Sally Greenberg, There's No 'Reset Password' for Your DNA, NEWSWEEK (Aug. 10, 2022, 8:00 AM),_https://www.newsweek.com/theres-no-reset-password-your-dna-opinion-1731849 [https://perma.cc/FC8H-WHD3].

decision, a compromise to this genetic information carries with it a risk for the individual's family.[21] Because of the Act's shortcomings, individuals are left to resort to these companies' terms of service and privacy statements, which vary in protections among these companies, and sometimes are not in the best interest of the consumer.[22]

Part I of this Comment provides background on DTC-GT companies, the different types of genetic testing services they offer, and their collection and retention practices. Part I also explores the growing privacy and security concerns of DTC-GT services and the current federal and state regulations in effect governing this industry. Part II examines NM-GIPA, its current scope of applicability, and the merits and shortcomings of the Act. This section also confronts the implications of not promulgating robust genetic data privacy regulations and how lack of these protections can expose consumers to improper uses of their genetic data, even when that data is anonymized. Finally, this Comment, in Part III, concludes with suggestions for amending NM-GIPA. New Mexico can adopt from recently enacted genetic privacy laws in other states in order to build its own genetic data regulations that help remedy the vulnerabilities that genetic testing by DTC-GT services pose.

I. DIRECT-TO-CONSUMER GENETIC TESTING

A. Background

Direct-to-consumer genetic testing (DTC-GT) emerged in the early 2000s as a means of providing consumers with a simpler alternative to obtaining a genetic test and learning more about their genetic makeup.[23] Unlike traditional clinical genetic testing—whereby individuals obtain genetic tests through orders from health care practitioners and which the tests are covered by health insurers—DTC-GT provides consumers with a variety of tests while also making it affordable and accessible.[24] The cost of DTC-GT services can range from less than $100 to more than $1000, depending on the type of test sought and the amount of DNA sequenced.[25] Additionally, the test collection methods are not invasive, usually requiring only gathering saliva or a cheek swab, instead of drawing blood.[26]

DTC-GT services also differ from traditional clinical genetic testing services as they are promoted directly to consumers "via television, radio, print

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[21] King, *supra* note 20, at 3.

[22] *See* 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, 35 (2018) (conducting a study on the privacy policies of ninety DTC-GT companies in the United States to identify the "extent those policies inform consumers about how their genetic information will be used and secured, with whom it will be shared, and a host of other issues.").

[23] Allyse et al., *supra* note 6, at 113–14.

[24] *See What is Direct-to-Consumer Genetic Testing?*, MEDLINEPLUS (June 21, 2022), https://medlineplus.gov/genetics/understanding/dtcgenetictesting/directtoconsumer [https://perma.cc/BDG6-TR4Y].

[25] *How Much Does Direct-to-Consumer Genetic Testing Cost, and Is It Covered by Health Insurance?*, MEDLINEPLUS (June 21, 2022), https://medlineplus.gov/genetics/understanding/dtcgenetictesting/dtccost [https://perma.cc/8Q9R-9TXV].

[26] Bermseok Oh, *Direct-to-Consumer Genetic Testing: Advantages and Pitfalls*, 17 GENOMICS & INFORMATICS, no. 33, Sept. 26, 2019, at 1, 1.

advertisements, or the Internet."[27] Consumers can purchase the test online or in stores.[28] Through the Internet, a consumer can order a genetic testing kit of their preferred test, submit their saliva sample or cheek swab through the mail, and receive the results directly within a few days without ever leaving home or needing to consult a health care practitioner.[29]

At the start of 2019, 26 million consumers had provided their samples for genetic testing to the four major DTC-GT companies at the time.[30] The rise in genetic testing consumers is likely due to the many types of genetic tests offered by these companies, at times acting as a form of entertainment for consumers,[31] and the way they are pushed and advertised to consumers.[32] Through one of these tests, a consumer could: learn about the origins of their ancestors and where they might have come from, as well as the genetic relationships between families;[33] identify perceived genetic risk for certain disease risks (such as Alzheimer's disease, Parkinson's disease, and celiac disease) and common conditions (including cystic fibrosis and sickle cell disease);[34] determine kinship among those who are biologically related through tests for paternity, maternity, sibling and grandparent identification;[35] or analyze lifestyle factors such as "athletic ability and fitness, nutrition, diet and weight management, cosmetics, beauty and anti-aging"[36]—which allow the consumer to purchase services, products, or programs that are tailored based on the consumer's test results.[37]

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[27] *What is Direct-to-Consumer Genetic Testing?*, *supra* note 24.

[28] *Id.*

[29] *Id.*; Phillips, *DTC Genetics*, *supra* note 8, at 16.

[30] Regalado, *supra* note 13.

[31] James W. Hazel, Catherine Hammack-Aviran, Kathleen M. Brelsford, Bradley A. Malin, Laura M. Beskow & Ellen Wright Clayton, *Direct-to-Consumer Genetic Testing: Prospective Users' Attitudes Toward Information About Ancestry and Biological Relationships*, PLOS ONE, Nov. 29, 2021, at 1, 14.

[32] *See* Horton et al., *supra* note 7, at 1 ("[A] recent analysis of advertising of DTC genetic tests noted that some tests were presented as potentially empowering, with the decision to take them portrayed as responsible—a way that people can take an active role in managing their own health.").

[33] *What Kinds of Direct-to-Consumer Genetic Tests Are Available?*, MEDLINEPLUS (June 21, 2022), https://medlineplus.gov/genetics/understanding/dtcgenetictesting/dtctesttypes [https://perma.cc/H8JS-3Z5Z]; Hazel & Slobogin, *supra* note 22, at 47.

[34] *What Kinds of Direct-to-Consumer Genetic Tests Are Available?*, *supra* note 33; Hazel & Slobogin, *supra* note 22, at 47.

[35] *What Kinds of Direct-to-Consumer Genetic Tests Are Available?*, *supra* note 33; Hazel & Slobogin, *supra* note 22, at 47; Phillips, *DTC Genetics*, *supra* note 8, at 18.

[36] Hazel & Slobogin, *supra* note 22, at 47.

[37] What Kinds of Direct-to-Consumer Genetic Tests Are Available?, *supra* note 33.

Even more than that, some DTC-GT companies provide for, and encourage,[38] surreptitious genetic testing services.[39] A consumer could "submit 'non-traditional' samples, such as cigarette butts, hair, gum, used condoms, [or] even articles of clothing suspected of containing biological material" for genetic testing without the knowledge or consent of the individual it was obtained from.[40] These types of services are marketed under different names, including "infidelity," "forensic," "discreet," and "special sample" testing,[41] and raise serious privacy concerns regarding DNA theft, the non-consensual taking of an individual's genetic information or biological sample for genetic testing.[42]

Moreover, DTC-GT companies are not limited to only those companies that send collection kits through the mail or that can be purchased in store. There are some DTC-GT companies that have physical locations, whereby consumers can walk in, choose the test or tests of their interest, submit their sample containing biological material within fifteen minutes or less, and receive results twenty-four to forty-eight hours later.[43] Additionally, third-party interpretation tools, websites, and databases have emerged that allow consumers to upload their raw genetic data—obtained through previous DTC-GT services—for further analysis.[44] These tools purport to provide consumers enhanced interpretation reports, with more information specified than may have been provided from the previously obtained DTC-GT reports.[45] While use of these tools may provide the consumer with additional information extracted from their genetic data, they may also lead to unfettered access from law enforcement, especially from those tools and databases that are public.[46]

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[38] Phillips, *DTC Genetics*, *supra* note 8, at 19. One company provides the following description regarding its infidelity genetic test:

> Do you suspect your spouse or significant other cheating on you? Find out now with the Infidelity DNA Test from ANY LAB TEST NOW®. Although the test results are not admissible in court, the Infidelity DNA Test answers any questions or concerns you may have about a possible cheating spouse or significant other. You will know the truth, allowing you to make an educated next step decision in your relationship.

Infidelity DNA Test, ANY LAB TEST NOW, https://www.anylabtestnow.com/wp-content/uploads/2018/09/DNA-TEST-INFIDELITY.pdf [https://perma.cc/EM37-DS49].

[39] Phillips, *DTC Genetics*, *supra* note 8, at 19.

[40] Hazel & Slobogin, *supra* note 22, at 48.

[41] *Id.*

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

[43] *E.g.*, ANY LAB TEST NOW, https://www.anylabtestnow.com [https://perma.cc/GG6K-SUSA] (which has over 220 privately owned locations across the U.S.); *Who We Are*, ANY LAB TEST NOW, https://www.anylabtestnow.com/company/who-we-are [https://perma.cc/S89G-KS4E].

[44] *See* Elias Rios III, *DNA Dystopia: How the National Security Apparatus Could Map the Entire Genome of America Without Violating the Fourth Amendment or the Constitutional Right to Privacy*, 87 BROOK. L. REV. 1387, 1387 (2022); Christina Swords, *DNA Sites – Guide to Paid and Free DNA Upload Sites*, NEBULA GENOMICS, https://nebula.org/blog/dna-sites [https://perma.cc/EV6X-B6YD].

[45] *See* Swords, *supra* note 44.

[46] *See* Christine Guest, Comment, *DNA and Law Enforcement: How the Use of Open Source DNA Databases Violates Privacy Rights*, 68 AM. U. L. REV. 1015, 1029–35 (2019) (providing background on open source (public) DNA databases and law enforcement's use of these databases to identify criminal suspects).

B. Collection and Retention Practices

As many DTC-GT companies offer their services through the Internet, consumers enter into electronic agreements that are common among online transactions.[47] These agreements usually consist of two forms: "clickwrap" contracts which command the consumer to click on a box labeled "I agree" or "I accept" at the bottom of the document to continue with their transaction; or "browsewrap" contracts which do not require the consumer to accept the terms, but instead acceptance is implied through the consumer's use of the website or service, and a hyperlink to the terms are made available for the consumer to access at their own will.[48] While consumers have the opportunity to read these agreements, many consumers often do not due to the length and complexity of the language in the documents proffered.[49]

These agreements can typically be identified on the website of the DTC-GT company as "Terms of Condition" or "Privacy Policy," or a combination of both;[50] there may be some with additional consent documents, such as consent for research or sample storage.[51] The accessibility of the agreements and the terms contained within vary among these companies: some may not even provide any information regarding the collection, use, or transmission of genetic data;[52] some only provide the policy document within the testing kit purchased, with no readily available document on the company's website.[53] Moreover, some companies provide that they reserve the right to modify the agreement "at any time" or "from time to time."[54] Few companies sufficiently notify consumers of updates or amendments made to the privacy policies, leaving it to consumers to revisit and review the policies in order to

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[47] *See* Andelka 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, 273–74 (2017) [hereinafter Phillips, *Reading the Fine Print*].

[48] *Id.* at 278.

[49] *Id.*

[50] Hazel & Slobogin, *supra* note 22, at 48. 23andMe, for example, provides consumers on its website both a "Terms of Service" and "Privacy Statement," as well as a "Data Protection" hyperlink to a page that details the company's commitment to "robust data privacy and security protections" in conformity with the European Commission's General Data Protection Regulation (GDPR), effective May 25, 2018. These additional rights—"including the right to object to the processing of their Personal Information, restrict the processing of their Personal Information, and to rectify inaccurate or incomplete Personal Information"—only apply to individuals within Europe and the United Kingdom. *Learn About Other Rights You Have Regarding Your Data*, Subheading to *General Data Protection Regulation Compliance*, 23ANDME, https://www.23andme.com/gdpr [https://perma.cc/CPJ6-5JPR].

[51] 23andMe, for example, provides documents for both research consent and sample storage. *See Research Consent Document*, 23ANDME, https://www.23andme.com/about/consent[https://perma.cc/M5V2-MV2M];
Biobanking Consent Document, 23ANDME, https://www.23andme.com/about/biobanking [https://perma.cc/3XUV-ENKF].

[52] Hazel & Slobogin, *supra* note 22, at 48.

[53] *Id.* at 48–49.

[54] Phillips, *Reading the Fine Print*, *supra* note 47, at 284; *see also* Hazel & Slobogin, *supra* note 22, at 49.

remain informed of the updates.[55] And, depending on the company, continued use of the company's website effectuates acceptance of the updated terms.[56]

When a consumer submits their biological sample to the DTC-GT company, that sample is usually sent to a laboratory to perform the testing of the sample before it is returned back to the DTC-GT company.[57] Sometimes personal information is provided alongside the sample to the laboratory performing the genetic testing.[58] Other times the sample is submitted with a unique barcode or identifier to substitute the personal information.[59] Several companies inform consumers of these practices in their agreements and provide "vague commitments to security or confidentiality at the testing facilities."[60] Some of these companies store the samples after having been tested and allow the consumer to opt-out of the default sample storage option.[61]

As to the genetic data retained from the samples, the terms vary between DTC-GT companies. Some companies explicitly provide in their policies that the information will be retained indefinitely or for a short period of time.[62] Others lack any indication as to how long the genetic data will be retained, "although many seem[] to imply that data would be retained, perhaps indefinitely."[63] Of the companies that allow for deletion of genetic data, the amount of data to be deleted varies: some allow for all, parts, or even none of a consumer's genetic data.[64] The inability to delete all genetic data is partly because the data is either shared with third parties or it is stripped of personally identifiable information and indexed in aggregate datasets for research purposes, making it nearly impossible to eliminate all of an individual's data.[65]

C. Privacy and Security Concerns

The rise in the use of DTC-GT services has not been without its faults. For one, the quality and validity of the tests has been called into question.[66] The tests may report to the consumer inaccurate results or false positives due to errors with the test itself,[67] or because of the different approaches taken by DTC-GT companies in

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[55] Hazel & Slobogin, *supra* note 22, at 49.

[56] Phillips, *Reading the Fine Print*, *supra* note 47, at 284.

[57] Hazel & Slobogin, *supra* note 22, at 50.

[58] *Id.*

[59] *Id.*

[60] *Id*.

[61] *Id.*

[62] *Id.* at 51.

[63] *Id.*

[64] *Id.*

[65] *Id.*

[66] *See Direct-to-Consumer Genetic Test*s, U.S. FOOD & DRUG ADMIN. (Dec. 20, 2019), https://www.fda.gov/medical-devices/vitro-diagnostics/direct-consumer-tests [https://perma.cc/U2GE-2GE4]; Horton et al., *supra* note 7, at 1.

[67] *See e.g.*, Stephany Tandy-Connor, Jenna Guiltinan, Kate Krempely, Holly LaDuca, Patrick Reineke, Stephanie Gutierrez, Phillip Gray & Brigette Tippin Davis, *False-Positive Results Released by Direct-to-Consumer Genetic Tests Highlight the Importance of Clinical Confirmation Testing for*

interpreting the results of the test.[68] The results may not provide a comprehensive assessment of the consumer's genetic risk and can lead to misinterpretation of the results by the consumer, especially because genetic counseling with a health care professional is not required or even sought by the consumer.[69]

Additionally, these services have raised serious concerns regarding the privacy and security of the genetic data.[70] As described in Section I.B., there is a lack of uniformity among the privacy policy statements of DTC-GT companies: some policies are long and complex to read, some are vague in terms of how and what information is or will be used, and some may not be provided to the consumer at all. Because there are no regulations standardizing the practices of companies performing DTC-GT services or requiring specific disclosures and duties to the consumer, the fate of a consumer's personal information and genetic data lies in the hands and control of these companies, which at times may not be aligned with the best interests of the consumer.[71]

Furthermore, the use of DTC-GT services and third-party interpretation tools, databases, and services has piqued the interest of law enforcement within the United States.[72] For example, in 2018, police in California used a DNA database—GEDmatch,[73] which allows users to submit the results of their raw genetic data for genealogical and family tree research purposes—to identify and capture the "Golden State Killer" through a third cousin who had provided their DNA information to the database.[74] By comparing crime scene DNA against the genetic data available on

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Appropriate Patient Care, 20 GENETICS MED. 1515, 1515, 1519 (2018); M.N. Weedon, L. Jackson, J.W. Harrison, K.S. Ruth, J. Tyrrell, A.T. Hattersley & C.F. Wright, *Use of SNP Chips to Detect Rare Pathogenic Variants: Retrospective, Population Based Diagnostic Evaluation*, BMJ, no. 372, Feb. 16, 2021, at 1, 1.

[68] The FDA provided the following answer to a frequently asked question (FAQ) about why an individual may receive different results among DTC-GT companies:

> Different companies may test for different sets of variants, much like a store may offer different brands of products. One direct-to-consumer test company may look for one set of variants linked to a disease or condition, while a different test company may look at a different set. Additionally, direct-to-consumer tests may disagree on the interpretation on whether a variant is disease-causing or not.

*Direct-to-Consumer Genetic Test*s, *supra* note 66.

[69] Tandy-Connor et al., *supra* note 67, at 1520.

[70] *See, e.g.*, Grayson L. Ruhl, James W. Hazel, Ellen Wright Clayton & Bradley A. Malin, *Public Attitudes Toward Direct to Consumer Genetic Testing*, AMIA ANN. SYMP. PROC., Mar. 4, 2020, at 774, 774; Hazel et al., *supra* note 31, at 1.

[71] DTC-GT companies are like any other company doing business: seeking to make profits. These companies continue that tradition, and more, by selling a consumer's genetic data to researchers or third parties seeking to use that information for purposes that may be unknown to the consumer. The information can be sold with or without the consumer's knowledge or consent and can be provided in an anonymized form. However, even anonymized (or "de-identified") data can still be re-identified to a person. DNA is unique to each individual and remains mostly stable and unchanged throughout its lifetime. Unlike other forms of personal information that one may give to a company, once the information is breached or provided to someone else—also increasing the chances of vulnerability and breach of the data now that it has left the original source—that information is out there with no ability to secure it; you cannot change your DNA like you can with a password.

[72] *See* Fuller, *supra* note 11; King, *supra* note 20, at 3–4.

[73] GEDMATCH, https://www.gedmatch.com [https://perma.cc/LZN6-9DB9].

[74] *See* Fuller, *supra* note 11.

GEDmatch, and through the help of a genealogist,[75] police detectives were able to identify the "unknown suspected serial killer and rapist."[76]

Moreover, in 2019, FamilyTreeDNA, one of the largest DTC-GT companies, came under attack when it failed to inform consumers that the company was voluntarily providing FBI investigators access to its genetic database.[77] This contradicted how the company marketed itself to its consumers.[78] FamilyTreeDNA had agreed in 2018 to test, upload, and compare DNA samples submitted by FBI investigators to its database of about 2 million customers.[79] After its practices were revealed, the company issued a statement reassuring customers that law enforcement would only have the same level of access to its database as any standard user would; if they sought additional information, they would need a subpoena or warrant.[80] Additionally, the company updated its terms to allow customers to opt out of sharing their personal information with law enforcement agencies.[81]

Following this event, FamilyTreeDNA went on to advertise that consumers "of any DNA testing and family tracking service [could] . . . upload their profiles and a copy of their record" to the FamilyTreeDNA database for the purpose of helping "unfortunate families of murder victims or violent crime waiting for a

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[75] The process used by law enforcement in tracking down suspects through data provided from DTC-GT companies works as follows:

> [A] search takes place by uploading a genetic profile from a suspect, found at the crime scene, in either the genealogical website GEDmatch or the DTC company FamilyTreeDNA to search for distant relatives. Through this distant relative, an expert genealogist examines the intersections between the family trees of the relative and the crime scene DNA. The group of individuals identified can then be narrowed down by using information such as the age and gender of the suspect, or where this person was living at the time of the crime until one can eventually zero in on a single individual or a number of siblings. Depending on how complex and distant found relations are, finding a suspect can take less than 2 hours but may also take up to 6 months.

Nina F. de Groot, Britta C. van Beers & Gerben Meynen, *Commercial DNA Tests and Police Investigations: A Broad Bioethical Perspective*, 47 J. MED. ETHICS 788, 788 (2021) (footnotes omitted).

[76] King, *supra* note 20, at 3.

[77] *See* Salvador Hernandez, *One of the Biggest At-Home DNA Testing Companies Is Working with the FBI*, BUZZFEED NEWS (Jan. 31, 2019, 6:52 PM), https://www.buzzfeednews.com/article/salvadorhernandez/family-tree-dna-fbi-investigative-genealogy-privacy [https://perma.cc/DZ2J-XSZT]; Matthew Haag, *FamilyTreeDNA Admits to Sharing Genetic Data with F.B.I.*, N.Y. TIMES (Feb. 4, 2019), https://www.nytimes.com/2019/02/04/business/family-tree-dna-fbi.html [https://perma.cc/29F5-3N8J].

[78] *See* Haag, *supra* note 77 ("In the booming business of consumer DNA testing and genealogy, FamilyTreeDNA had marketed itself as a leader of consumer privacy and a fierce protector of user data, refusing, unlike some of its competitors, to sell information to third parties.").

[79] *See id.*; Antonio Regalado, *A Consumer DNA Testing Company Has Given the FBI Access to Its Two Million Profiles*, MIT TECH. REV. (Feb. 1, 2019),https://www.technologyreview.com/2019/02/01/137608/a-consumer-dna-testing-company-has-given-the-fbi-access-to-its-two-million [https://perma.cc/LBF4-PNX7].

[80] *Press Release: Helping Connect the Dots*, FAMILYTREEDNA BLOG (Feb. 1, 2019), https://blog.familytreedna.com/press-release-connecting-families-and-saving-lives [https://perma.cc/N8KS-EQQ7].

[81] Adam Vaughan, *Home DNA-Testing Firm Will Let Users Block FBI Access to Their Data*, NEW SCIENTIST (Mar. 13, 2019), https://www.newscientist.com/article/2196433-home-dna-testing-firm-will-let-users-block-fbi-access-to-their-data [https://perma.cc/Z3ZM-NU7R].

suspect to be identified or prosecution to take place."[82] The television advertisement states, "If you are one of the millions of people that have participated in a home DNA test, your help can provide the missing link."[83]

Additionally, DTC-GT services are as vulnerable to data breaches and leaks as any other company collecting personal information from consumers.[84] DTC-GT companies sometimes share consumers' genetic data with third parties, thereby increasing the risk of that data being "leaked or breached in a way that causes real harm."[85] Genetic data, unlike other sensitive personal information, is "immutable."[86] Because of DNA's sensitive nature and familial link, any breach of DTC-GT genetic data not only has adverse effects on the consumer whose data is exposed, but also to the consumer's relatives.[87]

While there have been relatively low data breaches targeting DTC-GT companies reported, it does not minimize the issue and it may not be the case for long.[88] For example, in 2018 MyHeritage experienced a data breach where 92 million consumers' account details, including email addresses and hashed passwords (*i.e.*, passwords transformed into unreadable strings of characters), were uncovered sitting on a server.[89] In late 2023, 23andMe disclosed that hackers had gained unauthorized access to the personal data of 0.1% of its consumers, affecting approximately 14,000 individuals.[90] Moreover, by accessing those accounts the hackers inadvertently collected "the personal information of about 5.5 million people who opted-in to 23andMe's DNA Relatives feature, which allows customers to automatically share some of their data with others."[91] Of those people who opted-in to the DNA Relatives feature, 1.4 million consumers also "had their Family Tree profile information accessed."[92] The data stolen by the hackers included information

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[82] Charlie Osborne, *Home DNA Kit Company Asks You to Upload Your Family Tree for the FBI*, ZDNET (Apr. 3, 2019, 4:03 AM), https://www.zdnet.com/article/home-dna-kit-company-asks-you-to-upload-your-family-tree-for-the-fbi [https://perma.cc/U6CX-PBJC].

[83] *Id*.

[84] Dan Rafter, *Is Your DNA Info Safe from Data Breaches, and What Are the Privacy Concerns?*, NORTON (Aug. 8, 2018), https://us.norton.com/blog/privacy/dna-data-breaches-and-privacy-concerns [https://perma.cc/4V7J-R4X4].

[85] Thorin Klosowski, *The State of Consumer Data Privacy Laws in the US (and Why It Matters)*, N.Y. TIMES: WIRECUTTER (Sep. 6, 2021), https://www.nytimes.com/wirecutter/blog/state-of-privacy-laws-in-us [https://perma.cc/3KZT-6ZH8].

[86] *Genetic Testing: The Law Must Protect Consumers' Genetic Privacy*, CONSUMER REPS. 7 (July 2020), https://advocacy.consumerreports.org/wp-content/uploads/2020/07/DTC-Genetic-Testing-White-Paper.pdf [https://perma.cc/URR8-M5AT].

[87] *Id.*

[88] Rafter, *supra* note 84.

[89] Joseph Cox, *Hacked: 92 Million Account Details for DNA Testing Service MyHeritage*, VICE (June 5, 2018, 8:53 AM), https://www.vice.com/en/article/vbqyvx/myheritage-hacked-data-breach-92-million [https://perma.cc/B6EE-VJ5W]; *see also MyHeritage Statement About a Cybersecurity Incident*, MYHERITAGE BLOG (June 4, 2018), https://blog.myheritage.com/2018/06/myheritage-statement-about-a-cybersecurity-incident [https://perma.cc/H8CH-MW7G].

[90] Lorenzo Franceschi-Bicchierai, *23andMe Confirms Hackers Stole Ancestry Data on 6.9 Million Users*, TECHCRUNCH (Dec. 4, 2023, 10:56 AM), https://techcrunch.com/2023/12/04/23andme-confirms-hackers-stole-ancestry-data-on-6-9-million-users [https://perma.cc/D7UM-858A].

[91] *Id.*

[92] *Id.*

related to a "person's name, birth year, relationship labels, the percentage of DNA shared with relatives, ancestry reports and self-reported location."[93]

While no raw genetic data seems to have been compromised by either of these breaches, future breaches could expose genetic data and other personally identifiable and sensitive information.[94] The DTC-GT industry continues to grow, as the global DTC-GT market exceeded $1.4 billion in 2021, with estimates the market will reach upwards of $4.4 billion by 2028.[95] The growing number of consumers using DTC-GT services will continue to increase interest in targeting the genetic information within these DNA databases by cybercriminals and bad actors seeking to expose and sell the information on online forums and the dark web.[96]

D. Current Federal and State Regulatory Framework

Currently, there are few federal privacy regulations governing the practices of DTC-GT companies. Unlike the European Union, which enacted the General Data Protection Regulation (GDPR)[97] to provide consumers robust protections and disclosures of how their personal information is used, the United States is limited to patchwork legislation governing DTC-GT services.[98] The Health Insurance Portability and Accountability Act of 1996 (HIPAA),[99] which provides privacy protections to an individual's health information under its "Privacy Rule," only applies to "covered entities" such as health care providers, health plans, or health care clearinghouses.[100] Since consumers purchase the genetic testing kits directly, without involving a health care provider or requiring coverage of the test through a health insurer, most DTC-GT companies are not subject to HIPAA.[101] Moreover, the Genetic Information Nondiscrimination Act of 2008 (GINA)[102] only prohibits health insurers or employers from discriminating against an individual based on their genetic information. However, it does not prohibit discriminatory conduct from other insurers "providing disability, long-term care, or life insurance."[103] Additionally, GINA only applies to employers with fifteen or more employees.[104]

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[93] *Id.*

[94] Cox, *supra* note 89; *see also MyHeritage Statement About a Cybersecurity Incident*, *supra* note 89.

[95] *Direct-to-Consumer Genetic Testing Market*, *supra* note 14.

[96] Rafter, *supra* note 84; *see also* Lorenzo Franceschi-Bicchierai & Zack Whittaker, *Hackers Advertised 23andMe Stolen Data Two Months Ago*, TECHCRUNCH (Oct. 10, 2023, 4:00 PM), https://techcrunch.com/2023/10/10/hackers-advertised-23andme-stolen-data-two-months-ago [https://perma.cc/V7PT-JRU7] (discussing how a hacker "advertised a set of 23andMe user data that matches some of the data leaked" on a hacking forum).

[97] 2016 O.J. (L 119) 679.

[98] Hazel & Slobogin, *supra* note 22, at 39.

[99] Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified in various titles of the U.S.C.).

[100] 45 C.F.R. §§ 160.102–.103.

[101] King, *supra* note 20, at 4.

[102] Pub. L. No. 110-233, 122 Stat. 881 (2008) (codified as amended in scattered sections of 29, 42 U.S.C.).

[103] Rafter, *supra* note 84.

[104] *Fact Sheet: Genetic Information Nondiscrimination Act*, U.S. EQUAL EMP. OPPORTUNITY COMM'N (Sept. 9, 2014) [hereinafter *GINA Fact Sheet*], https://www.eeoc.gov/laws/guidance/fact-sheet-genetic-information-nondiscrimination-act [https://perma.cc/VK5L-K96R].

DTC-GT companies are subject to the Federal Trade Commission's (FTC) "protections around privacy disclosures" and some of the Food and Drug Administration's (FDA) "standards for how data is used in drug and medical device research."[105] However, the FTC's authority on the claims made by DTC-GT companies is limited only to instances where the companies participate in "unfair or deceptive acts or practices."[106] Thus, this leaves DTC-GT companies to mostly self-regulate with respect to the disclosures they make to consumers.[107] Additionally, the FDA elected to exercise "enforcement discretion,"[108] which limits the FDA's authority over DTC-GT to only those companies offering genetic health risk tests[109]—*e.g.*, tests that purport to reveal carrier status of a gene variant[110] or genetic predisposition to a disease or condition.[111] The FDA's authority, however, does not extend to a majority of the genetic tests out on the market.[112] The FDA does caution consumers that DTC-GT services are not an alternative option to "traditional health care evaluation, including health screenings and visits to your health care provider."[113]

As for New Mexico, regulations protecting consumer privacy of genetic data—let alone privacy protections regulating the general collection of personal information by any business[114]—is sparse. The most prominent regulation on genetic

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[105] Kim Hart, *Genetic Testing Firms Share Your DNA Data More than You Think*, AXIOS (Feb. 25, 2019), https://www.axios.com/2019/02/25/dna-test-results-privacy-genetic-data-sharing [https://perma.cc/8B4A-W8PY].

[106] *A Brief Overview of the Federal Trade Commission's Investigative and Law Enforcement Authority*, U.S. FED. TRADE COMM'N (May 2021), https://www.ftc.gov/about-ftc/mission/enforcement-authority [https://perma.cc/MJ9G-PEKQ]; Hazel & Slobogin, *supra* note 22, at 41.

[107] Hazel & Slobogin, *supra* note 22, at 41.

[108] *Regulation of Genetic Tests*, NAT'L HUM. GENOME RSCH. INST. (Feb. 2, 2022), https://www.genome.gov/about-genomics/policy-issues/Regulation-of-Genetic-Tests [https://perma.cc/2S9D-TD7V].

[109] *Direct-to-Consumer Genetic Test*s, *supra* note 66; *see also FDA Allows Marketing of First Direct-to-Consumer Tests That Provide Genetic Risk Information for Certain Conditions*, U.S. FOOD & DRUG ADMIN. (Apr. 6, 2017) [hereinafter *FDA Allows Marketing*], https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-direct-consumer-tests-provide-genetic-risk-information-certain-conditions [https://perma.cc/5DSC-A7BF].

[110] *See FDA Permits Marketing of First Direct-to-Consumer Genetic Carrier Test for Bloom Syndrome*, ESMO (Feb. 23, 2015), https://www.esmo.org/oncology-news/archive/fda-permits-marketing-of-first-direct-to-consumer-genetic-carrier-test-for-bloom-syndrome [https://perma.cc/LT9T-VV7X].

[111] *See FDA Allows Marketing*, *supra* note 109.

[112] *See Direct-to-Consumer Genetic Test*s, *supra* note 66; *FDA Allows Marketing*, *supra* note 109.

[113] *Direct-to-Consumer Genetic Test*s, *supra* note 66.

[114] New Mexico has made efforts to adopt comprehensive consumer privacy protections, known as the Consumer Information Privacy Act (CIPA), which seeks to establish consumer rights and obligations for any business that collects or uses a consumer's personal information. S.B. 176, 54th Leg., 1st Sess. (N.M. 2019). The CIPA, however, failed to pass in the Senate in 2019 and has been postponed indefinitely. *See id.* Additionally, New Mexico passed the Data Breach Notification Act (DBNA) in 2017, which requires, among other things, persons possessing an individual's personal identifying information to securely store and dispose of data containing personal information and to notify the individual of a security breach. H.B. 15, 53d Leg., 1st Sess., 2017 N.M. Laws 365. The DBNA, however, fails to include DNA, genetic information, or the results from genetic analysis as part of the definition for "personal identifying information." *See* N.M. STAT. ANN. § 57-12C-2(C) (2017).

information in New Mexico is the Genetic Information Privacy Act (NM-GIPA or Act),[115] which is discussed below in Part II. NM-GIPA provides general prohibitions on the collection of genetic information or samples for genetic analysis without the individual's informed consent.[116] The Act's use of narrow definitions in defining genetic testing, analysis, and information,[117] its inadequate consent requirements,[118] and its numerous blanket exceptions,[119] limit the Act's applicability to consumer genetic testing and genetic data. As Part II demonstrates and Part III discusses, NM-GIPA's shortcomings and lack of foresight should be circumvented to conform with the current landscape of genetic testing, which has changed since the Act's enactment. Other states tackling this issue have enacted genetic privacy laws that the New Mexico legislature can adopt from to protect against the concerns and vulnerabilities that come with DTC-GT and the handling of genetic data by companies providing these services.

II. NEW MEXICO'S GENETIC INFORMATION PRIVACY ACT

A. Background

New Mexico's Genetic Information Privacy Act (NM-GIPA or Act) was enacted in 1998, in response to rising concerns regarding the sensitivity of genetic information and its predictive nature, and just as many other states were adopting similar laws.[120] The Act's main goal is to prohibit the non-consensual taking or use of an individual's DNA or genetic information.[121] Specifically, no person[122] can obtain an individual's genetic information or sample for genetic analysis without first obtaining informed and written consent from the individual (or their authorized representative).[123] Additionally, no person can perform genetic analysis of an individual's sample or collect, retain, transmit, or use their genetic information

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[115] N.M. STAT. ANN. §§ 24-21-1 to -7 (2015).

[116] *Id.* § 24-21-3.

[117] *Id.* § 24-21-2(C)–(D), (F).

[118] *Id.* § 24-21-3. The Act does not set out any requirements of practices required when obtaining an individual's genetic information or sample, such as providing full disclosure to the individual regarding use, retention, maintenance, transmission, etc., and requiring that disclosure be made when the genetic information or sample is transferred or used for a purpose different than was originally disclosed to and consented by the individual. The Act only vaguely requires that informed consent be obtained from the individual.

[119] *Id.* § 24-21-3(C) (enumerating eleven exceptions to the general prohibition on the collection, retention, transmission, and use of genetic information or genetic analysis without the individual's informed consent).

[120] *See State Genetic Privacy Laws*, NAT'L CONF. OF STATE LEGIS., http://pierce.wesleyancollege.edu/faculty/hboettger-tong/docs/hbt%20public%20folder/FYS/State%20Genetic%20Summary%20Table%20on%20Privacy%20Laws.htm [https://perma.cc/KQ7Y-38TG].

[121] § 24-21-3.

[122] The Act's definition section does not define "person." *See id.* § 24-21-2. However, under New Mexico's Uniform Statute and Rule Construction Act, a "person," in the statutes or rules of New Mexico, "means an individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture or any legal or commercial entity[.]" N.M. STAT. ANN. § 12-2A-3(E) (1997).

[123] § 24-21-3(A).

without the individual's (or their authorized representative's) informed and written consent.[124]

However, the Act enumerates eleven exceptions where an individual's DNA, genetic information, or results from genetic analysis may be collected, retained, transmitted, or used without the individual's informed consent.[125] These exceptions include:

(1) identifying an individual in a criminal investigation by a law enforcement agency;
(2) for purposes of maintaining a DNA database for law enforcement, where the individual is convicted of a felony;
(3) identifying a deceased individual;
(4) establishing parental identity;
(5) screening newborns;
(6) where DNA, genetic information, or results from genetic analysis is not identifiable with the individual or their family members;
(7) by a court determining damage awards pursuant to this Act;
(8) by medical repositories or registries;
(9) for purposes of medical and scientific research, where identity is not disclosed;
(10) for purposes of emergency medical treatment; and
(11) by a laboratory conducting an analysis or test pursuant to a written order from a health care practitioner or their agent.[126]

An individual can object to exceptions (5), (8), (9), (10), or (11) if they provide the person with notice of their "objection on the basis of religious tenets or practices."[127]

Retention by a person of an individual's genetic information, gene products, or samples for genetic analysis is prohibited unless the individual's informed and written consent is obtained first, unless the person is otherwise excepted.[128] An individual can request the sample or genetic information to be destroyed "promptly" unless retention is:

(1) necessary for the investigation of a crime or death, or for a criminal or juvenile proceeding;
(2) authorized by an order from a court of competent jurisdiction;
(3) authorized under a research protocol approved by an institution review board pursuant to federal law or a medical registry or repository authorized by state or federal law; or
(4) pursuant to the eleven exceptions discussed above.[129]

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[124] *Id.* § 24-21-3(B).

[125] *Id.* § 24-21-3(C).

[126] *Id.* § 24-21-3(C)(1)–(11).

[127] *Id.* § 24-21-3(E).

[128] *Id.* § 24-21-5(A). The Act's retention provision additionally provides that "[t]his subsection does not affect the status of original medical records of patients, and the rules of confidentiality and accessibility applicable to the records continue in force." *Id.*

[129] *Id.* § 24-21-5(B).

Exempt from this provision on retention are "[a]ctions of an insurer and third parties dealing with an insurer in the ordinary course of conducting and administering the business of life, disability income or long-term care," pursuant to prior disclosure to the applicant or the insured of the use, transmission, or retention of the information for these stated purposes.[130]

Additionally, the Act promulgates prohibitions against discrimination on the basis of genetic analysis, genetic information, or genetic propensity.[131] Health insurers are prohibited from considering genetic propensity, susceptibility, or carrier status as a pre-existing condition for the purpose of limiting or excluding benefits, establishing rates or providing coverage.[132] However, life, disability, and long-term care insurers are not prohibited from using genetic analysis, genetic information, or genetic propensity if used in the ordinary conduct of business and "underwriting is based on sound actuarial principles or related to actual or reasonably anticipated experience."[133] The Act also provides a general ban on the use of genetic information in decisions related to employment, recruiting, housing, or lending, or in providing public accommodations and services.[134]

Any individual whose rights are violated under the provisions of the Act can initiate a civil action for damages or other relief.[135] Relief includes actual damages,[136] damages up to five thousand dollars (plus any economic loss if the violation is a consequence of willful or grossly negligent conduct),[137] and reasonable attorney fees and court costs.[138] Insurers that violate the Act, except where exemptions apply, might be required to provide a policy for hospital and medical expenses, as would have applied to the individual had the violation not occurred.[139]

In determining the cause of damages or injury and penalty awards, the court may use genetic information as part of its determination.[140] The Act makes clear that "[e]ach instance of wrongful collection, analysis, retention, disclosure or use of genetic information constitutes a separate and actionable violation of the [Act]."[141] The attorney general or a district attorney reserves the right to enforce the provision of this Act and may bring a civil action against a person for violations.[142]

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[130] *Id.* § 24-21-5(C).

[131] *Id.* § 24-21-4(A). Genetic propensity is defined as "the presence in an individual or members of an individual's family of real or perceived variations in DNA or other genetic material from that of the normal genome that do not represent the outward physical or medical signs of a genetic disease at the time of consideration." *Id.* § 24-21-2(E).

[132] *Id.* § 24-21-4(B).

[133] *Id.* § 24-21-4(C).

[134] *Id.* § 24-21-4(D).

[135] *Id.* § 24-21-6(B).

[136] *Id.* § 24-21-6(C)(2).

[137] *Id.* § 24-21-6(C)(3).

[138] *Id.* § 24-21-6(C)(4).

[139] *Id.* § 24-21-6(C)(1).

[140] § 24-21-6(D).

[141] § 24-21-6(E).

[142] § 24-21-6(A).

B. The Merits

Before discussing the shortcomings of NM-GIPA, it is important to note that the Act is well-intentioned in its attempts at promulgating privacy protections with regards to DNA, genetic information, and genetic testing. The Act provides stronger protections to genetic information compared to many of its counterparts in other states.[143]

Read broadly, the Act attempts to prevent non-consensual, surreptitious genetic testing and analysis, or discrimination based on the individual's genetic information. The Act provides a general ban making it unlawful for any person, including business entities, from taking an individual's genetic information or sample for genetic analysis without first obtaining informed consent. It provides comprehensive coverage of conduct banned by the Act, including the collection, retention, transmission, and use of genetic information.

Moreover, the Act expands prohibitions against discrimination based on genetic information beyond that of GINA's scope, which only extends to employers and health insurers.[144] NM-GIPA prohibits discrimination based on genetic information in decisions related to employment, insurance (including life, disability, and long-term care), recruiting, housing, or lending.[145] It also prohibits discrimination based on genetic information by persons providing public accommodations and services.[146] This expansion to other areas was included in a 2005 amendment to the Act,[147] predating the enactment of GINA.[148]

Finally, violations of the Act can incur civil penalties, enforced by the attorney general or a district attorney, and an individual is afforded a private right of action.[149] An individual has standing to seek relief whenever their genetic information, or sample for genetic analysis, is collected, retained, transmitted, or used in contravention with any provision of the Act.[150]

Nonetheless, NM-GIPA continues to be limited in its scope of applicability and therefore leaves DTC-GT companies largely unregulated by the Act's provisions. The next section examines the shortcomings associated with NM-GIPA, followed by a discussion of the implications concerning these shortcomings.

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[143] *See State Genetic Privacy Laws*, *supra* note 120.

[144] *See* Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (codified as amended in scattered sections of 29, 42 U.S.C.).

[145] § 24-21-4(D).

[146] *Id.*

[147] *See* H.B. 183, 47th Leg., 1st Sess. (N.M. 2005).

[148] Although GINA was enacted after NM-GIPA, GINA's definitions and provisions preempt those included in state legislation. This means that a state definition that is defined narrowly (such as New Mexico's definition for "genetic testing") is preempted by GINA's counter-part definition, which may be broader and non-exhaustive. This Comment uses GINA's definition, at times, where there is absences or ambiguity in NM-GIPA's definitions.

[149] § 24-21-6(A)–(B).

[150] § 24-21-6(B), (E).

C. The Shortcomings

While the Act has undergone several amendments, it has largely remained the same in content since its enactment.[151] However, since that time, the landscape of genetic testing and analysis has evolved significantly. Most notably, genetic testing has become more voluntary, eliminating the need for an intermediary, such as a health care provider, to order a test. The genetic tests are accessible and affordable, no longer requiring insurance approval for coverage. Furthermore, the entire process can all be done in the comfort of one's home—ordering the test online and submitting the biological sample through the mail.

Through the Legislature's use of narrow definitions in defining genetic testing, genetic analysis, and genetic information, along with inadequate consent requirements and numerous blanket exceptions, the legislature inadvertently limited the scope of the Act's applicability. Consequently, DTC-GT companies are left largely unaffected by NM-GIPA.

i. Narrow Definitions

First, the Act is limited in scope because it constrains the definitions of "genetic testing" and "genetic information" to tests for disease-related genes or information associated with an increased risk of disease. Under the Act, genetic testing is defined as "a test of an individual's DNA, ribonucleic acid, chromosomes or proteins, including carrier status, that are *linked* with physical or mental disorders, impairments or genetic characteristics or that *indicate* that an individual may be predisposed to an illness, disease, impairment or other disorder[.]"[152] Genetic information is "information about the genetic makeup of an individual or members of an individual's family," encompassing information that results from genetic testing or analysis, DNA composition, involvement in genetic research or use of genetic services.[153]

The Act further defines genetic analysis as "a test of an individual's DNA, gene products or chromosomes that *indicates* a propensity for or susceptibility to illness, disease, impairment or other disorders, whether physical or mental; that *demonstrates* genetic or chromosomal damage due to environmental factors; or that *indicates* carrier status for disease or disorders."[154] However, "routine physical

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[151] Since 1998, the Act has seen three amendments: in 1999, 2005, and 2015. *See generally* H.B. 646, 44th Leg., 1st Sess. (N.M. 1999); H.B. 183, 47th Leg., 1st Sess. (N.M. 2005); H.B. 369, 52d Leg., 1st Sess. (N.M. 2015). These amendments largely consisted of minute, technical changes (such as providing additional definitions or replacing "person" in some areas with "individual"). The 2005 amendment added the definition of "genetic testing" to mean a test of an individual's DNA, ribonucleic acid, chromosomes or proteins. H.B. 183. The 2005 amendment also made it unlawful for a person to use genetic information in employment, recruiting, housing or lending decisions or in extending public accommodations and services. *Id.* The 2015 amendment defined laboratory and enumerated an eleventh exception to the general prohibition on genetic analysis or the collection, retention, transmission, and use of genetic information without the individual's informed consent. H.B. 369. The exception pertained to a laboratory conducting an analysis or test of a specified individual pursuant to a written order from a health care practitioner or its agent. *Id.*

[152] § 24-21-2(F) (emphasis added).

[153] § 24-21-2(D).

[154] § 24-21-2(C) (emphasis added).

measurements, chemical, blood and urine analysis, tests for drugs, tests for the presence of HIV virus[,] and any other tests or analyses commonly accepted in clinical practice at the time ordered[,]" are excluded from the Act's definition of genetic analysis.[155]

In reconciling the bounds of these definitions, it is unclear whether DTC-GT companies are within NM-GIPA's scope. Not all DTC-GT companies provide services that necessarily furnish information about a consumer's risk of genetic-related diseases. These include services for identifying ancestral genealogy or familial relationships (kinship) between consumers who have used the service.[156] Only one company, 23andMe, has been approved by the FDA to sell a diagnostic test for carrier status for disease or conditions.[157] Results from these particular types of tests could fall within the Act's promulgations. However, Ancestry.com, for example, only offers consumers genealogy testing. By the Act's definition, it would likely be excluded from the Act's requirements. The same would apply to other companies offering genealogy or kinship testing, or services not focused on providing individuals with information about their risk of genetic-related diseases.

GINA, which defines genetic testing[158] broadly and is not limited to tests for identifying disease, may preempt NM-GIPA's definition. GINA was enacted to provide minimum protections against employment discrimination on the basis of genetic information or improper access to and disclosure of genetic information.[159] As such, GINA "does not preempt any state or local law that provides equal or greater protections from employment discrimination on the basis of genetic information."[160] Nor does GINA "limit the rights or protections under federal, state, local or tribal laws that provide greater privacy protection to genetic information[.]"[161] However, any GINA protections only extend as far as its scope, which only applies to health insurers and employers with fifteen or more employees.[162]

Additionally, "genetic services" as described in the definition of genetic information is not inclusive of the services offered by DTC-GT companies. Genetic services, while not explicitly defined in the Act, refers to "a genetic test, genetic counseling (including obtaining, interpreting, or assessing genetic information), or genetic education."[163] While the Act defines "genetic testing," "genetic counseling" and "genetic education" are not defined. However, "genetic counseling" refers to an

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[155] *Id.*

[156] *See* sources cited *supra* note 9.

[157] *See FDA Allows Marketing*, *supra* note 109.

[158] GINA defines genetic testing as "an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes." 42 U.S.C. § 2000ff(7)(A).

[159] *Background Information for EEOC Final Rule on Title II of the Genetic Information Nondiscrimination Act of 2008*, U.S. EQUAL EMP. OPPORTUNITY COMM'N (Sept. 11, 2010), https://www.eeoc.gov/laws/guidance/background-information-eeoc-final-rule-title-ii-genetic-information-nondiscrimination [https://perma.cc/9CUG-FRLM].

[160] *Id.*

[161] *Id.*

[162] *GINA Fact Sheet*, *supra* note 104.

[163] NM-GIPA does not explicitly define "genetic services." However, the only definition that could be identified used in New Mexico is in the Insurance Code. N.M. Admin. Code. R. 13.10.24.7(D). This is also the same definition provided for in GINA. 42 U.S.C. § 2000ff(6).

individual seeking a consultation, whereas "genetic education" refers to an individual seeking a group information session related to genetic conditions.[164] While DTC-GT services may be informative to a consumer, they do not fall within the definitions of "genetic counseling" or "genetic education," especially as consumers are not required to consult with a genetic counselor or other health care professional to interpret the results of the test.[165] By these definitions, DTC-GT services are likely not considered a "genetic service" under NM-GIPA.

However, the Act does include "DNA composition" within its definition of genetic information.[166] As used in the Act, "DNA composition" likely refers to the four chemical bases that make up DNA—adenine (A), cytosine (C), thymine (T), and guanine (G).[167] After a consumer receives their results from a genetic test, they are able to download their raw genetic data, which contains the genotyped A's, C's, T's, and G's of their DNA and their position in the DNA.[168] The use of "DNA composition" may extend the scope of genetic information to that beyond disease-related genetic testing—possibly including genetic information acquired through a DTC-GT service. Even so, this is not enough to claim that the Act is strong in its

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[164] 42 U.S.C. § 2000ff(6). The proposed rule of "genetic services" under GINA only provides that "[g]enetic counseling and education are means by which individuals can obtain information and support about potential risks for genetic diseases and disorders." 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 Fed. Reg. 5566, 5662 (Jan. 25, 2013) (to be codified at 45 C.F.R. pts. 160, 164). The Uniform Law Commission (ULC) in its commentary for the Uniform Protection of Genetic Information in Employment Act (UPGIEA), a uniform legislation to expand GINA's protections on genetic information in employment, stated:

> Genetic education is typically less tailored to individual circumstances then a one-on-one genetic counseling session and may be delivered by individuals who would not necessarily be qualified to conduct genetic counseling. [UPGIEA]'s definition is meant to be broad enough to include information provided by support groups to groups or individuals who are concerned about a genetic condition. It is not meant to encompass general genetic education such as that received in biology class or medical school.

UNIF. PROT. GENETIC INFO. EMP. ACT § 2 cmt. 11 (UNIF. L. COMM'N, Draft May 24, 2011). The ULC further states: "'Counseling' implies an individual consultation, so the definition also includes 'genetic education' in order to capture group information sessions on genetic conditions." *Id.* § 2 cmt. 14. Under the UPGIEA, genetic education is defined as "the process by which an individual acquires information about an existing or suspected genetic condition of the individual or a family member of the individual." *Id.* § 2.11.

[165] *Direct-to-Consumer Genetic Testing FAQ for Healthcare Professionals*, NAT'L HUM. GENOME RSCH. INST. (June 14, 2023), https://www.genome.gov/For-Health-Professionals/Provider-Genomics-Education-Resources/Healthcare-Provider-Direct-to-Consumer-Genetic-Testing-FAQ [https://perma.cc/N6LA-7WHM] ("Another limitation is that DTC-GT is often completed without traditional genetic counseling, risk assessment or informed consent to confirm that the consumer fully understands the implications of the possible results. DTC-GT may give patients data that are overwhelming, non-actionable or distressing without the support of a qualified healthcare professional.").

[166] N.M. STAT. ANN. § 24-21-2(D) (2015).

[167] *What is DNA?*, MEDLINEPLUS (Jan. 19, 2021), https://medlineplus.gov/genetics/understanding/basics/dna [https://perma.cc/M6VQ-58YQ].

[168] *What Can Raw Data from a Direct-to-Consumer Genetic Test Tell Me?*, MEDLINEPLUS (June 23, 2022), https://medlineplus.gov/genetics/understanding/dtcgenetictesting/dtcrawdata [https://perma.cc/XV23-NCNP].

protections over DTC-GT companies since there are other areas where the Act falls short, as discussed in the following sections.[169]

ii. Inadequate Consent Requirements

Second, the Act's consent requirements are not adequate to implicate DTC-GT companies, as consent is typically obtained from the consumer through their use of the companies' services.[170] The Act requires that any person, including business entities, obtain "informed and written consent" prior to obtaining an individual's sample for genetic analysis or genetic information, [171] unless falling within one of the enumerated exceptions.[172] Informed and written consent is also needed for retention, transmission, or use of genetic information.[173] Nothing further is provided by the Act specifying requirements of disclosure to an individual.

As most DTC-GT companies conduct their business through the Internet, a consumer's consent to the company's privacy policies is usually obtained through the consumer's use of the website or through clicking a box that states, "I accept."[174] The company's privacy policy, written in long and complex language, lays out how the consumer's information will be used, and usually is read by very few consumers.[175] Once accepted, the consumer has consented to the collection, retention, transmission, and usage policies described within the privacy policies, whatever they may be. These privacy policies vary among DTC-GT companies, if provided at all.[176]

Additionally, informed consent may not be required in certain instances because the Act uses language, implicit and explicit, in its definitions that limit genetic testing, genetic analysis, and genetic information to that which has some relation to disease-related risk.[177] Since a genetic test may not always yield results of negative health effects, informed consent would not need to be acquired for information that does not fall within the limitations set by the Act's definitions. Thus, the Act's restrictive language provides loopholes for persons to evade the informed consent requirement.

iii. Blanket Exceptions

Finally, the Act enumerates eleven exceptions that remove barriers to performing genetic testing, but inadvertently may violate an individual's right to privacy. The Act provides instances where informed consent is not required prior to collection, retention, transmission, or usage. These include uses by law enforcement, medical repositories or registries, medical and scientific research, or laboratories

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[169] *See* discussion *infra* Sections II.C.*ii–iii*.

[170] *See* discussion *supra* Section I.B.

[171] § 24-21-3(A).

[172] *See* § 24-21-3(C).

[173] § 24-21-3(B).

[174] Phillips, *Reading the Fine Print*, *supra* note 47, at 278.

[175] *Id.*

[176] *See supra* text accompanying notes 50–56.

[177] *See* § 24-21-2(C)–(D), (F).

conducting a genetic test pursuant to a physician's order, among other instances.[178] Genetic information that cannot be traced to an individual and their family members is also excepted from the Act's prohibitions.[179]

The Act's blanket exception for law enforcement collection, retention, transmission, and use—whether for purposes of a criminal investigation or maintaining a criminal database—leaves unregulated control to law enforcement agencies. Because of DNA's predictive nature, an individual's genetic information could be used to identify the individual or members of the individual's family. This exception allows law enforcement agencies, in some instances, to act in contravention with the Fourth Amendment's protection of individuals from "unreasonable searches and seizures" by the government.[180] Law enforcement agencies could use the Act's exception to get around disclosure requirements made to individuals and obtain genetic information from DTC genetic testing companies.

Another concerning blanket exception allows the collection, retention, transmission, and use of genetic information or samples without informed consent for purposes of medical and scientific research. The use of genetic information in medical and scientific research plays a big role in making scientific and medical discoveries and advancements, including identifying genetic variants and developing new treatments. However, this exception could enable researchers to use genetic information for purposes beyond those originally disclosed to the participant.

The Havasupai Tribe, for example, experienced this exact issue which became the subject of a lawsuit.[181] The Tribe filed suit in 2004 against the Arizona Board of Regents, claiming that the researchers at Arizona State University (ASU) misused genetic samples from tribal members for purposes other than originally intended.[182] The DNA samples were collected between 1990 and 1994 from roughly 400 Havasupai Tribe members as part of a diabetes project by researchers at ASU.[183] The intent of the project "was to understand why more than half of Havasupai adults suffered from type 2 diabetes."[184] Informed consent was obtained from tribal members, who "were told that their samples would be used specifically for genetic studies on diabetes."[185]

However, unable to find a genetic link between type 2 diabetes, the researchers subsequently used the stored samples for unrelated studies, including

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[178] § 24-21-3(C)(1)–(11).

[179] § 24-21-3(C)(6).

[180] U.S. CONST. amend. IV. For a discussion on the application of Fourth Amendment rights with respect to the services of DTC-GT companies, see generally Claire Abrahamson, *Guilt by Genetic Association: The Fourth Amendment and the Search of Private Genetic Databases by Law Enforcement*, 87 FORDHAM L. REV. 2539 (2019); Caroline Spiers, *Keeping It in the Family: Direct-to-Consumer Genetic Testing and the Fourth Amendment*, 59 HOUS. L. REV. 1205 (2022); Ayesha K. Rasheed, *Personal Genetic Testing and the Fourth Amendment*, 2020 U. ILL. L. REV. 1249 (2020); *see also* Kelly Lowenberg, *Applying the Fourth Amendment When DNA Collected for One Purpose Is Tested for Another*, 79 U. CIN. L. REV. 1289 (2011).

[181] *See* Nanibaa' A. Garrison, *Genomic Justice for Native Americans: Impact of the Havasupai Case on Genetic Research*, 38 SCI. TECH. HUM. VALUES 201, 201 (2013).

[182] *Id.* at 201–02.

[183] *Id.* at 202.

[184] *Id.* at 202–03.

[185] *Id.* at 203.

studies on schizophrenia.[186] Members of the tribe "alleged that researchers had failed to make clear that the samples may be used for studies on schizophrenia and that no expanded informed consent was sought."[187] Had tribal members been informed of the researchers' intent to use their samples for studies on schizophrenia they would not have consented to the use because of the high stigmatization of mental illness within the Havasupai culture.[188] The case settled in favor of the tribe: "tribe members received $700,000 in direct compensation, funds for a tribal clinic and school and, most significantly from the standpoint of several tribe members, the return of the tribe's DNA samples."[189]

The issues presented by genetic research activities are not uncommon. Obtaining informed consent for research purposes poses many implications.[190] Research can last indefinitely and so too the consent given.[191] There is uncertainty as to what is being consented to as it is difficult to "foresee all of the future research for which [the biological sample or genetic data] might be used at the time they are collected."[192] The privacy risks involved are unclear and can persist throughout the span of the research.[193] Individuals have "[l]imited control over downstream access, use, and disclosure" of their samples or genetic information.[194] These issues can pose serious concerns for families and communities,[195] as illustrated above with the Havasupai Tribe.

Additionally, the Act exempts a laboratory conducting a genetic analysis or test in accord with a written order from a health care practitioner (or their agent) from obtaining consent for the collection, retention, transmission, and use of genetic information or samples.[196] Under the Act, a laboratory[197] is a facility in compliance with the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA).[198] CLIA regulates laboratories conducting certain tests to ensure the consistency, accuracy, and reliability of "materials derived from the human body for the purpose

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[186] *Id.*

[187] *Id.*

[188] *Id.*

[189] *Id.*

[190] *See* Amy L. McGuire & Laura M. Beskow, *Informed Consent in Genomics and Genetic Research*, 11 ANNU. REV. GENOMES & HUM. GENETICS 361 (2010).

[191] *Id.* at 363.

[192] *Id.* at 362.

[193] *Id.* at 363.

[194] *Id.*

[195] *Id.*

[196] N.M. STAT. ANN. § 24-21-3(C)(11) (2015).

[197] Under the NM-GIPA, a laboratory is defined as:

> [A] facility accredited pursuant to the federal clinical laboratory improvement amendments for the biological, microbiological, serological, chemical, immunohematological, 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 and includes procedures to determine, measure or otherwise describe the presence or absence of various substances or organisms in the body.

§ 24-21-2(H).

[198] *Id.*; Pub. L. No. 100-578, 102 Stat. 2903 (1988) (codified at 42 U.S.C. § 263a).

of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings."[199] Not all DTC-GT companies conduct their genetic testing within an accredited CLIA laboratory.[200]

This exception to laboratories conducting a genetic analysis or test pursuant to a written order from a health care practitioner (or their agent) was added to NM-GIPA in 2015.[201] In the Fiscal Impact Report for this amendment, the Attorney General noted that "eliminating the requirement that laboratories obtain informed consent prior to performing any testing may increase the use of information for improper purposes, and potential fraud, waste or abuse of such tests."[202] The Attorney General believed that by removing this barrier to performing genetic testing, it "may implicate an individual's privacy rights, and may facilitate the ability of a provider to commit fraud."[203] Even with these concerns raised by the Attorney General, the exception was still included.

Unfortunately, this laboratory exception raises questions concerning DTC-GT companies that directly market genetic testing to consumers and provide consumers with a physician's order. Individuals do not need to go through their own physician or insurer to receive issuance or approval of an order for genetic testing. For example, Any Lab Test Now, which has one location in New Mexico,[204] offers private DNA testing services, including ancestry, kinship, and infidelity testing, among others, that are marketed directly to consumers.[205] Within fifteen minutes, a consumer can obtain a physician's order—through one of their on-site physicians—and choose one of the types of services offered.[206] Because of the use of physician orders, Any Lab Test Now would technically fall under NM-GIPA's exception to the informed consent requirement since the genetic test was obtained through a physician's order. This loophole affords the private company unreserved control over the collected information or samples from consumers, subject only to the privacy statements provided by the company.

Finally, the Act excepts consent requirements when the DNA, genetic information, or results from genetic analysis cannot be identified with the individual or their family members. This, however, is problematic because DNA, by its nature, cannot be unidentifiable. DNA is unique to each individual and remains mostly stable

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[199] 42 U.S.C. § 263a(a); *CLIA Program & Medicare Lab Services*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 2021), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/cliabrochure.pdf [https://perma.cc/QJZ7-DV4W]. However, under CLIA, the Centers for Medicare and Medicaid Services only "certifies laboratories but does not evaluate the clinical validity of the tests those laboratories offer, instead leaving it up to the laboratory director's determination." Stuart Hogarth et al., *The Current Landscape for Direct-to-Consumer Genetic Testing: Legal, Ethical, and Policy Issues*, 9 ANN. REV. GENOMICS & HUM. GENETICS 161, 170 (2008).

[200] *How Can I Be Sure a Genetic Test Is Valid and Useful?*, MEDLINEPLUS (June 24, 2022), https://medlineplus.gov/genetics/understanding/testing/validtest [https://perma.cc/Z5QG-7ZGK].

[201] *See* H.B. 369, 52d Leg., 1st Sess. (N.M. 2015).

[202] Fiscal Impact Rep., H.B. 369, 52d Leg., 1st Sess., at 2 (N.M. 2015).

[203] *Id.*

[204] As of October 2022, when searching "New Mexico" through Any Lab Test Now's website location page, only one location is retrieved: the location being in Albuquerque, NM. *See Locations*, ANY LAB TEST NOW, https://www.anylabtestnow.com/locations [https://perma.cc/3ZTU-5V8F].

[205] *See Who We Are*, *supra* note 43.

[206] *Id.*

and unchanged throughout its lifetime.[207] Any person who obtains an individual's unidentifiable genetic information can easily reidentify the DNA with additional sources, such as genetic information uploaded on a genetic database, as further discussed below. In fact, studies have shown the ease of reidentifying "unidentifiable" genetic information.[208]

D. The Implications

Accessibility to genetic testing does have its benefits. It allows consumers to be proactive with their health and disease risks and to take steps that ensure their well-being. It also allows for new discoveries of genetic variants that can advance medical treatments and promote early intervention. However, for genetic tests to buttress our understanding of human biology and approaches to medicine, people must be encouraged to accept the costs and limitations that come with providing one's genetic data or sample to DTC-GT companies with the assurance that their genetic information will not be compromised or used for improper purposes.

NM-GIPA, as it stands, does not provide sufficient protections for consumers taking advantage of DTC-GT services. The growing rates of consumers providing samples and genetic information should be of concern to the New Mexico Legislature. Not only are consumers providing their genetic information to DTC-GT companies, but alongside it, sensitive personal information as well. This is the nature of the modern technological world: entering contracts with companies providing services has become easier than ever; it is conducted all through the Internet in the comfort of one's home; and with that comes an increase in the amount of data collected and retained by these companies. That is also the incentive for companies collecting sensitive personal information from consumers: it is profitable.[209]

What is critical about protecting genetic data and the information extracted from it is that DNA itself is immutable and the information extracted can lead to stigmatization against individuals based on the findings provided to consumers. Genetic data, like other types of medical information, is "private, intimate, and sensitive."[210] While 99.9% of DNA is the same from individual to individual, the 0.1% difference in the DNA is what makes individuals unique from each other, unless they are identical twins.[211] That 0.1% is an individual's identifying mark, as variations occur at different locations in the DNA.[212] Thus, DNA is uniquely

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[207] *See generally* Bruce Alberts, Alexander Johnson, Julian Lewis, David Morgan, Martin Raff, Keith Roberts & Peter Walter, *The Maintenance of DNA Sequences*, *in* MOLECULAR BIOLOGY OF THE CELL 237–39 (6th ed. 2015).

[208] *See, e.g.*, Zhen Lin, Art B. Owen & Russ B. Altman, *Genomic Research and Human Subject Privacy*, 305 SCIENCE 183 (2004); *see also* Amy L. McGuire, *Identifiability of DNA Data: The Need for Consistent Federal Policy*, 8 AM. J. BIOETHICS 75 (2008).

[209] *See, e.g.*, Marcy Darnovsky, *23andMe's Dangerous Business Model*, N.Y. TIMES (Mar. 2, 2015, 3:30 AM), https://www.nytimes.com/roomfordebate/2015/03/02/23andme-and-the-promise-of-anonymous-genetic-testing-10/23andmes-dangerous-business-model-17 [https://perma.cc/Z966-UDVJ].

[210] Lin et al., *supra* note 208, at 183.

[211] *Human Genomic Variation*, NAT'L HUM. GENOME RSCH. INST. (Apr. 6, 2018), https://www.genome.gov/dna-day/15-ways/human-genomic-variation [https://perma.cc/8M5D-HJHV].

[212] *Id.*

identifiable no matter how genetic data is anonymized to protect the privacy of the consumer.[213]

One of NM-GIPA's exceptions allows persons, researchers, or entities, to evade the informed consent requirements if the genetic information cannot be identified with the individual or their family members.[214] DTC-GT companies have similar practices, where consumers, accepting the privacy policies of the service, consent to their data being shared with other third parties, with the information shared being de-identified from them.[215] However, a 2004 study determined that access to just 30 to 80 statistically independent single nucleotide polymorphisms (SNPs)—*i.e.*, the genetic variations at a single position in the DNA that can be associated with certain traits[216]—was adequate to uniquely identify an individual.[217] This means that "[i]f someone has access to individual genetic data and performs matches to public SNP data, a small set of SNPs could lead to successful matching and identification of the individual."[218] With the increase of DNA interpretation tools and databases available to consumers, some of which are free, identifying an individual's DNA will only become easier.

This is to say that an individual's genetic data can be re-identified using public genetic databases or DNA interpretation tools, whether the data in these databases was provided by the individual or by a family member of the individual. Thus, the rest of the individual's genes, physical traits, and other information connected to the individual would become accessible.[219] This can also apply when the genetic data is aggregated in large datasets with other samples.[220] So, a third-party vendor, for instance, who receives unidentified or aggregated genetic data from a DTC-GT company could find means to re-identify an individual.

Additionally, NM-GIPA does not provide consequences for security breaches and leaks of genetic information. An individual's privacy is only as good as the security measures protecting the individual's sensitive personal information and genetic data. If the information is not protected well, exposure could cause harm to an individual. For one, sensitive personal information could be made available publicly, allowing access to any interested parties or bad actors looking to profit from the exposed information. DTC-GT companies are equally susceptible to security breaches and leaks, just like any other company collecting personal information.

Second, because of the predictive nature of DNA, exposed genetic data could be accessed by insurers and employers, among others. This could have adverse effects on the individual, as any information reported from the genetic data could be used against the individual in employment or insurance decisions, further increasing the chances of discrimination and stigmatization. This is especially problematic with

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[213] *See* Albert Henry, *supra* note 13.

[214] N.M. STAT. ANN. § 24-21-3(C)(6) (2015).

[215] *See* discussion *supra* Section I.B.

[216] *Single Nucleotide Polymorphism (SNPs)*, NAT'L HUM. GENOME RSCH. INST. (Nov. 18, 2023), https://www.genome.gov/genetics-glossary/Single-Nucleotide-Polymorphisms [https://perma.cc/4MV7-GHT7].

[217] Lin et al., *supra* note 208, at 183.

[218] *Id.*

[219] *Id.*

[220] *See* McGuire, *supra* note 208, at 75.

genetic data because the information reported by DTC-GT services to its users regarding their health and disease, or ancestry, is not always accurate and may result in false-positives. Thus, the varying validity and accuracy of the information from these services could further create problems for the individual.

DTC-GT companies, and other parties obtaining genetic data, whether anonymized or not, should be required to take active measures to ensure the security and privacy of an individual's genetic data. Exposed genetic data has consequences for both the individual and their family members.

III. FORMULATING ROBUST REGULATIONS THAT PROVIDE FOR PERSONAL CONTROL OVER GENETIC DATA

So, NM-GIPA is not perfect as it stands. While there are merits to the Act, such as its attempts to prevent non-consensual genetic testing and to prohibit discrimination in employment, insurance, and other areas, NM-GIPA does not provide adequate protections to genetic testing obtained through DTC-GT services. The Act's narrow definitions, inadequate consent requirements, and blanket exceptions leave DTC-GT companies outside the scope of the Act's applicability. However, New Mexico can amend NM-GIPA to be more encompassing to better protect consumers using DTC-GT services.

First, New Mexico needs to broaden its definitions of genetic testing, genetic analysis, and genetic information. The language within these definitions should be simplified so as not to restrict the applicability of the Act to testing or analysis for disease-related risk.[221] Genetic testing purposes have expanded. Not only is genetic testing used for health and disease purposes but also for the purposes of identifying ancestral genealogy and familial relationships. By broadening and simplifying the definitions, the Act's applicability can extend for a longer period of time as genetic technology and the uses of it continues to develop.

Second, the Act needs to address and provide for adequate disclosure and consent requirements. Because NM-GIPA fails to set adequate and comprehensive disclosure and consent requirements, DTC-GT companies only need to rely on the consumer's acceptance of the privacy policies as the main and, usually, only form of consent. Whether the genetic data is anonymized or not, disclosure and consent should be provided and obtained from the individual. Disclosure and consent should also be provided and obtained for additional uses of the genetic data. As illustrated above,[222] not obtaining additional consent for different uses of the genetic samples or genetic data can violate personal autonomy and have implications to families and communities.

Third, the eleven blanket exceptions provided for in the Act need to be limited so as not to allow for loopholes to evade consent requirements. Coinciding

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[221] For example, compare California's definition of "genetic testing," which it defines as "any laboratory test of a biological sample from a consumer for the purpose of determining information concerning genetic material contained within the biological sample, or any information extrapolated, derived, or inferred therefrom." CAL. CIV. CODE § 56.18(b)(8) (West 2022). This definition is more encompassing and does not limit itself to only tests for disease-related risks.

[222] See discussion *supra* Section II.C.*iii*. (illustrating the Havasupai Tribe's experience with researchers who used tribal members' biological samples for purposes beyond what it was originally obtained for).

with the second point, while removing consent requirements for certain actions may decrease barriers to genetic testing and analysis, it also minimizes an individual's privacy protections and personal autonomy. It increases the chances of the genetic information being exposed or used for improper purposes. And because of DNA's identifiable nature, it can have consequences for an individual's family members, who may not have consented to their information being used.

Finally, DTC-GT companies and others collecting and retaining genetic data should be held accountable if that information is exposed through a security breach or leak. More and more personal information is being collected through use of the Internet and with that comes risks of the information being exposed by bad actors. Making holders of genetic data liable increases the chances that security measures are taken to ensure the safety of personal and genetic information. Lack of adequate security measures minimize the privacy protections afforded to individuals.

In promulgating robust genetic data regulations, New Mexico can look to other states that have enacted regulations on consumer genetic data and DTC-GT companies. States like Arizona, California, Kentucky, Maryland, Utah, and Wyoming have enacted legislation to protect consumer genetic data since 2021,[223] with other states following pursuit.[224] All these genetic privacy acts are relatively similar and seek to regulate DTC-GT companies, or any other company, that collects, uses, maintains, or discloses genetic testing data collected or derived from a DTC-GT product or service, or provided directly by a consumer. A DTC-GT company is required to provide consumers with information that details "the company's policies and procedures for the collection, use, maintenance, and disclosure" of genetic data, as well as to provide an outline of its privacy practices written in plain language.[225] DTC-GT companies must obtain express consent when genetic data is collected or used beyond the primary purpose for which it was obtained, as well as when genetic data is transferred to a third-party.[226] And to ensure that consumers' genetic data is protected "against unauthorized access, destruction, use, modification, or

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[223] *See generally* Arizona's Genetic Information Privacy Act, ARIZ. REV. STAT. ANN. §§ 44-8001 to -8004 (effective Sept. 29, 2021); California's Genetic Information Privacy Act, CAL. CIV. CODE §§ 56.18 to .186 (West, effective Jan. 1, 2022); Kentucky's Genetic Information Privacy Act, KY. REV. STAT. ANN. § 311.705 (West, effective July 14, 2022); Maryland's Genetic Information Privacy Act, MD. CODE ANN., COM. LAW §§ 14-4401 to -4408 (West, effective Oct. 1, 2022); Utah's Genetic Information Privacy Act, UTAH CODE ANN. §§ 13-60-101 to -106 (West, effective May 5, 2021); Wyoming's Genetic Data Privacy Act, WYO. STAT. ANN. §§ 35-32-101 to -105 (West, effective July 1, 2022).

[224] *See* Montana's Genetic Information Privacy Act, S.B. 351, 68th Leg., Reg. Sess. (2023); Minnesota's Genetic Information Privacy Act, H.F. 1520, 93d Leg., 2023 Reg. Sess.; Virginia's Genetic Data Privacy Act, S. 1087, 2023 Reg. Sess.

[225] CAL. CIV. CODE § 56.181(a)(1) (West 2022); *see* ARIZ. REV. STAT. ANN. § 44-8002(A)(1) (2022); KY. REV. STAT. ANN. § 311.705(2)(a) (West 2022); MD. CODE ANN., COM. LAW §§ 14-4403 (West 2022); UTAH CODE ANN. § 13-60-104(1)(a) (West 2023); WYO. STAT. ANN. § 35-32-102(c)(i) (West 2022).

[226] *See* ARIZ. REV. STAT. ANN. § 44-8002(A)(2) (2022); CAL. CIV. CODE § 56.181(a)(2) (West 2022); KY. REV. STAT. ANN. § 311.705(2)(b) (West 2022); MD. CODE ANN., COM. LAW § 14-4404 (West 2022); UTAH CODE ANN. § 13-60-104(1)(b)–(c) (West 2023); WYO. STAT. ANN. § 35-32-102(c)(ii) (West 2022).

disclosure," these genetic privacy laws also require DTC-GT companies to implement and maintain reasonable security measures.[227]

Florida also enacted a genetic privacy law in 2021, but with a focus on criminalizing the unlawful collection, retention, analysis, and disclosure of an individual's DNA samples or results from DNA analysis without the individual's express consent.[228] Florida's law is fairly similar to NM-GIPA in its objective to prevent the unlawful taking of DNA without an individual's consent, except that Florida's law does not use narrow language that limits its applicability to genetic testing and analysis of disease-related risks.[229] Where NM-GIPA provides a civil remedy for the unlawful taking of an individual's DNA, Florida's law criminalizes the conduct.[230] Thus, Florida's law provides strong regulations against DNA theft.

While these genetic privacy laws from other states are not flawless,[231] they are a step forward for New Mexico to consider while developing its own genetic data privacy regulations. These regulations should provide adequate protection of consumers' genetic data and any information associated with it, addressing the concerns and implications posed by DTC-GT services.

CONCLUSION

As the landscape of genetic testing and analysis continues to advance, laws regulating genetic privacy rights and consumer protection must adapt to the times. We are in unprecedented times: no longer does one need authorization from a health care provider or insurer to perform a genetic test. The accessibility, affordability, and, at times, entertainment value of genetic testing kits provided by DTC-GT services continue to increase in appeal among consumers. However, the use of these services should not come at the cost of compromising an individual's personal autonomy or privacy.

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[227] CAL. CIV. CODE § 56.181(d)(1) (West 2022); *see* ARIZ. REV. STAT. ANN. § 44-8002(A)(4) (2022); KY. REV. STAT. ANN. § 311.705(2)(d) (West 2022); MD. CODE ANN., COM. LAW § 14-4405(b) (West 2022); UTAH CODE ANN. § 13-60-104(1)(e) (West 2023); WYO. STAT. ANN. § 35-32-102(c)(iv) (West 2022).

[228] *See* Florida's Protecting DNA Privacy Act, FLA. STAT. ANN. §§ 760.40, 817.5655 (West 2021).

[229] *Compare* FLA. STAT. ANN. § 760.40(1)(a), (b) (West 2021) (defining "DNA analysis" and "DNA sample") *with* N.M. STAT. ANN. § 24-21-2(A)–(F) (2015) (defining "DNA," "gene products," "genetic analysis," "genetic information," "genetic propensity," and "genetic testing").

[230] *Compare* FLA. STAT. ANN. § 817.5655 (West 2021) (describing the criminal penalties for unlawful uses of DNA) *with* N.M. STAT. ANN. § 24-21-6 (2015) (describing the civil penalties for wrongful collection, analysis, retention, disclosure, or use of genetic information). Florida's law does except conduct of a "person who discloses another person's DNA analysis results that were previously voluntarily disclosed by the person whose DNA was analyzed." FLA. STAT. ANN. § 817.5655(4) (West 2021).

[231] For example, all the genetic privacy laws in these states, except California, require DTC-GT companies to establish measures that allow for the disclosure of a consumer's genetic data to "law enforcement or any other government agency without a consumer's express written consent." ARIZ. REV. STAT. ANN. § 44-8002(A)(3) (2022); KY. REV. STAT. ANN. § 311.705(2)(c) (West 2022); MD. CODE ANN., COM. LAW § 14-4405(a) (West 2022); UTAH CODE ANN. § 13-60-104(1)(d) (West 2023); WYO. STAT. ANN. § 35-32-102(c)(iii) (West 2022). Additionally, California is the only one of these states to require DTC-GT companies to provide notice that the consumer's genetic de-identified (anonymized) genetic information "may be shared with or disclosed to third parties for research purposes." CAL. CIV. CODE § 56.181(a)(1)(C) (West 2022).

Paralyzed by the lack of effective and broad regulations, individuals are left to concede to the policies of these services. New Mexico needs to amend the Genetic Information Privacy Act to be all encompassing, incorporating DTC-GT services within its scope of applicability. To do this, New Mexico must expand the Act's definitions to incorporate all kinds of genetic testing and data, not just those specific to identifying disease-related risks. Additionally, the consent requirements need to be extended to require additional consent at each step and use of that genetic data, regardless of whether that genetic data is anonymized or not, or whether used for commercial or research purposes. Finally, the Act's blanket exceptions allowing law enforcement and researchers, among others, to evade consent requirements is problematic. To limit access and improper use of an individual's genetic information, these exceptions need to be constrained to ensure that such persons are not bypassing consent requirements. Consumers should receive full disclosure, in plain language, by parties collecting and retaining genetic information, especially by DTC-GT companies.

New Mexico is not alone on this issue. Other states have promulgated legislation enforcing restrictions on DTC-GT companies. New Mexico can gain inspiration from these states in amending the Act to build a set of robust regulations promoting a consumer's personal autonomy and control over their personal and genetic data. It is proactive legislation like this that will ensure the protection of a consumer's personal and sensitive genetic information while minimizing the risk of improper uses or exposure.