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The Privacy Risks of Direct-to-Consumer Genetic Testing: A Case Study of 23andMe and Ancestry

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THE PRIVACY RISKS OF DIRECT-TO- CONSUMER GENETIC TESTING: A CASE STUDY OF 23ANDME AND ANCESTRY

SAMUAL A. GARNER AND JIYEON KIM*

ABSTRACT

Direct-to-consumer genetic testing (DTC-GT) companies have proliferated and expanded in recent years. Using biospecimens directly submitted by consumers, these companies sequence and analyze the individual's genetic information to provide a wide range of services including information on health and ancestry without the guidance of a healthcare provider. Given the sensitive nature of genetic information, however, there are growing privacy concerns regarding DTC-GT company data practices. We conduct a rigorous analysis, both descriptive and normative, of the privacy policies and associated privacy risks and harms of the DTC-GT services of two major companies, 23andMe and Ancestry, and evaluate to what extent consumers' genetic privacy is protected by the policies and practices of these two companies. Despite the exceptional nature of genetic information, the laws and agency regulation surrounding genetic privacy and DTC-GT services are fragmented and insufficient. In this analysis, we propose three categories of privacy harms specific to DTC-GT—knowledge harms, autonomy and trust-based harms, and data misuse harms. Then, through the normative lens of exploitation, we argue that 23andMe and Ancestry's data practices and privacy policies provide consumers with insufficient protection against these harms. Greater efforts from both the industry and legal system are necessary to protect DTC-GT consumers' genetic privacy as we advance through the era of genomics and precision medicine.

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INTRODUCTION

The rapid advances in sequencing technology and genomics have fueled the expansion of the Direct-to-Consumer Genetic Testing (DTC-GT) industry. According to industry estimates, over 12 million people had used DTC-GT services by 2017,¹ and the global DTC-GT market was valued at \$359 million in 2017.² Recent years have been particularly exciting for the

1. Ancestry.com has tested more than seven million people, followed by 23andMe, which has tested over three million people. Antonio Regalado, *2017 Was the Year Consumer DNA Testing Blew Up*, MIT TECH. REV. (Feb. 12, 2018), <https://www.technologyreview.com/s/610233/2017-was-the-year-consume-r-dna-testing-blew-up/> [https://perma.cc/EH4Z-6N5A].

2. *Global \$928 Million Consumer DNA (Genetic) Testing Market 2018–2023 with 23andMe, Ancestry, Color Genomics and Gene by Gene Dominating*, PR NEWswire (May 1, 2018, 7:30 AM), <https://www.prnewswire.com/news-releases/global-928-million-consumer-dna-genetic-testing-market-2018-2023-with-23andme-ancestry-color-genomics-and-gene-by-gene-dominating-300640236.html> [https://perma.cc/RN6Q-ZUY6].

industry as the Food and Drug Administration (FDA) authorized 23andMe, a leading DTC-GT company, to sell the first DTC test for Bloom Syndrome in 2015³ and, more recently in April 2017, approved 23andMe's Health Predisposition tests, known as genetic health risk (GHR) tests under FDA regulations, for ten diseases.⁴ FDA is continuing its pro-DTC-GT stance by announcing plans to exempt DTC GHR tests from premarket review⁵ and authorizing 23andMe's GHR test for three BRCA breast cancer gene mutations in March 2018⁶ and a test for hereditary colorectal cancer syndrome in January 2019.⁷ Advertisements for DTC-GT are omnipresent,⁸ and Ancestry, another popular DTC-GT company, has partnered with the music streaming service Spotify claiming to offer music tailored to one's DNA.⁹

However, given the sensitive nature of data collected and used, DTC-GT companies have not been free from privacy concerns. For example, in July 2018, 23andMe announced that GlaxoSmithKline (GSK), a large pharmaceutical company, acquired a \$300 million stake in the company thereby allowing GSK to use 23andMe consumers' genetic information for drug discovery.¹⁰ The recent arrest of the suspected Golden State Killer

3. Letter from Courtney H. Lias, Dir., Div. of Chemistry & Toxicology Devices, Office of *In Vitro* Diagnostics & Radiological Health, Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., to Kathy Hibbs, Chief Legal & Regulatory Officer, 23andMe, Inc. (Oct. 1, 2015), https://www.accessdata.fda.gov/cdrh_docs/pdf14/den140044.pdf [https://perma.cc/9B95-ZLKM].

4. *FDA Allows Marketing of First Direct-to-Consumer Tests that Provide Genetic Risk Information for Certain Conditions*, U.S. FOOD & DRUG ADMIN. (April 6, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm551185.htm> [https://perma.cc/D78P-R5VE].

5. *Statement from FDA Commissioner Scott Gottlieb, M.D.*, U.S. FOOD & DRUG ADMIN. (Nov. 6, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583885.htm> [https://perma.cc/3GUG-MEW6].

6. *FDA Authorizes, with Special Controls, Direct-to-Consumer Test that Reports Three Mutations in the BRCA Breast Cancer Genes*, U.S. FOOD & DRUG ADMIN. (Mar. 6, 2018), <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm599560.htm> [https://perma.cc/P9F5-VU33].

7. *23andMe Receives FDA Clearance for Genetic Health Risk Report that Looks at a Hereditary Colorectal Cancer Syndrome*, 23ANDME (Jan. 22, 2019), <https://blog.23andme.com/health-traits/23andme-receives-fda-clearance-for-genetic-health-risk-report-that-looks-at-a-hereditary-colorectal-cancer-syndrome/> [https://perma.cc/TW82-PB92].

8. See, e.g., Catherine Ho, *DNA Testing Companies Get into the Black Friday Game*, S.F. CHRON. (Nov. 23, 2018, 4:00 AM), <https://www.sfchronicle.com/business/article/DNA-testing-companies-get-into-the-Black-Friday-13415212.php> [https://perma.cc/8Z94-Q2MP].

9. *Listen on Spotify*, ANCESTRY, <https://www.ancestry.com/cs/spotify> [https://perma.cc/2LA8-ASUV]. The service launched on September 21, 2018, and more than 10,000 people signed up within one day. Aisha Hassan, *Spotify and Ancestry Can Use Your Real DNA to Tell Your "Musical DNA,"* QUARTZY (Sept. 22, 2018), <https://qz.com/quartz/1399279/spotify-can-use-your-ancestry-dna-test-to-tell-your-musical-dna/> [https://perma.cc/7N5K-WVKC].

10. Jamie Ducharme, *A Major Drug Company Now Has Access to 23andMe's Genetic Data. Should You Be Concerned?*, TIME (July 26, 2018), <http://time.com/5349896/23andme-glaxo-smith-kline/> [https://perma.cc/BU23-DE6S].

using DNA evidence from a public database brings additional scrutiny to DTC-GT services.¹¹

Worries about genetic privacy, while not new, are one part of the growing concerns over health information privacy as the collection of non-traditional medical information grows. For example, an increasingly large number of devices, such as the Apple Watch or One Drop's Bluetooth Glucose Meter,¹² collect an individual's medical information, from electrocardiogram (ECG) to blood sugar levels, and send it to private companies.¹³ The concern over genetic privacy is also a part of the "privacy crisis" our society seems to be facing. Almost every month, we seem to be hearing about another large data breach or the alarming data practices of major technology companies concerning user data.¹⁴

However, some of our most private and essential information is in the possession of DTC-GT companies, which are subject to an inadequate patchwork of laws.¹⁵ The Health Insurance Portability and Accountability Act (HIPAA)¹⁶, for example, does not have jurisdiction to regulate medical information outside of the traditional healthcare context, and traditional federal agency regulation appears inadequate.¹⁷ And, among medical information, genetic information may be particularly sensitive because it is immutable and uniquely identifiable.¹⁸ Genetic information, because it is hereditary, may also implicate genetically related family members, as well as a racial or ethnic group.

Meanwhile, the existing legal scholarship on genetic privacy and DTC-GT companies has largely been surveys of companies' privacy policies and guidelines. Some studies have either provided an overview of the problems posed by the DTC-GT services¹⁹ or consumer understanding of the

11. See, e.g., Thomas May, *Sociogenetic Risks—Ancestry DNA Testing, Third-Party Identity, and Protection of Privacy*, 379 NEW ENG. J. MED. 410, 410 (2018), <https://www.nejm.org/doi/full/10.1056/NEJMp1805870>.

12. *Glucose Meter*, ONE DROP, <https://onedrop.today/products/glucose-meter> [<https://perma.cc/R2YX-SUHL>].

13. Alex Fitzpatrick, *An Inside Look at Apple's Biggest Step Yet in Health Care*, TIME (Dec. 6, 2018), <http://time.com/5472329/apple-watch-ecg/> [<https://perma.cc/463P-YEJ4>].

14. Woodrow Hartzog & Neil Richards, *It's Time to Try Something Different on Internet Privacy*, WASH. POST (Dec. 20, 2018), https://www.washingtonpost.com/opinions/its-time-to-try-something-different-on-internet-privacy/2018/12/20/bc1d71c0-0315-11e9-9122-82e98f91ee6f_story.html [<https://perma.cc/Q4JD-VWE3>].

15. See *infra* Part I.

16. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 42 U.S.C.).

17. See *infra* Part I.

18. See *infra* Part III.A.

19. See, e.g., 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 (2016); Sivan Tamir, *Direct-To-Consumer Genetic Testing: Ethical-Legal Perspectives and Practical Considerations*, 18 MED. L. REV. 213 (2010).

companies' privacy policies.²⁰ One study conducted a framework analysis on thirty DTC-GT companies' privacy policies and practices using a "codebook" developed by synthesizing guidelines from professional societies and public bodies,²¹ and another recent paper used the FTC's Fair Information Practice Principles (FIPPs) as a baseline framework to evaluate the privacy policies of ninety DTC-GT companies.²² While instructive, the survey studies have remained largely descriptive. In addition, although there have been concerns about the risks of DTC-GT—the validity and utility of the tests, inappropriate healthcare decisions, emotional harm, data security—since the advent of DTC-GT,²³ a focused and rigorous legal analysis of particular DTC-GT company practices has been wanting.

This Article contributes by being the first to conduct a rigorous analysis, both descriptive and normative, of the privacy policies and associated privacy risks of the DTC-GT services of two major companies—23andMe and Ancestry (focusing on AncestryDNA)—and evaluates to what extent consumers' genetic privacy is protected by the policies and practices of these two companies. The reason we focus on these two companies is that 23andMe and Ancestry are industry leaders. As industry leaders, they can set the industry standard and lead the industry for better data practices and privacy protection.

Our analysis is structured into five parts. Part I provides an overview of the current legal landscape in the United States surrounding DTC-GT companies and their consumers, including federal laws and agencies, state law, and common law. We address that while there are many laws and agencies that *appear* to govern the DTC-GT industry, they do so in a piecemeal and incomplete manner. As a consequence, consumers' genetic privacy is left particularly vulnerable. This work focuses on the practices of 23andMe and Ancestry, and, thus, Part II will briefly review the services provided by these two companies. Part III introduces exploitation theory as

20. See, e.g., Emily Christofides & Kieran O'Doherty, *Company Disclosure and Consumer Perceptions of the Privacy Implications of Direct-to-Consumer Genetic Testing*, 35 NEW GENETICS & SOC'Y 101 (2016).

21. Linnea I. Laestadius et al., *All Your Data (Effectively) Belong to Us: Data Practices Among Direct-to-Consumer Genetic Testing Firms*, 19 GENETICS. MED. 513, 514 (2017).

22. 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).

23. See, e.g., 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 (2008); Heidi C. Howard, Bartha Maria Knoppers & Pascal Borry, *Blurring Lines: The Research Activities of Direct-to-Consumer Genetic Testing Companies Raise Questions About Consumers as Research Subjects*, 11 EMBO REP. 579 (2010); Emilia Niemiec & Heidi C. Howard, *Ethical Issues in Consumer Genome Sequencing: Use of Consumers' Samples and Data*, 8 APPLIED & TRANSLATIONAL GENOMICS 23 (2016); J. Scott Roberts & Jenny Ostergren, *Direct-to-Consumer Genetic Testing and Personal Genomics Services: A Review of Recent Empirical Studies*, 1 CURRENT GENETIC MED. REP. 182 (2013).

the guiding normative framework, which requires consideration of the distribution of benefits and risks in a transaction. We break risk into a three-part analysis, including defining the type of harm, the magnitude of that harm, and the probability that the harm will materialize.²⁴ We propose three categories of harms that most helpfully capture the potential privacy harms of DTC-GT: (1) knowledge harms; (2) autonomy and trust-based harms, which include worries about notice, choice, and deception; and (3) the harms related to data misuse. We further argue that the risks associated with genetic information are heightened relative to other consumer or even health data because of the special nature of genetic information, supporting the notion of genetic exceptionalism. Part IV will assess to what extent these companies adequately protect against the privacy risks discussed in Part III through a combination of their consent, privacy policies, and data management practices. We conclude in Part V by examining how the DTC-GT consumers' genetic privacy can be better protected by valuing trust, more stringent agency oversight, and potentially comprehensive data privacy legislation.

I. REGULATION OF DIRECT-TO-CONSUMER GENETIC TESTING

In the United States, a number of laws and agencies have jurisdiction to regulate genetic information or govern the DTC-GT industry. However, the regulation is fragmented and incomplete.²⁵ Genetic privacy of DTC-GT consumers can be protected in two ways: directly by regulating the collection, processing, use, and/or storage of genetic information; or indirectly by regulating the DTC-GT companies themselves. This Part examines the legal landscape surrounding the DTC-GT industry by categorizing the relevant laws and agencies into four groups and analyzing whether they are effective in regulating DTC-GT companies and/or genetic information produced by those companies: (1) federal laws that can regulate genetic information; (2) federal agencies that can regulate DTC-GT companies; (3) state laws that supplement the federal laws and agencies; and (4) common law privacy torts, in particular, the disclosure and intrusion torts.

24. Annette Rid et al., *Evaluating the Risks of Clinical Research*, 304 JAMA 1472, 1472 (2010).

25. For broader discussion on the piecemeal manner of privacy regulation in the U.S., see generally Kirsty Hughes & Neil M. Richards, *The Atlantic Divide on Privacy and Free Speech*, in *COMPARATIVE DEFAMATION AND PRIVACY LAW* 164 (Andrew T. Kenyon ed., 2016).

A. Federal Laws That Can Regulate Genetic Information

Privacy law in the United States is fragmented with different laws regulating different sectors and industries.²⁶ The Health Insurance Portability and Accountability Act (HIPAA)²⁷ provides the baseline privacy and data security rules for the healthcare industry. HIPAA's Privacy Rule²⁸ regulates the use and disclosure of individuals' "protected health information" by a "covered entity or business associate."²⁹ Under HIPAA, health information includes genetic information,³⁰ which encompasses information from genetic tests of an individual or family members or the manifestation of a disease in family members.³¹ Genetic information from DTC-GT, however, is health information that lies beyond HIPAA's jurisdiction.³² HIPAA defines "covered entities" as a health plan, health care clearinghouse, or health care provider³³ and "business associate" as a person or organization that performs certain functions or activities on behalf of or provides certain services for a covered entity involving protected health information.³⁴ As DTC-GT companies do not qualify as such "covered entities" or "business associates" under HIPAA, DTC-GT

26. See Daniel J. Solove & Woodrow Hartzog, *The FTC and the New Common Law of Privacy*, 114 COLUM. L. REV. 583, 587 (2014) ("[I]t is fair to say that U.S. privacy law regulates only specific types of data when collected and used by specific types of entities.") In contrast, the European Union (EU) General Data Protection Regulation (GDPR) protects privacy broadly by regulating the processing of "personal data" defined as "any information relating to an identified or identifiable natural person." Regulation 2016/679, art. 4(1), 2016 O.J. (L 119) 1, 33. The Privacy Act of 1974 seeks to protect privacy generally, yet only covers personal information that is maintained in systems of records by federal agencies. 5 U.S.C. § 552a (2018).

27. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 42 U.S.C.).

28. 45 C.F.R. §§ 160, 164 (2018).

29. 45 C.F.R. § 164.502 (2018).

30. 45 C.F.R. § 160.103 (2018).

31. The full text of the provision is as follows:

Genetic information means:

... information about:

(i) The individual's genetic tests;

(ii) The genetic tests of family members of the individual;

(iii) The manifestation of a disease or disorder in family members of such individual; or

(iv) Any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by the individual or any family member of the individual.

Id.

32. For discussion on growing issues regarding health information "beyond HIPAA," see U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH INFORMATION PRIVACY BEYOND HIPAA: A 2018 ENVIRONMENTAL SCAN OF MAJOR TRENDS AND CHALLENGES (Dec. 13, 2017), https://ncvhs.hhs.gov/wp-content/uploads/2018/05/NCVHS-Beyond-HIPAA_Report-Final-02-08-18.pdf [<https://perma.cc/WG6M-R27U>].

33. 45 C.F.R. § 160.103.

34. *Id.*

consumers' genetic privacy is unlikely to be protected by HIPAA's Privacy Rule.³⁵

The Genetic Information Nondiscrimination Act (GINA)³⁶ and the Americans with Disabilities Act (ADA)³⁷ are federal laws that have jurisdiction to regulate the use of genetic information in certain contexts and remedy certain forms of discrimination. GINA was enacted in 2008 "to fully protect the public from [genetic] discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies."³⁸ Title I of GINA prohibits discrimination based on genetic information by health insurers, and Title II prohibits discrimination in employment based on genetic information. Under GINA, genetic information is defined as information from genetic tests of an individual or family members or the manifestation of a disease in family members and includes information from genetic services or genetic research.³⁹ Therefore, genetic information from DTC-GT falls under GINA's jurisdiction. Such information is treated as a "confidential medical record"⁴⁰ under GINA, and an employer is also prohibited from disclosing an individual's genetic information⁴¹ or from requesting, requiring, or purchasing genetic information⁴² except in a

35. An exception would be when a DTC-GT company partners with a covered entity and qualifies as a business associate under HIPAA. For example, in 2009, 23andMe announced its partnership with Palomar Pomerado Health (PPH), a health care district in California. Under such circumstances, PPH members' genetic information generated by 23andMe would be subject to HIPAA's Privacy Rule. *23andMe and Palomar Pomerado Health Partner to Give PPH Members Access to Their Genetic Information*, 23ANDME (Apr. 27, 2009), <https://mediacenter.23andme.com/press-releases/23andme-and-palomar-pomerado-health-partner-to-give-pph-members-access-to-their-genetic-information/> [<https://perma.cc/MT7K-ERRQ>].

36. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (codified as amended at 42 U.S.C. § 2000ff).

37. 42 U.S.C. §§ 12101–12213 (2018).

38. Genetic Information Nondiscrimination Act § 2(5), 122 Stat. at 881–82.

39. 42 U.S.C. § 2000ff(4).

(A) In general

The term "genetic information" means, with respect to any individual, information about—

- (i) such individual's genetic tests,
- (ii) the genetic tests of family members of such individual, and
- (iii) the manifestation of a disease or disorder in family members of such individual.

(B) Inclusion of genetic services and participation in genetic research

Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.

(C) Exclusions

The term "genetic information" shall not include information about the sex or age of any individual.

40. 42 U.S.C. § 2000ff-5(a).

41. 42 U.S.C. § 2000ff-5(b).

42. 42 U.S.C. § 2000ff-4(b).

number of defined exceptions.⁴³ Since 2010, the Equal Employment Opportunity Commission (EEOC) has received over 200 charges every year filed under GINA,⁴⁴ and in the first GINA case to go to trial,⁴⁵ an employer was faced with a \$2.25 million verdict for violation of GINA.⁴⁶ Despite such enforcement to protect against genetic discrimination, GINA only applies to discrimination in the employment and health insurance contexts and does not apply to life insurance or long-term care insurance or other potential discriminatory uses of genetic information.⁴⁷

The ADA prohibits discrimination based on disability in employment, public services, public accommodations, and communications.⁴⁸ While the statutory provisions of ADA do not make a reference to genetic traits or diseases, the EEOC issued an interpretation in 1995 stating that ADA applies to “discrimination on the basis of genetic information relating to illness, disease, or other disorders.”⁴⁹ However, the analysis has since been superseded by the ADA Amendments Act of 2008,⁵⁰ and the ADA Amendments Act does not address genetic discrimination. In addition, there have been no judicial interpretations on whether ADA applies to discrimination based on genetic information. Thus, it is unclear whether ADA can provide an additional layer of protection from discrimination based on genetic information from a DTC-GT company. Moreover, even if EEOC provides guidance on the issue, ADA and GINA are still confined to prohibiting the use of genetic information in discrimination and do not have

43. *Id.* The employment provisions have inspired a recent work to propose GINA as a blueprint for employee-privacy protection in the big data era. Bradley A. Areheart & Jessica L. Roberts, *GINA, Big Data, and the Future of Employee Privacy*, 128 *YALE L.J.* 710, 764–779 (2019).

44. *Genetic Information Non-Discrimination Act Charges*, U.S. EQUAL EMP’T OPPORTUNITY COMM’N, <https://www.eeoc.gov/eeoc/statistics/enforcement/genetic.cfm> [<https://perma.cc/DFX3-9HDL>].

45. *Lowe v. Atlas Logistics Grp. Retail Servs.*, 102 F. Supp. 3d 1360, 1361 (N.D. Ga. 2015) (finding that the employer violated GINA when it conducted genetic testing of two employees to identify the culprit of defecation episodes in its grocery distribution warehouse).

46. Natasha Gilbert, *Why the ‘Devious Defecator’ Case Is a Landmark for US Genetic-Privacy Law*, *NATURE: NEWS & COMMENT* (June 25 2015), <https://www.nature.com/news/why-the-devious-defecator-case-is-a-landmark-for-us-genetic-privacy-law-1.17857> [<https://perma.cc/28U8-88XT>].

47. See Mark A. Rothstein, *GINA, the ADA, and Genetic Discrimination in Employment*, 36 *J.L. MED. & ETHICS* 837, 837–38 (2008) (discussing deficiencies of GINA including its limited reach, application based on genotype but not phenotype, and a loophole related to ADA).

48. 42 U.S.C. §§ 12101–12213 (2018).

49. AMANDA K. SARATA & JODY FEDER, CONG. RESEARCH SERV., RL34584, *THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008 (GINA) 6* (2015) (quoting U.S. EQUAL EMP’T OPPORTUNITY COMM’N, 2 *COMPLIANCE MANUAL* 902, 915.002 (1995)), <https://fas.org/sgp/crs/misc/RL34584.pdf> [<https://perma.cc/WCA6-MRMB>].

50. *Section 902 Definition of the Term Disability*, EQUAL EMP’T OPPORTUNITY COMM’N, <https://www.eeoc.gov/policy/docs/902cm.html> [<https://perma.cc/6E7M-Q9N3>] (last modified July 25, 2012); see also ADA Amendments Act of 2008, Pub. L. No. 110-325, 122 Stat. 3553 (codified at 42 U.S.C. § 12101).

the jurisdiction to protect the DTC-GT consumers' genetic information in other contexts.

B. Federal Administrative Agencies That Can Regulate DTC-GT Companies

Three federal administrative agencies primarily regulate the DTC-GT industry: the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS) via the Clinical Laboratory Improvements Act (CLIA),⁵¹ and the Federal Trade Commission (FTC). FDA protects “the public health by assuring the safety, effectiveness, quality, and security of . . . drugs, vaccines and other biological products, and medical devices.”⁵² FDA has jurisdiction to regulate DTC-GTs as medical devices under the Federal Food, Drugs, and Cosmetics Act.⁵³ Specifically, FDA considers genetic tests as “in vitro diagnostic” devices, which are devices “intended for use in the diagnosis of disease or other conditions . . . [and] intended for use in the collection, preparation, and examination of specimens taken from the human body.”⁵⁴ Following an initial period of enforcement discretion,⁵⁵ FDA started to exercise its regulatory authority over the DTC-GT industry in 2010 by sending twenty-three Untitled Letters to DTC-GT companies⁵⁶ and, in 2013, sent a Warning Letter to 23andMe⁵⁷ which resulted in the company ceasing its sale of

51. Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, 102 Stat. 2903 (codified at 42 U.S.C. §§ 201, 263a).

52. *FDA Fundamentals*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/aboutfda/transparency/basics/ucm192695.htm> [<https://perma.cc/TS47-8DTP>].

53. 21 U.S.C. § 321(h) (2018) (defining a device to include “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease”).

54. 21 C.F.R. § 809.3(a) (2018).

55. See Kayte Spector-Bagdady & Elizabeth R. Pike, *Consuming Genomics: Regulating Direct-to-Consumer Genetic and Genomic Information*, 92 NEB. L. REV. 677, 703 (2014).

56. See, e.g., Letter from James Woods, Deputy Dir., Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., to James Plante, Founder & Chief Exec. Officer, Pathway Genomics Corp. (May 10, 2010), <https://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM211875.pdf> [<https://perma.cc/6ZWG-MKGE>]. FDA issues Untitled Letters for violations that are less significant than those warranting a Warning Letter. *Issuance of Untitled Letters*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ICECI/EnforcementActions/ucm511995.htm> [<https://perma.cc/YV7W-5HQR>].

57. See Letter from Alberto Gutierrez, Dir., Office of In Vitro Diagnostics & Radiological Health, Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., to Ann[e] Wojcicki, Chief Exec. Officer, 23andMe, Inc. (Nov. 22, 2013), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm> [<https://perma.cc/7YUD-4M55>]. FDA issues Warning Letters for significant violation of FDA regulations. The Letter highlights the violation and provides directions and a timeframe for the company to correct the violation. *Warning Letters*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm278624.htm> [<https://perma.cc/T6BJ-68N4>].

health-related genetic tests.⁵⁸ However, in 2015, FDA approved the first health-related DTC-GT for 23andMe's DTC test for Bloom Syndrome.⁵⁹ This has been followed by more FDA authorization of health-related DTC-GT, including 23andMe's Health Predispositions tests for ten diseases⁶⁰ and 23andMe's test for three BRCA breast cancer gene mutations in March 2018.⁶¹ However, FDA only has the jurisdiction to regulate DTC tests that diagnose a disease⁶² and, thus, does not regulate any of the DTC-GT tests or services related to genealogy or lifestyle (e.g., the wellness or traits tests). In addition, FDA does not have jurisdiction to regulate other aspects of DTC-GT companies' activities or data practices, thereby leaving the consumers' genetic privacy largely outside of FDA's reach.⁶³

In addition to FDA, CMS can regulate DTC-GT through enforcement of CLIA, which requires certification of "laboratories" that analyze biological materials to provide "information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings."⁶⁴ CMS requires the laboratories to ensure the accuracy, precision, and analytical validity of the tests.⁶⁵ However, similar to FDA, CMS only has the jurisdiction to regulate DTC tests that diagnose a disease or assess health. Indeed, while 23andMe states that its genotyping is performed in a CLIA-certified laboratory,⁶⁶ other DTC-GT companies providing non-health genetic testing do not appear to be going through CLIA certification. In addition, CLIA only concerns a test's analytical validity (how well the test detects a genetic variant) and not clinical validity (association of genetic variant with a disease) or clinical utility (whether the information is clinically useful or actionable).⁶⁷

Meanwhile, FTC has broad authority to regulate "unfair" or "deceptive" business practices under the Federal Trade Commission Act (FTCA).⁶⁸ Also, while FDA regulates medical device labeling,⁶⁹ FTC is responsible for

58. For a more detailed discussion of FDA enforcement actions against DTC-GT companies during 2010 to 2014, see Spector-Bagdady & Pike, *supra* note 55, at 704–17.

59. Letter from Courtney Lias to Kathy Hibbs, *supra* note 3.

60. U.S. FOOD & DRUG ADMIN., *supra* note 4.

61. U.S. FOOD & DRUG ADMIN., *supra* note 6.

62. See 21 C.F.R. § 809.3(a) (2018).

63. In addition to the medical device itself, FDA regulates the labeling of devices and advertising of prescription devices. See 21 U.S.C. § 352 (2018).

64. 42 U.S.C. § 263a(a) (2018); 42 C.F.R. § 493.2 (2018).

65. See 42 C.F.R. § 493.1253(b)(2) (2018).

66. *The Science Behind 23andMe*, 23ANDME, <https://www.23andme.com/genetic-science/> [https://perma.cc/BC5W-9V3M].

67. See *How Can Consumers Be Sure a Genetic Test Is Valid and Useful?*, U.S. NAT'L LIBRARY OF MED.: GENETICS HOME REFERENCE, <https://ghr.nlm.nih.gov/primer/testing/validtest> [https://perma.cc/8RN9-YPZ8].

68. Federal Trade Commission Act, Pub. L. No. 63-203, 38 Stat. 717, 719 (1914) (codified as amended at 15 U.S.C. §§ 41–58 (2018)).

69. See 21 U.S.C. § 352 (2012).

regulating non-prescription medical device advertising.⁷⁰ As DTC-GT, by its nature, is available without prescription, regulation of DTC-GT advertising falls under FTC's jurisdiction as well as DTC-GT companies' data practices. Unfortunately, FTC has thus far limited its actions in the DTC-GT field to issuing consumer bulletins.⁷¹ For example, in December 2017, FTC issued a statement warning consumers about the potential privacy risks of DTC-GT.⁷²

The most notable example of FTC's action against a DTC-GT company was a complaint filed in May 2014 against GeneLink, Inc. and Foru International Corporation, which used DTC genetic tests to match consumers to their nutritional supplements and skincare products.⁷³ FTC alleged that the companies' acts and practices related to data security were unfair or deceptive because they "[f]ailed to implement reasonable policies and procedures to protect the security of consumers' personal information" and "[c]reated unnecessary risks to personal information,"⁷⁴ where personal information included genetic information of "nearly 30,000 consumers."⁷⁵ The companies entered into a consent agreement with FTC, which required them "to establish and maintain comprehensive data security programs and submit to security audits by independent auditors every other year for 20 years."⁷⁶ Under the current regulatory regime, the FTC likely has the broadest and most effective authority to regulate genetic information from DTC-GT companies via enforcement actions.

70. Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18,539 (Sept. 16, 1971), <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/UCM518242.pdf> [<https://perma.cc/L6B9-BSKX>].

71. *Direct-to-Consumer Genetic Tests*, FED. TRADE COMM'N, <https://www.consumer.ftc.gov/articles/0166-direct-consumer-genetic-tests> [<https://perma.cc/KTM4-BCDH>].

72. Lesley Fair, *DNA Test Kits: Consider the Privacy Implications*, FED. TRADE COMM'N (Dec. 12, 2017), <https://www.consumer.ftc.gov/blog/2017/12/dna-test-kits-consider-privacy-implications> [<https://perma.cc/GB7D-DNHA>]. It has also been reported that the FTC might be investigating major DTC-GT companies including 23andMe and Ancestry.com regarding their privacy policies. Marcus Baram, *The FTC Is Investigating DNA Firms Like 23andMe and Ancestry over Privacy*, FAST COMPANY (June 5, 2018), <https://www.fastcompany.com/40580364/the-ftc-is-investigating-dna-firms-like-23andme-and-ancestry-over-privacy> [<https://perma.cc/ECT5-J8JC>].

73. Complaint at 1–2, *In re GeneLink, Inc.*, No. C4456, (F.T.C. May 8, 2014), <https://www.ftc.gov/system/files/documents/cases/140512genelinkcmpt.pdf> [<https://perma.cc/J27Q-YP2T>].

74. *Id.* at 13.

75. *Id.* at 2.

76. *FTC Approves Final Consent Orders Settling Charges that Companies Deceptively Claimed Their Genetically Modified Nutritional Supplements Could Treat Diseases*, FED. TRADE COMM'N (May 12, 2014), <https://www.ftc.gov/news-events/press-releases/2014/05/ftc-approves-final-consent-orders-settling-charges-companies> [<https://perma.cc/WRL3-XSTY>].

C. State Laws

State laws can add a layer of regulation complementing federal statutes and agencies by regulating DTC-GT or genetic information. Studies have found that thirteen,⁷⁷ or even fifteen,⁷⁸ states effectively prohibit DTC-GT, and twelve states limit access to DTC-GT in certain aspects.⁷⁹ However, the statutory language specifies the tests as those for diagnosis of disease or health. For example, New York prohibits laboratories from returning the test result “of a specimen submitted for evidence of human disease or medical condition” directly to a patient.⁸⁰ And Maryland prohibits medical laboratories from performing tests or releasing test results directly to a patient without authorization,⁸¹ where the “medical laboratory” is defined as a facility that performs tests for “diagnosis and control of human disease” or “assessment of human health, nutrition, or medical conditions.”⁸² Since the FDA authorization of 23andMe’s tests, however, 23andMe can sell its DTC genetic tests to customers in New York and Maryland because the tests are designated as over-the-counter devices and thereby do not fall under the state law restrictions.⁸³ In addition, it does not appear that Ancestry or other DTC-GT companies offering genealogy or lifestyle-related DTC-GT services are prohibited in these states.

More relevant for protecting consumers’ genetic privacy are state laws regulating genetic information in various aspects. Currently, thirty-five states and the District of Columbia prohibit genetic discrimination in employment,⁸⁴ forty-eight states and the District of Columbia prohibit genetic discrimination in health insurance,⁸⁵ and twenty-three states

77. Spector-Bagdady & Pike, *supra* note 55, at 727.

78. Helen C. Dick, Note, *Risk and Responsibility: State Regulation and Enforcement of the Direct-to-Consumer Genetic Testing Industry*, 6 ST. LOUIS U. J. HEALTH L. & POL’Y 167, 177 (2012).

79. Spector-Bagdady & Pike, *supra* note 55, at 727.

80. N.Y. COMP. CODES R. & REGS. tit. 10, § 58-1.8 (2018).

81. MD. CODE REGS. 10.10.01.02, 04 (2019).

82. MD. CODE REGS. 10.10.01.03B(39)(a) (2019). While there is an exception from the authorization requirement for “health awareness tests,” genetic tests are not listed as a health awareness test. MD. CODE REGS. 10.10.01.02B.

83. *23andMe Genetic Service Now Fully Accessible to Customers in New York and Maryland*, 23ANDME (Dec. 4, 2015), <https://mediacenter.23andme.com/press-releases/23andme-genetic-service-now-fully-accessible-to-customers-in-new-york-and-maryland/> [<https://perma.cc/G8SR-ZTAS>].

84. These states include Arizona, Arkansas, California, Connecticut, District of Columbia, Delaware, Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Rhode Island, South Dakota, Texas, Utah, Vermont, Virginia, Washington, and Wisconsin. *Genome Statute and Legislation Database*, NAT’L HUMAN GENOME RESEARCH INST., https://www.genome.gov/policyethics/legdatabase/pubsearchresult.cfm?content_type=1&content_type_id=1&topic=1&topic_id=1&source_id=1 [<https://perma.cc/47EV-P5NV>].

85. These states include Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri,

prohibit genetic discrimination in life insurance, disability insurance, or long-term care insurance.⁸⁶ In addition, forty-one states have laws protecting the privacy of genetic information.⁸⁷ Most notable among the state genetic nondiscrimination and privacy laws is California. The California Genetic Information Nondiscrimination Act (CalGINA), enacted in 2011, extends the areas of protection from genetic discrimination to emergency medical services, housing, mortgage lending, education, and state funded programs.⁸⁸ More importantly, the California Consumer Privacy Act of 2018 (CCPA)⁸⁹ is considered the most comprehensive and significant state privacy law comparable to the European Union's General Data Protection Regulation (GDPR).⁹⁰ CCPA provides broad protection of consumers' ("a natural person who is a California resident")⁹¹ genetic information ("biometric information")⁹² as a type of "personal information."⁹³

Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming. *Genome Statute and Legislation Database*, NAT'L HUMAN GENOME RESEARCH INST., https://www.genome.gov/policyethics/legdatabase/pubsearchresult.cfm?content_type=1&content_type_id=1&topic=2&topic_id=1&source_id=1 [<https://perma.cc/N53L-85SH>].

86. These states include Alabama, Arizona, California, Colorado, Florida, Idaho, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Montana, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oregon, Vermont, Wisconsin, and Wyoming. *Genome Statute and Legislation Database*, NAT'L HUMAN GENOME RESEARCH INST., https://www.genome.gov/policyethics/legdatabase/pubsearchresult.cfm?content_type=1&content_type_id=1&topic=3&topic_id=1&source_id=1 [<https://perma.cc/CK5S-DBN6>].

87. These states include Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wyoming. *Genome Statute and Legislation Database*, NAT'L HUMAN GENOME RESEARCH INST., https://www.genome.gov/policyethics/legdatabase/pubsearchresult.cfm?content_type=1&content_type_id=1&topic=4&topic_id=1&source_id=1 [<https://perma.cc/N9LS-SNMP>].

88. CAL. CIV. CODE § 51 (West 2011).

89. CAL. CIV. CODE §§ 1798.100–1798.199 (West 2018).

90. For comparison of CCPA and GDPR, see Gabriela Zanfir-Fortuna & Michelle Bae, *CCPA, Face to Face with the GDPR: An In Depth Comparative Analysis*, FUTURE PRIVACY F. (Nov. 28, 2018), <https://fpf.org/2018/11/28/fpf-and-dataguidance-comparison-guide-gdpr-vs-ccpa/> [<https://perma.cc/4U49-6ATP>].

91. CAL. CIV. CODE § 1798.140(g) (2018).

92. *Id.* § 1798.140(b). ("'Biometric information' means an individual's physiological, biological or behavioral characteristics, including an individual's deoxyribonucleic acid (DNA), that can be used, singly or in combination with each other or with other identifying data, to establish individual identity.")

93. *Id.* § 1798.140(o).

D. Common Law

While Warren and Brandeis advanced the tort concept of privacy in their influential article, *The Right to Privacy*, arguing that the common law should recognize a tort to protect an individual's "inviolate personality" against disclosure of private information,⁹⁴ it was William Prosser who later organized the concept into distinct torts, providing the foundation of the modern privacy tort.⁹⁵ Prosser categorized privacy torts into the following four torts:

1. Intrusion upon the plaintiff's seclusion or solitude, or into his private affairs.
2. Public disclosure of embarrassing private facts about the plaintiff.
3. Publicity which places the plaintiff in a false light in the public eye.
4. Appropriation, for the defendant's advantage, of the plaintiff's name or likeness.⁹⁶

Among these four torts, the intrusion tort and disclosure tort can potentially address the invasion of DTC-GT consumers' genetic privacy. Initially, it appears that misuse of an individual's genetic information by the DTC-GT company⁹⁷ would satisfy the elements of the intrusion tort, which are: (1) an intrusion into (2) the seclusion or private affairs that is (3) highly offensive to a reasonable person.⁹⁸ While the early concept of intrusion was grounded in physical or spatial disturbances,⁹⁹ it has evolved into preventing access to (or controlling) information about oneself.¹⁰⁰ Therefore, misuse of genetic information by a DTC-GT company could be considered as an intrusion into one's ability to control the information, thereby satisfying the first element. For the second and third elements, it is safe to assume that

94. Samuel D. Warren & Louis D. Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193, 205 (1890).

95. For detailed discussion on Prosser's influence on the development of privacy tort, see Neil M. Richards & Daniel J. Solove, *Prosser's Privacy Law: A Mixed Legacy*, 98 CALIF. L. REV. 1887, 1904-07 (2010).

96. William L. Prosser, *Privacy*, 48 CALIF. L. REV. 383, 389 (1960).

97. This would include, for example, a DTC-GT company using genetic information in a way that is not consistent with its privacy policy.

98. RESTATEMENT (SECOND) OF TORTS §652B (AM. LAW INST. 1977).

99. See June Mary Z. Makdisi, *Genetic Privacy: New Intrusion a New Tort?*, 34 CREIGHTON L. REV. 965, 983-84 (2001).

100. See Robert A. Reilly, *Conceptual Foundations of Privacy: Looking Backward Before Stepping Forward*, 6 RICH. J.L. & TECH. 6, ¶ 39 (1999) ("Where once the issue of 'privacy' was primarily one having to do with one's physical seclusion, one's personal domain, and one's physical withdrawal from society's gaze, it has now come to include access to information about one's self.").

genetic information is a private affair and a reasonable person could be highly offended if aspects of their genetic information were misused. This tort may also provide a cause of action following a data breach against an alleged hacker, though not necessarily the company itself.

Similarly, the disclosure tort's three elements—(1) publicity given to (2) private, non-newsworthy facts that are (3) highly offensive to a reasonable person¹⁰¹—could be satisfied in a case where a DTC-GT consumer's genetic information has been released due to a data breach in the company's database. A data breach would render the information “public,” thus satisfying the publicity element.¹⁰² The genetic information is likely to be considered “private facts,” and a reasonable person could be highly offended by the public release of their genetic information.¹⁰³

In theory, these torts can provide some level of redress for privacy harms to consumers and deter problematic conduct by hackers or companies. However, in reality, the privacy torts have not proven to be the most effective legal tool to protect consumer privacy.¹⁰⁴ Most notably, courts have explained that there is no privacy protection once the information has been made public or shared with others.¹⁰⁵ Therefore, the simple fact that an individual is a customer of the DTC-GT company—that is, the fact that the consumer has already consented for the company to collect and use his/her genetic information—might undermine the ability of consumers to protect their genetic privacy with privacy torts.¹⁰⁶ Regardless, the utility of privacy torts in this area is unclear because there is currently no legal precedent recognizing these torts for consumers' genetic information from DTC-GT companies.

II. SERVICES OFFERED BY 23ANDME AND ANCESTRY

A. *23andMe and Ancestry Services*

23andMe offers a number of ancestry and health information services.¹⁰⁷ Its testing services consist of the following five categories: (1) Health

101. RESTATEMENT (SECOND) OF TORTS §652D (AM. LAW INST. 1977).

102. *Id.* §652D cmt. a.

103. *Id.*

104. *See* Richards & Solove, *supra* note 95, at 1918 (“Privacy tort cases have proven quite difficult for plaintiffs to win, and the torts have not kept pace with contemporary privacy problems.”).

105. *Id.* at 1920–21.

106. *Id.* at 1918 (“[Privacy torts] have not adapted to new privacy problems such as the extensive collection, use, and disclosure of personal information by businesses.”).

107. *Health + Ancestry*, 23ANDME, <https://www.23andme.com/dna-health-ancestry/> [<https://perma.cc/4QJN-4N2S>].

Predispositions,¹⁰⁸ (2) Ancestry, (3) Wellness, (4) Carrier Status,¹⁰⁹ and (5) Traits. Importantly, as 23andMe states that its tests are CLIA-certified,¹¹⁰ the tests have approved analytical validity.¹¹¹ However, the categories of tests not approved by the FDA have uncertain clinical validity.¹¹²

23andMe has eleven FDA-approved Health Predispositions tests including, for example, tests for the BRCA1 and 2 mutations for risk of breast cancer, age-related macular degeneration, alpha-1 antitrypsin deficiency, celiac disease, G6PD deficiency, hereditary hemochromatosis, hereditary thrombophilia, late-onset Alzheimer's Disease, and Parkinson's Disease.¹¹³ Recently, on March 10, 2019, 23andMe announced that it will be providing a new Health Predispositions report on type 2 diabetes.¹¹⁴ The report is based on polygenic risk score¹¹⁵ developed from 23andMe's research data and is not approved by FDA.¹¹⁶ The ancestry testing for 23andMe covers more than thirty-five reports, including, for example, Ancestry Composition, Maternal Haplogroup, Paternal Haplogroup, Neanderthal Ancestry, Your DNA Family, and the DNA Relative Finder Tool.¹¹⁷ 23andMe's Wellness reports include alcohol flush reaction, caffeine consumption, deep sleep, genetic weight, lactose intolerance, muscle composition, saturated fat and weight, and sleep movement.¹¹⁸ The 23andMe Carrier Status reports cover more than forty reports, including, for example, Cystic Fibrosis, Sickle Cell Anemia, Hereditary Hearing Loss, Bloom Syndrome, Canavan Disease, Tay-Sachs Disease, and Usher Syndrome.¹¹⁹ And finally, the Traits reports include more than thirty reports. For example, consumers can receive information about hair color or male baldness, eye color, earwax type, cleft chin, cilantro taste aversion, cheek

108. These are FDA approved. *Id.*

109. These are FDA approved. *Id.*

110. *The Science Behind 23andMe*, 23ANDME, *supra* note 66.

111. See U.S. NAT'L LIBRARY MED., *supra* note 67.

112. The FDA approval process assesses analytical validity and clinical validity. *Direct-to-Consumer Tests*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm624726.htm> [<https://perma.cc/2S24-WMWB>] (last updated Nov. 1, 2018).

113. *Health + Ancestry*, 23ANDME, *supra* note 105.

114. 23andMe Offers New Genetic Report on Type 2 Diabetes, 23ANDME (Mar. 10, 2019), <https://blog.23andme.com/health-traits/type-2-diabetes/>

115. Polygenic risk score calculates the a person's odds of developing a medical condition based on many genetic variants. *Id.*

116. 23andMe's new type 2 diabetes polygenic score report likely falls under FDA's exemption for low-risk devices intended for general wellness use. U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS: POLICY FOR LOW RISK DEVICES (Jul. 29, 2016), <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429674.pdf>.

117. *Health + Ancestry*, 23ANDME, *supra* note 105.

118. *Id.*

119. *Id.*

dimples, the ability to match musical pitches, mosquito bite frequency, and wake-up time.¹²⁰

Ancestry, as their website states, is a service that “helps you understand your genealogy.”¹²¹ When combined with a consumer’s DNA sample, the AncestryDNA service seeks to provide more comprehensive ancestry information. Ancestry provides estimates of your ethnicity, where ancestors might have come from, “sometimes down to a city,” “a timeline of historical changes with expert-curated content,” migration information, and DNA matches to living relatives.¹²² AncestryDNA will also provide consumers with traits information similar to 23andMe, including, for example, finger length, sweet sensitivity, cilantro aversion, eye color, hair type, iris patterns, freckles, cleft chin, and earwax type.¹²³

Both companies allow consumers the option to participate in clinical research. For example, a consumer’s genetic information from 23andMe can be integrated into Apple’s ResearchKit app to be used for large scale medical studies.¹²⁴ Ancestry consumers can participate in the “Ancestry Human Diversity Project” of which Ancestry is a part with other institutions and businesses.¹²⁵

B. The Potential Benefits of Using 23andMe and Ancestry Services

Consumers may benefit in important ways by using the services of 23andMe and Ancestry.¹²⁶ The direct-to-consumer nature of the services means that consumers can access genetic testing without the healthcare system as a gatekeeper thereby providing more autonomy and potentially a lower price.¹²⁷ The information provided can empower consumers to mitigate the risks of certain diseases, allow for more informed family planning, or gain a better understanding of their heritage.¹²⁸ To the extent consumers choose to participate in the research activities of 23andMe and Ancestry, they can contribute to the generalizable knowledge produced by the research. In fact, 23andMe’s collaboration with academic centers has resulted in 124 scientific publications since 2010 which have illuminated

120. *Id.*

121. ANCESTRY, <https://www.ancestry.com/> [<https://perma.cc/S598-EVSL>].

122. DNA, ANCESTRY, <https://www.ancestry.com/dna/> [<https://perma.cc/LW7S-WDF3>] (What Your Results Will Include tab).

123. *Id.* (Explore Ancestry DNA Traits tab).

124. *Research*, 23ANDME, <https://www.23andme.com/research/> [<https://perma.cc/QDD4-3N32>].

125. *AncestryDNA Research and Collaboration*, ANCESTRY, <https://www.ancestry.com/cs/collaborations> [<https://perma.cc/W5CX-BSBZ>].

126. *See, e.g.,* Effy Vayena, *Direct-to-Consumer Genomics on the Scales of Autonomy*, 41 J. MED. ETHICS 310 (2015); Tobias Hausermann et al., *Genes Wide Open: Data Sharing and the Social Gradient of Genomic Privacy*, 9 AJOB EMPIRICAL BIOETHICS 207 (2018).

127. Vayena, *supra* note 126, at 310

128. *Id.* at 313.

the link between genetics and numerous medical conditions such as alcohol dependence and skin cancer.¹²⁹

Of course, 23andMe and Ancestry also benefit from these transactions. Presumably, these companies profit from the prices they charge to consumers for their services. More importantly, however, they benefit immensely by collecting and sharing, to the extent permissible by their respective privacy policies, large amounts of private information about consumers.¹³⁰ 23andMe not only collaborates with academic institutions and non-profit organizations but also with a number of pharmaceutical companies including Genentech and Pfizer.¹³¹ Industry also often invests in 23andMe such as the recent \$300 million investment by GSK.¹³²

III. GENETIC PRIVACY, RISK, AND HARM

DTC-GT companies have been criticized since their inception more than a decade ago.¹³³ Many of these critiques are ultimately grounded in concerns about exploitation of consumers, even if this isn't explicitly stated. Here, we ask whether 23andMe and Ancestry protect consumer privacy in a justifiable manner. To answer this question, we need a normative framework to help us evaluate the risks to consumers, the benefits to the company and the consumer, and to what extent the fairness of the transaction justifies the data hygiene of 23andMe and Ancestry. As we explain below, transactions do not have to be risk-free, including free of privacy risk, to be justifiable. However, the privacy risks do have to be reasonable in relation to the benefits to be justifiable—this is what exploitation theory helps us understand, albeit in a rough sense. Using a more robust normative framework also helps minimize the use of intuition in the analysis. Finally, the unfairness of the transaction helps us determine to what extent there should be legal intervention.

129. *Since 2013, 23andMe Has Published 130 Papers*, 23ANDME, <https://www.23andme.com/publications/> [<https://perma.cc/A86M-65FP>].

130. Laestadius, *supra* note 21, at 513; Sheldon Krinsky & David Cay Johnston, *Ancestry DNA Testing and Privacy: A Consumer Guide*, COUNCIL FOR RESPONSIBLE GENETICS (2017), at 9, <http://www.councilforresponsiblegenetics.org/img/Ancestry-DNA-Testing-and-Privacy-Guide.pdf> (quoting a 23andMe board member who explained that amassing the data helps 23andMe “become the Google of personalized healthcare.”).

131. *Research*, 23ANDME, *supra* note 124.

132. Ducharme, *supra* note 10.

133. *See, e.g.*, Charis Eng & Richard R. Sharp, *Bioethical and Clinical Dilemmas of Direct-to-Consumer Personal Genomic Testing: The Problem of Misattributed Equivalence*, 2 SCI. TRANSLATIONAL MED. 17cm5 (2010) *passim*; Amy L. McGuire & Wylie Burke, *An Unwelcome Side Effect of Direct-to-Consumer Personal Genome Testing: Raiding the Medical Commons*, 300 JAMA 2669 *passim* (2008); Katherine Wasson et al., *Direct-to-Consumer Online Genetic Testing and the Four Principles: An Analysis of the Ethical Issues*, 22 ETHICS & MED. 83 *passim* (2006).

To this end, this Part is structured into three sub-parts. First, we begin by sketching a theory of exploitation for our analysis. We then explain why privacy concerns in genetics may be heightened over other kinds of health information, a view known as “genetic exceptionalism.” And, finally, because exploitation requires an analysis of the risks and benefits, we provide an account of risk and harm in the DTC-GT context.

A. The Central Normative Concern: Exploitation

Exploitation is essentially the idea that it is wrong to take unfair advantage of someone. However, not all exploitation is morally troubling. In the nonmoral sense, exploitation “simply means to *use* something to advantage.”¹³⁴ For example, “[a] weight lifter exploits his muscles to lift weights, a carpenter exploits his tools to build beautiful chairs, a scientist exploits a quirk of nature to make a new cosmological discovery or synthesize a new molecule.”¹³⁵ The worry in the case of DTC-GT services is whether consumers are taken advantage of in some unfair or inappropriate way.

Concerns about exploitation apply not only to the commercial transactions between consumers and 23andMe or Ancestry, but also to the research the DTC-GT companies conduct.¹³⁶ However, because research ethics involves separate considerations, including other federal regulations, we will not pursue those issues here.

Although there has been a substantial growth in contemporary scholarship on exploitation, especially in the clinical research context, we rely on Alan Wertheimer’s framework, which focuses on the distribution of benefits and burdens.¹³⁷ Under Wertheimer’s view, exploitative transactions fall into two groups—consensual or nonconsensual transactions that are (1) harmful or (2) mutually advantageous. Harmful transactions are the most straightforward instances of exploitation and occur when “A gains by imposing a harm on B”—e.g., “slavery, extortion, [or] fraud.”¹³⁸ Mutually advantageous exploitation, on the other hand, occurs when “both parties [to a transaction] . . . reasonably expect to gain from the transaction as contrasted with the pretransaction status quo.”¹³⁹

134. Jennifer S. Hawkins & Ezekiel Emanuel, *Introduction: Why Exploitation?*, in *EXPLOITATION AND DEVELOPING COUNTRIES* 1, 13 (Jennifer S. Hawkins & Ezekiel J. Emanuel eds., 2008).

135. *Id.*

136. *See, e.g., supra* text accompanying note 10.

137. Alan Wertheimer, *Exploitation in Clinical Research*, in *EXPLOITATION AND DEVELOPING COUNTRIES*, *supra* note 134, at 63.

138. Wertheimer, *supra* note 137, at 70.

139. *Id.* at 67–68.

To be clear, even though there may be consent to a transaction, the transaction can still be problematically exploitative.¹⁴⁰ The reverse may also be true—there may be a nonconsensual transaction with a fair distribution of benefits that is, therefore, non-exploitative.¹⁴¹ This may just mean that the transaction is unethical for other reasons,¹⁴² for example, because it's wrong to violate someone's autonomy. The central inquiry, again, is whether a transaction is unfair. However, consent is still important—"the absence of valid consent is often a good indication that [a] transaction is a case of harmful exploitation rather than mutually advantageous exploitation."¹⁴³ Acknowledging the difficulty in developing a precise account of unfairness, Wertheimer explains that "some mutually advantageous transactions are unfair by reference to an appropriate normative standard and that A exploits B when A gains more than A should (or B gains less than B should) from the transaction."¹⁴⁴ To put mutually advantageous exploitative transactions in a rough numerical format, there might be three possibilities: (1) no transaction, where A and B both gain nothing; (2) an unfair, mutually advantageous transaction, where A gains ten while B only gains one; and (3) a fair transaction, where A and B both gain five.¹⁴⁵

These transactions should be evaluated with several important factors in mind. First, these transactions should be evaluated from "an all-things-considered point of view"—meaning, even if a transaction has negative elements (e.g., exchanging money for a product), we would not necessarily say the loss of money for one party and the loss of the product for the other amounts to a *harmful* transaction.¹⁴⁶ Similarly, here, we would not necessarily say that exchanging money and genetic data for the services of 23andMe or Ancestry is *harmful* simply because there are some privacy risks associated with the service. Second, the transactions should be evaluated from "an *ex ante* rather than an *ex post* point of view."¹⁴⁷ This means that even if a transaction ends up being disappointing—e.g., not finding oil on land where one hoped to find oil—the transaction is not morally problematic if the "*ex ante* utility is clearly positive."¹⁴⁸ And third, a mutually advantageous transaction is not necessarily problematic "simply because A takes advantage of B's vulnerabilities or desperate situation to

140. *Id.* at 68.

141. *Id.* at 74.

142. *Id.*

143. *Id.*

144. *Id.* at 73–74.

145. *Id.* at 79.

146. *Id.* at 70 (emphasis omitted).

147. *Id.* at 71.

148. *Id.*

strike a deal.”¹⁴⁹ There is an important distinction, Wertheimer explains, “between moral defects in B’s *background situation* and moral defects in the transactions that occur within that situation.”¹⁵⁰

However, even if a transaction is exploitative, there is a separate question of to what extent there should be some kind of “interference”—that is, a legal intervention to regulate these transactions.¹⁵¹ Wertheimer calls this the “moral force” of the claim of exploitation, emphasizing that “[w]rongness is one thing, and interference is another.”¹⁵² He explains that there is a fairly straightforward *prima facie* case for prohibiting an exploitative transaction when it is both harmful and nonconsensual.¹⁵³ However, Wertheimer argues that there should be a strong presumption *against* prohibiting exploitative, or otherwise problematic, transactions that are mutually advantageous and consensual, so long as the transaction has no negative effects on others.¹⁵⁴ Importantly, the exploited party could still “reasonably refuse to participate in the transaction”—the question is whether the state should intervene.¹⁵⁵ This “presumption” is called the “principle of permissible exploitation (PPE).”¹⁵⁶ Wertheimer reasons, in part, that the PPE may be defensible as “a plausible principle of *nonideal* moral theory.”¹⁵⁷ In other words, unjust background conditions do exist and people have to make decisions in this unjust context. There should be a presumption that allows parties under these conditions to better their circumstances without state intervention, even though the terms of the transaction are unfair.¹⁵⁸

As the preceding discussion suggests, determining whether a practice is impermissibly exploitative can be complex and imprecise. However, the basic analysis should involve at least three components: (1) the adequacy of the consent, (2) the harms, and (3) the benefits. Accordingly, in Part IV, we evaluate the extent to which 23andMe and Ancestry’s various privacy policies can serve as an adequate consent for consumers, and the privacy harms and risks of the transaction to consumers as compared to the benefits to both the companies and consumers. Importantly, we want to emphasize that the use of DTC-GT services does not have to be harmless to be permissible from an all-things-considered perspective. Rather, it is the relationship between the various factors—consent, harms, and benefits—

149. *Id.*

150. *Id.* at 76.

151. *Id.* at 78.

152. *Id.* at 78–79.

153. *Id.* at 78.

154. *Id.* at 78–84.

155. *Id.* at 83.

156. *Id.* (emphasis omitted).

157. *Id.* at 84.

158. *Id.* at 83.

that determines the permissibility of these services. Because there are significant gaps in the legal system's ability to properly regulate DTC-GT companies,¹⁵⁹ the following normative analysis should help clarify what the primary concerns are and how the law can mitigate these concerns. Before providing an exploitation-based analysis of the policies and practices of 23andMe and Ancestry, we provide an account of why genetic privacy might require additional attention.

B. Genetic Exceptionalism and Genetic Privacy

The view known as “genetic exceptionalism” is “the claim that genetic information is sufficiently different from other kinds of health-related information that it deserves special protection or other exceptional measures.”¹⁶⁰ While genetic exceptionalism has its supporters,¹⁶¹ many have argued against this view, claiming that genetic information is neither unique nor sufficiently different from other kinds of medical information.¹⁶² However, several important features of genetic information strongly support genetic exceptionalism: familial nature, predictive ability, function as a unique identifier, stability and immutability, and potential for discrimination and stigmatization based on genetic information.¹⁶³

First, genetic information reveals inherently shared information between genetically related family members. Of course, other medical information often has a familial nature. For example, infectious diseases such as tuberculosis and sexually transmitted infections (STIs) can be transmitted between family members living together.¹⁶⁴ However, while tuberculosis in an individual suggests the mere possibility of an uncertain rate that family members might share the disease only if they were in contact or

159. See *supra* Part I.

160. Thomas H. Murray, *Genetic Exceptionalism and “Future Diaries”: Is Genetic Information Different from Other Medical Information?*, in *GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA* 60, 61 (Mark A. Rothstein ed., 1997). A stronger form of genetic exceptionalism was proposed by the authors of a model Genetic Privacy Act stating that “genetic information is uniquely powerful and uniquely personal, and thus merits unique privacy protection.” George J. Annas, Leonard H. Glantz & Patricia A. Roche, *Drafting the Genetic Privacy Act: Science, Policy, and Practical Considerations*, 23 *J.L. MED. & ETHICS* 360, 365 (1995).

161. See, e.g., Ronald M. Green & A. Mathew Thomas, *DNA: Five Distinguishing Features for Policy Analysis*, 11 *HARV. J.L. & TECH.* 571, 572–87 (1998) (arguing that genetic information is different from other medical information based on five quantitative and qualitative features including informational risks, longevity of DNA, DNA as an identifier, familial risks, and community impacts).

162. See, e.g., Murray, *supra* note 160, at 67–72; Lawrence O. Gostin & James G. Hodge, Jr., *Genetic Privacy and the Law: An End to Genetics Exceptionalism*, 40 *JURIMETRICS* 21, 31–36 (1999).

163. See Annas, Glantz & Roche, *supra* note 160, at 362; Lawrence O. Gostin, *Genetic Privacy*, 23 *J.L. MED. & ETHICS* 320, 324 (1995).

164. Murray, *supra* note 160, at 65.

cohabited,¹⁶⁵ the shared nature of genes—excluding spontaneous mutations—is absolute and mathematically predictable: one inherits half of each biological parent’s genes, shares at least a quarter of genetic material with one’s biological siblings, and so forth. The familial nature of genes also extends to relatives that one might have never encountered or lived with.¹⁶⁶ This certainty of the shared nature of genetic information has inspired debates about whether an index patient with the primary genetic information has a duty to inform the family about the genetic information that also pertains to them and whether the family members can claim a right to know (or not know).¹⁶⁷ It has also led to a proposal for the “joint account” model of genetic information¹⁶⁸ and recommendations for “cascade genetic testing” for family members in genetic diseases.¹⁶⁹

The second notable characteristic is the ability of genetic information to provide predictive information regarding an individual’s disease and health. This feature of genetic information becomes powerful when combined with its immutable nature. While results from most medical tests change over time, genome sequencing is a one-shot test with a raw result that remains constant over an individual’s lifetime.¹⁷⁰ In addition, compared to other medical information, genetic information provides a myriad of information regarding one’s disease potential and phenotypes in the future—thus, “such a massive prospective difference in quantity effectively makes a qualitative difference.”¹⁷¹ This aspect of genetic information is often captured by the “future diary” metaphor.¹⁷² Of course, such metaphors must be treated with

165. *Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC*, CDC (Dec. 16, 2005), <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5415a1.htm> [<https://perma.cc/FRN2-TW6T>] (“The likelihood of infection depends on the intensity, frequency, and duration of exposure.”)

166. For example, in a recent English case, *ABC v. St George’s Healthcare NHS Trust* [2017] EWCA (Civ) 336 (Eng.), the plaintiff’s father, who had killed her mother and was detained for conviction of manslaughter on the grounds of diminished responsibility, was diagnosed with Huntington’s disease, which is a genetic disease. Later, the plaintiff, now with a daughter of her own, learned of her father’s diagnosis and that she herself was also diagnosed with Huntington’s. The plaintiff claimed that had she been informed of the diagnosis, she would have tested prior to giving birth and would have opted for abortion. *Id.* at [4]–[15].

167. See, e.g., Ruth Chadwick, Mairi Levitt & Darren Shickle, *The Right To Know and the Right Not To Know: The Emerging Debate*, in *THE RIGHT TO KNOW AND THE RIGHT NOT TO KNOW: GENETIC PRIVACY AND RESPONSIBILITY* 13, 19–21 (Ruth Chadwick, Mairi Levitt & Darren Shickle eds., Cambridge Univ. Press 2d ed. 2014).

168. Michael Parker & Anneke Lucassen, *Genetic Information: A Joint Account?*, 329 *BMJ* 165, 166 (2004).

169. See, e.g., Amy C. Sturm et al., *Clinical Genetic Testing for Familial Hypercholesterolemia*, 72 *J. AM. C. CARDIOLOGY* 662, 669–70 (2018).

170. We acknowledge that this is a generalized statement and somatic mutations, especially in cancer, do occur through life. See Sian Jones et al., *Personalized Genomic Analyses for Cancer Mutation Discovery and Interpretation*, 283 *SCI. TRANSLATIONAL MED.*, Apr. 15, 2015, <http://stm.sciencemag.org/content/scitransmed/7/283/283ra53.full.pdf> [<https://perma.cc/D3D2-F3ZS>].

171. Murray, *supra* note 160, at 65.

172. Annas, Glantz & Roche, *supra* note 160, at 360.

caution given their potential to promote “genetic determinism” or “genetic prophecy.”¹⁷³ With advances in genomic science and medicine, most diseases with a genetic basis are found to be multifactorial with multiple genes contributing in varying degrees with varying penetrance.¹⁷⁴

Third, genetic information can be used to identify an individual. Combined with the stable and immutable nature, this feature is one that is wholly unique to genetic information. The recent arrest of the suspected Golden State Killer based on DNA evidence more than thirty years after his crimes has demonstrated the power of genetic information.¹⁷⁵ Moreover, studies have demonstrated that surnames can be recovered from de-identified genome sequences available on public databases and that surname, in combination with other metadata such as age and state, can be used to identify the individual¹⁷⁶ and that genetic information can be used to computationally predict a three-dimensional model of an individual’s face.¹⁷⁷

Finally, genetic information can be used to stigmatize or discriminate against people. Indeed, it could be argued that the enactment of GINA and genetic nondiscrimination laws in health insurance and/or employment in forty-eight states demonstrates our society’s acceptance of genetic exceptionalism, especially based on this potential for genetic discrimination.¹⁷⁸

Two additional aspects of genetic information—incidental findings and variability—which are not discussed in earlier works on genetic exceptionalism, further support the special nature of genetic information. Genetic test results often harbor incidental findings (IFs).¹⁷⁹ IFs can occur in whole genome sequencing (WGS) or gene panels rather than traditional single gene tests.¹⁸⁰ While a WGS (or a large-scale genetic test) is initially performed to find variants associated with specific symptoms or a potential diagnosis, the sequencing may find unexpected variants associated with

173. See Murray, *supra* note 160, at 62, 67.

174. See, e.g., Judy H. Cho & Peter K. Gregersen, *Genomics and the Multifactorial Nature of Human Autoimmune Disease*, 365 *NEW ENG. J. MED.* 1612 (2011).

175. Megan Molteni, *The Future of Crime-Fighting is Family Tree Forensics*, *WIRED* (Dec. 26, 2018, 8:00 AM), <https://www.wired.com/story/the-future-of-crime-fighting-is-family-tree-forensics/> [https://perma.cc/HT82-2NCY].

176. Melissa Gymrek et al., *Identifying Personal Genomes by Surname Inference*, 339 *SCIENCE* 321, 321–24 (2013).

177. Peter Claes et al., *Modeling 3D Facial Shape from DNA*, 10 *PLOS GENETICS*, Mar. 2014, at 1, 2.

178. See AMANDA K. SARATA, CONG. RESEARCH SERV., RL34376, *GENETIC EXCEPTIONALISM: GENETIC INFORMATION AND PUBLIC POLICY* 6 (2011).

179. Robert C. Green et al., *ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing*, 15 *GENETICS MED.* 565, 565 (2013).

180. *Id.*

other conditions.¹⁸¹ Again, however, IFs are not unique to genetic testing. Several other medical tests share this characteristic such as the physical exam (one of the most traditional medical tests, ironically) and radiological tests.¹⁸² For example, a routine physical exam might find an unusual mole that turns out to be a skin carcinoma, or a chest X-ray to diagnose pneumonia might show an unexpected mass in the lung later determined as lung cancer. However, the key difference between these IFs and IFs in genetic tests is that while IFs from a physical exam or radiology are initial suggestions of a potential abnormality with clear next steps for further diagnosis, IFs in genetics often have no effective treatment or have unclear clinical significance thereby raising disagreements about the appropriate next steps.¹⁸³ This fact inspires the debate on whether one's right not to know IFs can (or should) be protected.¹⁸⁴

Genetic information shows variability both between tests and with time. Raw data from an initial genetic test is not interpretable by any human being. Only after analysis through computational methods does the data start to adopt a form that is understandable, albeit only to trained bioinformaticians and genetics researchers. Interpretation of data, especially to reach a form understandable by patients, requires many steps including genotype-phenotype correlation and a proper understanding of causality involving multiple factors aided by Bayesian analysis.¹⁸⁵ Analysis of WGS is still in flux in that there are multiple analysis programs that are being used and no standard of practice exists.¹⁸⁶ In fact, there have been reports where 23andMe and Ancestry have provided completely differing results to a consumer.¹⁸⁷ Also, there is a temporal dimension of variability in genetic information. That is, the significance of information can change in light of new scientific or clinical findings. Genetics is a rapidly evolving field, and information from current data is being fed to generate more information about particular genotypes and mutations and, subsequently, phenotypes

181. *Id.* at 572.

182. *Incidental Findings*, AM. COLL. OF RADIOLOGY, <https://www.acr.org/Clinical-Resources/Incidental-Findings> [<https://perma.cc/DT6R-L43X>].

183. Bartha Maria Knoppers, Ma'n H. Zawati & Karine Sénécal, *Return of Genetic Testing Results in the Era of Whole-Genome Sequencing*, 16 NATURE REVS. GENETICS 553 (2015).

184. See, e.g., Graeme Laurie, *Recognizing the Right Not to Know: Conceptual, Professional, and Legal Implications*, 42 J.L. MED. & ETHICS 53 (2014).

185. Anthony J. Brookes & Peter N. Robinson, *Human Genotype-Phenotype Databases: Aims, Challenges and Opportunities*, 16 NATURE REVS. GENETICS 702, 706–10 (2015).

186. Anton Nekrutenko & James Taylor, *Next-Generation Sequencing Data Interpretation: Enhancing Reproducibility and Accessibility*, 13 NATURE REVS. GENETICS 667, 667–68 (2012).

187. See, e.g., Laura Hercher, *23andMe Said He Would Lose His Mind. Ancestry Said the Opposite. Which Was Right?*, N.Y. TIMES (Sept. 15, 2018), <https://www.nytimes.com/2018/09/15/opinion/sunday/23andme-ancestry-alzheimers-genetic-testing.html> [<https://perma.cc/ZP9F-QWM4>].

and pathogenicity. A variant of unknown significance (VUS) might later be found to be pathogenic as we learn more about the genome.¹⁸⁸

Thus, while opponents of genetic exceptionalism argue that the features of genetic information are not unique or are not sufficient to warrant special treatment of genetic information, we believe the preceding arguments support the notion of genetic exceptionalism. Notably, Professor Mark Rothstein has been especially critical of genetic exceptionalism, arguing that it is difficult to clearly define genetic information and separate genetic information from nongenetic information.¹⁸⁹ Yet such arguments appear to conflate certain practical challenges with the conceptual argument for genetic exceptionalism. Moreover, these practical barriers can be overcome with the use of the electronic health record¹⁹⁰ and the adoption of a narrow definition of genetic information in genetic-specific statutes.¹⁹¹ Therefore, while genetic information shares many characteristics with health information in general, the additional characteristics and related concerns likely provide sufficient support for genetic exceptionalism and warrant a more careful analysis and discussion of genetic privacy.

C. Defining Risk and Harm

In the context of DTC-GT, “genetic privacy” can be defined as the notion “that everyone should enjoy protection of his or her genetic information from unauthorized collection, processing, use and distribution, and that certain uses of genomic data must be forbidden because they impact data subjects in ways that are considered unjust, unfair, or outright discriminatory.”¹⁹² As this definition suggests, the collection, storage, use, and transfer of data poses a number of important risks to individual consumers when they use DTC-GT services. Evaluating risk involves a three-part analysis: (1) defining the kind of harm, (2) determining the magnitude of that harm, and (3) empirically assessing the likelihood that the harm will occur.¹⁹³

A common definition of harm is philosopher Joel Feinberg’s notion that harm “is a set-back to a legitimate interest.”¹⁹⁴ A person is harmed “if they

188. Euan A. Ashley et al., *Clinical Assessment Incorporating a Personal Genome*, 375 LANCET 1525, 1534 (2010); Jae Yeon Cheon, Jessica Mozersky & Robert Cook-Deegan, *Variants of Uncertain Significance in BRCA: A Harbinger of Ethical and Policy Issues to Come?*, 6 GENOME MED. 121 (2014).

189. Mark A. Rothstein, *Genetic Exceptionalism and Legislative Pragmatism*, 35 J.L. MED. & ETHICS 59, 60–61 (2007); see also Gostin & Hodge, *supra* note 162, at 32–33.

190. Rothstein, *supra* note 189, at 61.

191. See, e.g., 42 U.S.C. § 2000ff(4) (2018).

192. Haeusermann et al., *supra* note 126, at 208.

193. Rid et al., *supra* note 24, at 1472–73.

194. Claire Finkelstein, *Is Risk a Harm?*, 151 U. PA. L. REV. 963, 971 (2003) (citing JOEL FEINBERG, HARM TO OTHERS 34–38 (1984)).

are in worse shape than they would be in had the activity not occurred.”¹⁹⁵ For a harm to be legally cognizable, the law must recognize that the harm is “worthy of redress, deterrence, or punishment.”¹⁹⁶

In the field of privacy law, harm is defined in many ways. Among those, three leading frameworks are notable. First, Professor Ryan Calo divides privacy harms into two categories—subjective and objective harms.¹⁹⁷ A subjective privacy harm “is the perception of unwanted observation,” where “observation” encompasses information revealed, either directly or by inference, from a data breach.¹⁹⁸ In the health context, anxiety, embarrassment, or stigma are examples of subjective privacy harms.¹⁹⁹ Importantly, subjective privacy harms have real implications for an individual’s health. Pervasive stigma, for example, serves as a crucial barrier to quelling the HIV epidemic because patients’ lack of trust in the healthcare system encourages them to forego care.²⁰⁰ HIV aside, health data breaches may also undermine an individual’s trust in the health care system in general, and they may therefore avoid treatment or lie about or withhold health information resulting in inappropriate or inadequate treatment.²⁰¹ Importantly, many patients, not just the victims of a data breach, have withheld health information from care providers because of privacy concerns.²⁰²

Objective privacy harms, on the other hand, are those “that are external to the victim and involve the forced or unanticipated use of personal information.”²⁰³ For example, in a recent Ninth Circuit genetic discrimination case, *Chadam v. Palo Alto Unified School District*,²⁰⁴ the unauthorized disclosure of a student’s genetic information, and subsequent

195. Daniel J. Solove & Danielle Keats Citron, *Risk and Anxiety: A Theory of Data-Breach Harms*, 96 TEX. L. REV. 737, 747 (2018).

196. *Id.*

197. M. Ryan Calo, *The Boundaries of Privacy Harm*, 86 IND. L.J. 1131, 1142–43 (2011).

198. *Id.* at 1144.

199. *Id.* See also NAT’L ACAD. OF SCI., BEYOND THE HIPAA PRIVACY RULE: ENHANCING PRIVACY, IMPROVING HEALTH THROUGH RESEARCH 77 (Sharyl J. Nass et al. eds., 2009) (“When personally identifiable health information, for example, is disclosed to an employer, insurer, or family member, it can result in stigma, embarrassment, and discrimination. Thus, without some assurance of privacy, people may be reluctant to provide candid and complete disclosures of sensitive information even to their physicians. Ensuring privacy can promote more effective communication between physician and patient, which is essential for quality of care, enhanced autonomy, and preventing economic harm, embarrassment, and discrimination.”).

200. Anish P. Mahajan et al., *Stigma in the HIV/AIDS Epidemic: A Review of the Literature and Recommendations for the Way Forward*, 22 AIDS (SUPPLEMENT 2) 67, 67 (2008).

201. Deven McGraw & Alice Leiter, *Risk-Based Regulation of Clinical Health Data Analytics*, 12 COLO. TECH. L.J. 427, 432 (2014).

202. *Id.*

203. Calo, *supra* note 197, at 1148.

204. 666 F. App’x 615 (2016).

inaccurate perceptions of that information, led to him being moved to another middle school.²⁰⁵

Second, Professors Daniel J. Solove and Woodrow Hartzog derive several categories of harms by analyzing enforcement actions brought by the FTC under Section 5 for unfair or deceptive trade practices.²⁰⁶ Because the vast majority of enforcement actions brought by the FTC have resulted in settlement agreements, there are very few court opinions defining the rules and norms for company privacy policies.²⁰⁷ However, companies do rely on the FTC settlements as a sort of common law defining, or at least guiding, company information privacy obligations.²⁰⁸ For deception claims, four categories of harms emerged: (1) broken promises of privacy, (2) general deception, (3) insufficient notice, and (4) data security.²⁰⁹ For unfairness claims brought by the FTC, there were five categories of harms: (1) retroactive changes, (2) deceitful data collection, (3) improper use of data, (4) unfair design or unfair default settings, and (5) unfair data security practices.²¹⁰

And finally, Professor Joel R. Reidenberg and colleagues derived several categories of privacy harms by conducting a more comprehensive analysis including FTC enforcement actions as well as “all federal class action complaints alleging online privacy violations filed” over an almost fifteen-year period.²¹¹ Based on this data, the most common privacy harms were (1) unauthorized disclosure of personal information, (2) surreptitious collection of personal information, (3) failure to secure personal information, and (4) unlawful retention of personal information.²¹² Reidenberg and colleagues then explain that while the notice and choice framework is the most common for managing consumer privacy, there are limits to the effectiveness of notice and choice to manage or mitigate the privacy harms consumers experience.²¹³ So long as notices are “complete, understandable for users, accurate, and specific” and “accompanied by meaningful choice,” this model is most helpful for unauthorized disclosure, surreptitious collection, and, to some extent, improper retention.²¹⁴ They argue, however, that notice and choice cannot protect consumers against inadequate data

205. *Id.* at 616.

206. Solove & Hartzog, *supra* note 26, at 628.

207. *Id.* at 611.

208. *Id.* at 625.

209. *Id.* at 628–38.

210. *Id.* at 638–43.

211. Joel R. Reidenberg et al., *Privacy Harms and the Effectiveness of the Notice and Choice Framework*, 11 *I/S: J.L. & POL'Y FOR INFO. SOC'Y* 485, 497 (2015).

212. *Id.* at 512.

213. *Id.* at 518.

214. *Id.*

security practices, deception (i.e., acting contrary to a privacy policy), and other instances of the wrongful retention of data.²¹⁵

While these frameworks provide an important conceptual model for evaluating privacy harms, they do not provide a complete account for the unique privacy harms posed by DTC-GT services. Therefore, we propose three categories of privacy harms of DTC-GT for the purpose of our analysis: (1) knowledge harms, (2) autonomy and trust-based harms, and (3) the harms of data misuse.

Knowledge harms, although acknowledged or implied by the bioethics literature in some form,²¹⁶ are unaccounted for by the extant frameworks in privacy law and include the harms associated with receiving health information (e.g., in the form of test results), expected or unexpected, that is troubling, inaccurate, or misleading. To the extent the information is sufficiently accurate, it is irrevocable—that is, one cannot unknow the information. For example, ancestry testing may reveal unexpected information about a family's ethnicity, country of origin, or paternity and maternity.²¹⁷ This information may be welcome to many consumers but may also cause significant distress, strain family relations, or undermine someone's self-identity.²¹⁸ Or a consumer might unexpectedly find out they have a significant risk of developing a disease later in life.²¹⁹ Alternatively, the test results may reveal expected information, but individuals may feel very differently about the information than originally anticipated. At the core of this privacy harm is losing control over the nature and impact of the information. Importantly, because genetic information is familial and hereditary, knowledge harms also include potential implications for genetically related family members who, in many instances, may not have even agreed to or been informed of the testing.

Additionally, knowledge harms include the often drastic steps people may take to minimize their risk of disease. For example, after finding that she had an 87% chance of getting breast cancer, Angelina Jolie underwent a double mastectomy.²²⁰ In addition, individuals may choose to forgo

215. *Id.* at 520–23.

216. *See, e.g.*, Laestadius, *supra* note 21, at 518.

217. *See, e.g.*, *Privacy Highlights*, 23ANDME, <https://www.23andme.com/about/privacy/> [<https://perma.cc/R747-KVPY>]; George Doe, *With genetic testing, I gave my parents the gift of divorce*, VOX (Sept. 9, 2014), <https://www.vox.com/2014/9/9/5975653/with-genetic-testing-i-gave-my-parents-the-gift-of-divorce-23andme>; Cara Rose DeFabio, *If you're black, DNA ancestry results can reveal an awkward truth*, SPLINTER (Sept. 29, 2016), <https://splinternews.com/if-you-re-black-dna-ancestry-results-can-reveal-an-awk-1793862284>; Libby Copeland, *Who was she? A DNA test only opened new mysteries*, WASH. POST (July 27, 2017), https://www.washingtonpost.com/graphics/2017/lifestyle/she-thought-she-was-irish-until-a-dna-test-opened-a-100-year-old-mystery/?utm_term=.e3126e929f61.

218. *Id.* *See also*, Phillips, *supra* note 19, at 18.

219. *See* text accompanying *supra* notes 179–184.

220. Angelina Jolie, *My Medical Choice*, N.Y. TIMES (May 14, 2013), <https://www.nytimes.com/2013/05/14/opinion/my-medical-choice.html> [<https://perma.cc/7TCV-SC8A>].

having children because of their carrier status test results. Such choices and actions can be problematic given that the information returned to consumers may be inaccurate, misunderstood, or incomplete. Inaccurate results include both false positives—the test incorrectly finds a genetic variant that is not actually present—and false negatives—the test does not find a genetic variant that is actually present. Because 23andMe and Ancestry offer services that are direct-to-consumer, they do not, by definition, have an expert intermediary to evaluate and explain results. Thus, it is easy for consumers to misinterpret results by not considering or taking seriously non-genetic factors like lifestyle. Consumers may also not realize that other genetic variants not accounted for in the test results play an important role in health outcomes. These potential inaccuracies or misunderstandings may cause consumers to experience unnecessary stress over test results, obtain unnecessary healthcare,²²¹ or miss a critical opportunity to prevent or manage future illness.

By contrast, autonomy and trust-based harms are the focus of a large literature and encompass concerns regarding notice and choice.²²² Autonomy and trust are the central principles at stake when consumers cannot adequately consent to the collection and use of their private information or companies disclose or use information in unauthorized ways. Although there is disagreement on the precise definition of autonomy, autonomy can roughly be described as the notion that individuals should have the right to control what happens to their information and bodies without “controlling interference by others.”²²³ Trust can be defined as “the ‘favourable expectation regarding other people’s actions and intentions,’ or the belief that others will behave in a predictable manner.”²²⁴ Proper consent allows consumers to make decisions consistent with their values and, to some degree, protect their own welfare, but it also promotes trust between consumers and companies.

Finally, data misuse harms include data breaches, which are a kind of data misuse; the unauthorized reidentification of otherwise deidentified data sets; or other consequences of unauthorized data use. These harms can encompass both the subjective and objective harms of the Calo framework, for example, anxiety following a data breach (subjective) or genetic

221. See McGuire & Burke, *supra* note 133, at 2671.

222. See, e.g., Christina R. Lachance et al., *Informational Content, Literacy Demands, and Usability of Websites Offering Health-Related Genetic Tests Directly to Consumers*, 12 GENETICS MED. 304 (2010).

223. See, e.g., TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 58 (5th ed. 2001).

224. ARI EZRA WALDMAN, PRIVACY AS TRUST: INFORMATION PRIVACY FOR AN INFORMATION AGE 7 (2018) (quoting Guido Möllering, *The Nature of Trust: From Georg Simmel to a Theory of Expectation, Interpretation and Suspension*, 35 SOCIOLOGY 403, 404 (2001)).

discrimination (objective). A data breach occurs when personal information, stored electronically or otherwise,²²⁵ is lost, stolen, or otherwise accessed without proper authorization.²²⁶ Following a data breach of, for example, a bank, retailer, or consumer reporting agency, critical personal information, including a social security number, name, and address, may be revealed about a victim. This information is certainly sensitive and may subject data breach victims to identity theft or an increased risk of identity theft, anxiety over the potential misuse of their private information, and identity theft mitigation costs.²²⁷ Identity theft occurs when someone's personal information is used for fraudulent purposes, including, for example, unauthorized credit card purchases or taking out a loan.²²⁸

The magnitude of harm in the privacy context may be difficult to precisely define because, for example, social norms change over time or new laws are enacted to protect people against various forms of discrimination. However, based on the preceding discussion on genetic exceptionalism, we can see that the magnitude of genetic privacy harms may be quite significant because, for example, genetic information serves as a unique identifier, it implicates third parties, and it cannot be replaced. Consumers may also make consequential medical decisions based on both accurate or inaccurate information or may choose to forgo having children because of carrier test results. Finally, as we explained in Section III.B, the value of genetic information changes over time as we learn more about the predictive power of the genome. So not only does genetic information currently contain a significant volume of consequential information about you and your family, but the volume and utility of that information will only grow over time.

Accordingly, we can see that the magnitude of a genetic privacy harm can be quite significant. But how likely are these harms to occur? Given the wide variety of potential genetic privacy harms, we need more data on the likelihood that certain harms will occur. However, data breaches involving health data are growing in frequency and account for forty percent of data breaches.²²⁹ In 2013, almost sixty-three percent of data breaches involved

225. See, e.g., *Beck v. McDonald*, 848 F.3d 262 (4th Cir. 2017) (combined appeal where one case involved the theft of a computer containing personal health information and the other case involved the potential theft of paper pathology reports).

226. Claire Wilka, Note, *The Effects of Clapper v. Amnesty International USA: An Improper Tightening of the Requirement for Article III Standing in Medical Data Breach Litigation*, 49 CREIGHTON L. REV. 467, 477 (2016).

227. See Solove & Citron, *supra* note 195, at 747–50.

228. Wilka, *supra* note 226, at 477.

229. Lucy L. Thomson, *Health Care Data Breaches and Information Security: Addressing Threats and Risks to Patient Data*, in HEALTH CARE IT: THE ESSENTIAL LAWYER'S GUIDE TO HEALTH CARE INFORMATION TECHNOLOGY AND THE LAW 253, 253 (Arthur Peabody, Jr. ed., 2014).

patient medical records.²³⁰ A 2012 report from the Ponemon Institute found that more health care organizations are having multiple breaches and negligence continues to be at the root of many data breaches.²³¹ Furthermore, the data breaches are expensive, costing the organizations participating in their study \$2.4 million over a two-year period.²³² Thomson explains that many health data breaches are the result of poor security practices. For example, “more than one-third of data breaches resulted from the theft or loss of laptops, computers, hard drives, backup tapes, PDAs, or other portable media containing unencrypted personal information.”²³³ Health data breaches also result from insider attacks, hackers, inadvertent postings on websites, or other disclosures, like when medical records were dumped on a sidewalk or found in a dumpster.²³⁴

In addition, as we noted in Section I.A, the EEOC has received over 200 charges per year filed under GINA since 2010. This may be a relatively low number of discrimination claims, but this serves as a useful indicator that genetic discrimination is happening with some regularity. The likelihood of harm may also increase, for example, as we learn more about the genome, it becomes easier to de-identify anonymized datasets, or the risks of data breaches grow. All of these risk considerations weigh in favor of more comprehensive and substantial legal reforms.

IV. ANALYSIS OF 23ANDME AND ANCESTRY POLICIES AND PRACTICES

In this Part, we will assess to what extent 23andMe and Ancestry protect against the privacy risks discussed in Part III through a combination of their consent and data management practices. The primary goal, in our view, is to minimize the exploitation of consumers. Because both 23andMe and Ancestry amass a significant amount of private information when consumers use their services, there are, as already explained, important risks to using their services. However, consumers can take on risk—we allow people to purchase and drive cars, fly, or skydive. The issue, again, is whether there is a fair distribution of benefits.

A. The Adequacy of 23andMe’s Privacy Policies

As explained in Part III.B, exploitative transactions may be either consensual or nonconsensual, but consent matters because the lack of consent may be probative of a harmful transaction or make a transaction

230. *Id.*

231. *Id.* at 255.

232. *Id.*

233. *Id.*

234. *Id.* at 260.

otherwise unethical even if the transaction is nonexploitative. Worries about consent generally encompass concerns about voluntariness, the adequacy of the information provided, and the competence of the party tokening consent.²³⁵

23andMe provides information to consumers about their privacy practices and the risks of their services in a number of different pages throughout their website. There is a clear effort to provide much of this information in an accessible format in addition to a more comprehensive privacy policy²³⁶ and terms of service.²³⁷ For example, on the “What Unexpected Things Might I Learn From 23andMe?” page, a helpful overview is given of the kinds genetic information returned to consumers, including information about health, ancestry, family, and relationships.²³⁸ The site encourages consumers to obtain genetic counseling and addresses many of the knowledge harms explained above. In addition, the full privacy policy begins with a relatively short “Privacy Highlights” section that gives an overview of the information collected, how that information is used, the extent to which consumers can control how their data is used, who has access to consumer data, data security practices, and the risks of using their services. And finally, the research consent document provides a helpful “Key Points” section prior to the more detailed consent document.²³⁹ This section explains, for example, what information is used, who gets to see that information, and the risks and benefits of participating in their research activities.

In addition to the main privacy and consent documents, the 23andMe health reports returned to consumers attempt to provide test results in an accessible and properly qualified format. For example, in the Alzheimer’s Disease sample report, consumers are provided helpful background information about Alzheimer’s, the purpose of the genetic test, the limitations of the test, and information about other factors that contribute to Alzheimer’s.²⁴⁰ A similar format is used to provide information about “Genetic Weight” test results as part of 23andMe’s wellness services.²⁴¹

235. Wertheimer, *supra* note 137, at at 75–77.

236. *Privacy Highlights*, 23ANDME, *supra* note 217.

237. *Terms of Service*, 23ANDME, <https://www.23andme.com/about/tos/> [<https://perma.cc/FQ4N-NG7C>].

238. *What Unexpected Things Might I Learn from 23andMe?*, 23ANDME, <https://customer-care.23andme.com/hc/en-us/articles/202907980-What-unexpected-things-might-I-learn-from-23andMe-> [<https://perma.cc/3D7C-W789>].

239. *Research Consent Document*, 23ANDME, <https://www.23andme.com/about/consent/> [<https://perma.cc/J4ED-RWB2>].

240. *Sample Report: Late-Onset Alzheimer’s Disease*, 23ANDME, https://permalinks.23andme.com/pdf/samplerreport_genetichealth.pdf [<https://perma.cc/7XF4-CUGH>].

241. *Sample Report: Genetic Weight*, 23ANDME, https://permalinks.23andme.com/pdf/samplerreport_wellness.pdf [<https://perma.cc/GY2S-9PNP>].

Despite these attempts to aid consumer comprehension, however, it is unlikely these documents allow consumers to make sufficiently informed decisions. There are at least five separate pages on the 23andMe site that provide critical privacy information—“What Unexpected Things Might I Learn From 23andMe,” the terms of service, the privacy policy, the research consent document, and the biobanking consent document. The privacy policy, terms of service, and the full research consent form are long, complex, and difficult to understand and amount to roughly fifty printed pages of reading. A 2010 study of the readability of DTC-GT websites found that the average reading level required was “grade 15.”²⁴² It is well-known that consumers generally do not read privacy policies or terms of service.²⁴³ It is also essentially impossible for consumers to spend the time reading all the terms of service documents they might be presented with even if they wanted.²⁴⁴ However, given that this is not a normal consumer transaction, consumers may be more motivated to actually read these privacy policies before agreeing to the service, but this is unclear. But even if consumers do read the policies, it’s difficult to see how they could come away with a sufficient understanding of the risks and benefits of using this service.

For example, while the page on unexpected results provides a helpful overview of the potential knowledge harms, the most comprehensive explanation of the risks is provided in the terms of service. The discussion of risk provided in the terms of service is well-organized and offers a more detailed risk discussion than anywhere else on the 23andMe website. The problem is that the terms of service, like those of any other website, are long and technical and consumers are, again, unlikely to understand or even read the terms of service. This makes sense, however, because some research shows that consumers become less interested in DTC-GT services when they are provided with more risk information.²⁴⁵

Given that 23andMe’s Health Predispositions tests report predisposition to specific diseases, there is greater risk of knowledge harms especially when consumers misinterpret the results. For example, 23andMe’s BRCA1/BRCA2 test only looks at three BRCA variants that are most common in the Ashkenazi Jewish population and not in other ethnicities while there are more than 1,000 BRCA variants associated with risk of

242. Lachance, *supra* note 222, at 310.

243. See, e.g., Aaron Perzanowski & Chris Jay Hoofnagle, *What We Buy When We Buy Now*, 165 U. PA. L. REV. 315, 320 (2017) (“The overwhelming majority of online shoppers ignore license terms.”).

244. Alexis C. Madrigal, *Reading the Privacy Policies You Encounter in a Year Would Take 76 Work Days*, ATLANTIC (Mar. 1, 2012), <https://www.theatlantic.com/technology/archive/2012/03/reading-the-privacy-policies-you-encounter-in-a-year-would-take-76-work-days/253851/> [<https://perma.cc/93FW-EEPA>].

245. Laestadius, *supra* note 21, at 518.

breast and ovarian cancer.²⁴⁶ While 23andMe's website presents this information clearly and, in fact, emphasizes it,²⁴⁷ it is still possible that a consumer with a "negative" 23andMe BRCA report might misconstrue the result and believe that she will not get breast cancer. In addition, the polygenic score for type 2 diabetes is another test that is vulnerable to misinterpretation. While 23andMe clearly states that the test "does not diagnose type 2 diabetes or prediabetes and should not be used to make medical decisions[.]"²⁴⁸ experts have questioned the value of the genetic predisposition information for type 2 diabetes and emphasized the potential for misinterpretation based on one's ethnicity given that 23andMe's polygenic score is based on its own database which is largely people of European ancestry.²⁴⁹

Ambiguous language in the privacy policies might constitute additional autonomy and trust-based harms. For example, if a consumer does not consent to 23andMe Research,²⁵⁰ 23andMe provides that:

If you choose not to complete a Consent Document or any additional agreement with 23andMe, your *Personal Information* will not be used for 23andMe Research. However, your *Genetic Information* and *Self-Reported Information* may still be used by us and shared with our third party service providers to as outlined in this Privacy Statement.²⁵¹

While a consumer is likely to assume that no consent means no personal information—including genetic information and any self-reported information—would be used for additional research, 23andMe somehow differentiates "personal information" from "genetic information," and "self-reported information" in this context. However, under its definition of terms, both genetic information and self-reported information are sub-types of "personal information" alongside with "registration information," "sensitive information," "user content," and "web-behavior information."²⁵² Thus, 23andMe's privacy policy appears to contradict itself and thereby provides inadequate notice to consumers.

246. *BRCA*, 23ANDME, <https://www.23andme.com/brca/>.

247. *Id.*

248. *Type 2 Diabetes*, 23ANDME, <https://www.23andme.com/topics/health-predispositions/type-2-diabetes/>.

249. Antonio Regalado, *23andMe thinks polygenic risk scores are ready for the masses, but experts aren't so sure*, MIT TECH. REV. (Mar. 8, 2019), <https://www.technologyreview.com/s/613095/23andme-thinks-polygenic-risk-scores-are-ready-for-the-masses-but-experts-arent-so-sure/>.

250. *Privacy Highlights*, 23ANDME, *supra* note 217 ("3.d. . . . What happens if you do NOT consent to 23andMe Research?").

251. *Id.* (emphasis added).

252. *Id.* ("1.4. Personal Information").

Also, it is unclear from these documents which test results are, in some sense, accurate and what that means for consumers when they are interpreting their results—including analytic validity, clinical validity, and clinical utility. For example, although several of their genetic tests are approved by the FDA, ancestry and wellness testing is not. FDA approval for some tests but not others may give other test results an inappropriate amount of legitimacy. Several documents also include disclaimers about the accuracy and utility of the results provided which further undermines the ability of consumers to make informed decisions.²⁵³

B. The Adequacy of Ancestry's Privacy Policies

Similar to the 23andMe website, the Ancestry and AncestryDNA websites attempt, at various points, to provide important privacy information in a clear and accessible manner. For example, there is a brief, but useful, video about how Ancestry protects consumers' private information.²⁵⁴ Ancestry also has a user-friendly privacy center website, emphasizing transparency of data practices, simplicity in their policies, and consumer control over their data. This page also provides several FAQs regarding the data collected, consumer privacy, data security, data sharing, and advertising and cookies.

The Ancestry policies, however, suffer from the same defects as 23andMe. There are several primary privacy documents, including the privacy policy,²⁵⁵ the terms and conditions of service,²⁵⁶ and the informed consent for those who wish to participate in research.²⁵⁷ Like most privacy policies, these documents are long, complex, and difficult to read and understand. Unlike the 23andMe website, Ancestry provides almost no information about the potential risks of using its services. While Ancestry does provide information about its data security practices and how consumer data is kept secure, the only webpage with risk information is the research consent form.²⁵⁸ The consent form helpfully provides a discussion of the risks of a data breach and some of the potential knowledge harms associated with test results. However, not every person that uses Ancestry

253. *What Unexpected Things Might I Learn from 23andMe?*, 23ANDME, *supra* note 238.

254. Ancestry, *AncestryDNA | Your Privacy | Ancestry*, YOUTUBE (May 3, 2018), <https://www.youtube.com/watch?v=WoiD-r5sZ50> (video embedded at <https://www.ancestry.com/dna/>) [<https://perma.cc/9D6S-SM7D>].

255. *Your Privacy*, ANCESTRY, <https://www.ancestry.com/cs/legal/privacystatement> [<https://perma.cc/HX77-LBBF>].

256. *Ancestry Terms and Conditions*, ANCESTRY, <https://www.ancestry.com/cs/legal/termsandconditions> [<https://perma.cc/8CMN-PATL>] (effective June 5, 2018).

257. *AncestryDNA Informed Consent*, ANCESTRY, <https://www.ancestry.com/dna/lp/informedconsent-v4-en> [perma.cc/5YF3-TBL7] (effective July 24, 2018).

258. *Id.*

services will choose to participate in research and read the consent form, and the research consent form only addresses the risks of participating in the research, not necessarily the risks of using Ancestry services more broadly.

In addition, without any FDA-approval or CLIA-certification, there is no additional information on Ancestry's website regarding the validity of its tests, including its ancestry services and various other "Ancestry DNA Traits" like cilantro aversion, freckles, earwax type, bitter sensitivity, and cleft chin.²⁵⁹ Indeed, the Ancestry Terms and Conditions explicitly disclaims the accuracy and reliability of their test results.²⁶⁰ As explained above, if consumers are going to pay for a service and take on the risks associated with sharing private information, especially genetic information, the service provided should offer some discernable benefit.

The misleading nature of the privacy policies of 23andMe and Ancestry do not mean there is *per se* exploitation—there may be a fair distribution of benefits here—but, as explained in Part III.B, the inadequacy of the consent here may be probative of harmful exploitation or otherwise unethical. Additionally, and more importantly for our purposes, problematic privacy policies may subject 23andMe and Ancestry to legal challenges, for example, by the FTC.

C. *The Distribution of Benefits*

As noted above, whether or not a transaction is consensual, the transaction may be (1) harmful and exploitative, (2) mutually advantageous but still exploitative, or (3) sufficiently fair to be nonexploitative. This depends on the distribution of the harms and benefits to consumers and the companies. Accordingly, we first address some of the primary benefits of these transactions to both consumers and companies. Second, we consider some of the primary harms. Third, and finally, we evaluate to what extent the distribution of benefits from these transactions amounts to a fair distribution.

We explained in Part II.B. that there may be a number of benefits to consumers who use 23andMe and Ancestry. In the form of test results, both companies provide ancestry information and genetic traits testing, while 23andMe also provides a number of FDA-approved tests for things like the BRCA mutation or genetic variants associated with Celiac Disease, Parkinson's Disease, or Late-Onset Alzheimer's Disease. A number of obvious benefits may flow from these test results, such as making

259. *DNA, ANCESTRY*, *supra* note 122 (Explore Ancestry DNA Traits tab).

260. *Ancestry Terms and Conditions, ANCESTRY*, *supra* note 256.

appropriate lifestyle changes, beginning early treatment for a disease, clarifying family relationships, or better understanding one's heritage.

However, these benefits, and any others, all hinge on whether the test results provided by 23andMe and Ancestry are sufficiently reliable. Aside from the FDA-approved tests, there is no indication that the other tests provide consumers with sufficiently reliable results. This is not to say that test results must be perfectly accurate to provide consumers with a sufficient benefit, but there should be some standardized method for assessing the reliability of genetic traits testing and ancestry testing in order for this testing to be considered a benefit to consumers. Importantly, as noted above, both 23andMe and Ancestry disclaim the accuracy of many of their test results.

23andMe's FDA-approved tests do plausibly provide consumers with a benefit because those tests should accurately identify the relevant genetic variants (analytic validity) and those genetic variants should be associated with a disease (clinical validity). However, their tests are not validated for clinical utility.²⁶¹ This is, in part, because the tests are also not fully comprehensive, unlike clinical diagnostic tests, and do not necessarily identify the broader range of variants associated with a disease.²⁶² In addition, one recent study found a 40% false-positive rate for genetic health tests when the raw genetic data was interpreted either by the company that did the sequencing or by a third party interpreting raw sequencing data provided by another company.²⁶³ However, to the extent 23andMe minimizes the false positive and negative rates of its genetic health tests, these tests can be considered beneficial for providing some insight into a consumer's health risks.

The benefits to 23andMe and Ancestry are fairly patent. They receive revenue in exchange for their services and they receive a significant amount of private information about an individual, most notably in the form of biospecimen and resultant genetic data. In addition, the companies are also working with pharmaceutical companies and research institutes to conduct research with the data they receive from consumers.²⁶⁴

As we explained in Part III.C, the potential harms of DTC-GT can be broken into three categories—(1) knowledge harms, (2) autonomy and trust-based harms, and (3) the harms of data misuse. Knowledge harms include the harms associated with receiving health information in the form of test

261. Scott D. Grosse & Muin J. Khoury, *What Is the Clinical Utility of Genetic Testing?*, 8 GENETICS MED. 448, 449–50 (2006).

262. Stephany Tandy-Connor et al., *False-Positive Results Released by Direct-to-Consumer Genetic Tests Highlight the Importance of Clinical Confirmation Testing for Appropriate Patient Care*, 20 GENETICS MED. 1515, 1515 (2018).

263. *Id.* at 1518–19.

264. *See supra* text accompanying notes 131–132.

results, expected or unexpected, that are troubling, inaccurate, or misleading. If the information is sufficiently accurate, consumers may experience nonnegligible, but still not clinically significant stress or anxiety over their test results.²⁶⁵ While test results could inspire positive behavioral health changes, some studies suggest that these benefits are fairly modest²⁶⁶ or have no effect.²⁶⁷ However, test results are not always accurate—as explained above, the accuracy of many tests is uncertain and one study found a 40% false positive rate with genetic data from DTC-GT companies.²⁶⁸ All of these studies are general, thus it is unclear to what extent or how often these concerns apply specifically to 23andMe and Ancestry.

Autonomy and trust-based harms encompass concerns about notice, choice, and deception. As described above, 23andMe and Ancestry do not provide sufficiently clear and understandable information for consumers to offer a valid consent. It is unclear whether 23andMe and Ancestry are actually deceiving consumers without more information about their data security and management practices.

The harms of data misuse are the harms associated with, for example, data breaches or the reidentification of otherwise deidentified data sets. Data breaches are growing in frequency, and health data breaches account for a large portion of these breaches.²⁶⁹ 23andMe and Ancestry claim to use industry standard data protection methods.²⁷⁰ However, given the frequency of data breaches, it is unclear how protective these data security measures could be. Without access to the data security measures taken by 23andMe and Ancestry, we cannot make definitive claims about the security risks to consumer data. However, we can at least infer that these risks are nonnegligible if data breach trends are any indicator. Furthermore, even if the probability of a data breach is fairly low—especially as compared to the rest of the industry—the magnitude of the harm is more considerable for a breach of consumer genetic data than other kinds of consumer data. That is, genetic information is immutable and not replaceable, whereas a consumer can much more easily replace a credit card or even a social security number. Thus, the risks of data breaches to 23andMe and Ancestry are greater

265. D.L. Boeldt et al., *Influence of Individual Differences in Disease Perception on Consumer Response to Direct-to-Consumer Genomic Testing*, 87 *CLINICAL GENETICS* 225, 229 (2015).

266. See, e.g., Deanna Alexis Carere et al., *The Impact of Direct-to-Consumer Personal Genomic Testing on Perceived Risk of Breast, Prostate, Colorectal, and Lung Cancer: Findings from the PGen Study*, 8 *BMC MED. GENOMICS*, Oct. 15, 2015, article no. 63, at 8.

267. See, e.g., Boeldt et al., *supra* note 265, at 229.

268. Tandy-Connor et al., *supra* note 262, at 1515.

269. Thomson, *supra* note 229, at 253.

270. *Your Privacy*, ANCESTRY, *supra* note 255; *Privacy Highlights*, 23ANDME, *supra* note 217.

because of the more substantial harm magnitude, even if the probability of a data breach is similar to other consumer data breaches.

Overall, there may be an unfair distribution of benefits—test results to consumers and money and genetic data to the companies—and burdens—the privacy risks that consumers take on for the services. The privacy policies, including the terms of service and various other documents aimed at informing consumers, are also problematically unclear. Whether the consumers benefit assumes the accuracy and utility of the test results, which is uncertain for all but the FDA-approved genetic health tests provided by 23andMe. To be clear, this is not to say that the test results do not provide a benefit, just that this is an open question without further validation. Thus, consumers are trading money and valuable data to 23andMe and Ancestry for a service that is, *ex ante*, of questionable benefit—again, excepting the FDA-approved tests. Even assuming that there is some benefit to consumers, but the transaction is still unfair and therefore mutually advantageous exploitation, there are at least two reasons for more substantial and comprehensive legal reform. First, as we explained in Section III.A, when a mutually advantageous exploitative transaction implicates third parties and not just a party to the transaction, legal intervention is more appropriate. Genetic information necessarily implicates third parties. Second, even with a better consent, consent has its limits—especially in this context where it is unlikely that consumers read the relevant privacy policies. But if consumers did read the policies, the preceding discussion should demonstrate that the risks of using DTC-GT are both conceptually and empirically complex. This makes it hard for consumers to protect their own welfare via consent.

Accordingly, in the following Part, we provide a number of recommendations to help reduce the disparities in these transactions and better protect consumers.

V. POTENTIAL SOLUTIONS

Given the inadequacy of DTC-GT companies' privacy policies to protect the consumers' genetic privacy and other issues posed by DTC-GT services, this Part examines several potential solutions to this problem. First, the DTC-GT industry can improve self-regulation by updating privacy policies or data practices and grounding test results in validated science. Second, FTC can provide more stringent regulatory activity in overseeing the DTC-GT companies' data practices. And, finally, we encourage comprehensive data privacy legislation which includes genetic information.

We have already argued that legal reform to promote genetic privacy can be justified by protecting consumers from exploitation. However, protection

of genetic privacy can also be guided by the normative and legal notion of trust. The “Partial Entrustment Model,” proposed by philosopher Henry Richardson, offers an ethical justification for obligations of medical researchers towards study participants.²⁷¹ Richardson provides that a special moral duty of researchers stems from the participants’ partial entrustment of some “aspects of their health to the researchers.”²⁷² Privacy rights serve as one of the three moral assumptions for the Partial Entrustment model where “[a]ll individuals have privacy rights pertaining to their bodies . . . and their medical histories” which “limit others’ access thereto.”²⁷³ Richardson explains that the research participants’ privacy rights are selectively waived through the consent process and such waiver results in transfer of responsibility to the researchers.²⁷⁴ This model not only applies to the clinical research context but can also serve as a normative basis for other relationships requiring special duties and/or involving sensitive information.²⁷⁵ This view is broadly consistent with Professors Neil Richards and Woodrow Hartzog’s argument to adopt a trust-based framework in privacy law.²⁷⁶ A trust-based framework can induce DTC-GT companies to ensure substantial and meaningful protection of the consumers’ genetic privacy as well as provide justification for better regulatory oversight as suggested below.

A. Improving DTC-GT Industry Self-Regulation

With significant gaps in regulatory oversight of the DTC-GT industry and its data practices,²⁷⁷ the current standard governing the protection of DTC-GT consumers’ genetic privacy is largely left to the industry’s self-regulation. Despite the companies’ efforts to establish industry-wide “Best

271. HENRY S. RICHARDSON, MORAL ENTANGLEMENTS: THE ANCILLARY-CARE OBLIGATIONS OF MEDICAL RESEARCHERS 23–24 (2012).

272. *Id.* at 23.

273. *Id.* at 60.

274. *Id.* at 61.

275. In fact, at one of the meetings of the Presidential Commission for the Study of Bioethical Issues, the Partial Entrustment Model was applied to the DTC genetic testing area. Presidential Comm’n for the Study of Bioethical Issues, Transcript of Meeting 14, Session 1, at 36 (Aug. 19, 2013), https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/TRANSCRIPT%20Opening%20Remarks%20and%20Session%201_0.pdf [<https://perma.cc/SQ5S-D8DH>] (“And then finally in the DTC area we seem to be simply left with something like the partial entrustment model.”).

276. Neil Richards & Woodrow Hartzog, *Privacy’s Trust Gap: A Review*, 126 YALE L.J. 1180, 1217 (2017) (“The main effect of the shift in perspective [to trust] is to keep the party entrusted with personal information from shifting the risk of loss back onto the trusting party. It thus places obligations on the powerful entities best able to protect against loss, rather than blaming the powerless individuals who are often at their mercy.”).

277. *See supra* Part I.

Practices,”²⁷⁸ however, the current practices remain inadequate to protect the consumers from privacy risks.²⁷⁹ Based on our analysis, there are a number of areas where 23andMe and Ancestry can improve their privacy policies. For example, 23andMe can clarify its confusing definition of various types of personal information which, at its current state, is potentially misleading to consumers.²⁸⁰ Ancestry cleverly focuses on the importance of trust and consumer privacy, but should also have an explicit discussion of the privacy *risks* of using their services. And, both Ancestry and 23andMe can provide more information regarding their efforts to prevent data breaches and plans to mitigate the harm if a breach were to occur. Ultimately, however, these profit-driven entities are unlikely to make the substantial changes needed to their privacy policies and practices because those changes undermine their business model. Accordingly, legal intervention is the better route to improve consumer privacy. And, even if these companies did substantially improve their self-regulation, there would still be important gaps for the law to fill.

B. Increased Federal Agency Oversight

Among the federal agencies that have jurisdiction to regulate DTC-GT companies,²⁸¹ FTC has the capacity and specific jurisdiction to oversee the data practices of the companies to ensure the protection of consumers’ genetic privacy. FTC has thus far limited its regulatory action to issuing statements for consumers,²⁸² and more stringent oversight is required from the FTC in order to protect the DTC-GT consumers’ genetic information.²⁸³ Through its consent orders, FTC can require companies to make changes to their privacy policies or implement comprehensive privacy programs. For example, FTC ordered Sony BMG to have “a clear and conspicuous notice” regarding its data practice on personal information from children in its

278. See, e.g., FUTURE OF PRIVACY FORUM, PRIVACY BEST PRACTICES FOR CONSUMER GENETIC TESTING SERVICES 1–2 (2018), <https://fpf.org/wp-content/uploads/2018/07/Privacy-Best-Practices-for-Consumer-Genetic-Testing-Services-FINAL.pdf> [<https://perma.cc/SH46-Q7CR>] (setting a baseline for DTC-GT practices based on a FIPPs-based framework to address issues related to genetic privacy).

279. See, e.g., *supra* Part IV; see also Dana A. Elfin, *DNA Testing? You Might Want to Wait for More Legal Protection*, BLOOMBERG LAW (Jan. 7, 2019, 4:40 AM), <https://news.bloomberglaw.com/pharma-and-life-sciences/dna-testing-you-might-want-to-wait-for-more-legal-protection> [<https://perma.cc/52JX-MZR9>].

280. See *supra* text accompanying notes 250–252.

281. See *supra* Part I.B.

282. See *supra* notes 71, 72.

283. There have been reports that the FTC might be investigating 23andMe and Ancestry regarding their privacy policies, but the agency has declined to comment. Baram, *supra* note 72.

privacy policy,²⁸⁴ and mandated Google to “establish and implement . . . a comprehensive privacy program that is reasonably designed to: (1) address privacy risks related to the development and management of new and existing products and services for consumers, and (2) protect the privacy and confidentiality of covered information.”²⁸⁵ FTC should consider whether such enforcement actions can be done to DTC-GT companies if an investigation finds their privacy policies and/or practices to be inadequate.²⁸⁶

In addition, FTC should consider interagency collaboration with the FDA and/or the U.S. Department of Health and Human Services (HHS) given these agencies’ expertise regarding medical devices and health information and practices. For example, the Secretary’s Advisory Committee on Genetics, Health, and Society’s report on DTC-GT recommends a joint HHS-FTC task force to develop guidelines for FTC in its regulation of DTC-GT companies.²⁸⁷ FTC already provides a “Best Practices” guideline for mobile health app developers with an emphasis on data privacy and security.²⁸⁸ Such guidelines can serve as a prototype for DTC-GT companies and FTC’s accompanying regulation of such companies’ data practices.

C. Comprehensive Data Privacy Legislation

Since 1991, there have been several failed attempts to pass genetic privacy legislation.²⁸⁹ However, given the heightened interest and concern for genetic privacy, is the time finally ripe for a comprehensive genetic privacy law? With the enactment of GINA, however, it would not be feasible to have yet another law specifically concerning genetic information. The more realistic approach would be to seek protection of DTC-GT consumers’ genetic privacy as a part of a more comprehensive privacy law.

284. *United States v. Sony BMG Music Entm’t*, No. 1:08-cv-10730, at 4 (S.D.N.Y. Dec. 15, 2008) (consent decree), <https://www.ftc.gov/sites/default/files/documents/cases/2008/12/081211consentp0823071.pdf> [<https://perma.cc/378D-PB9E>].

285. *Google Inc.*, 152 F.T.C. 435, 454 (2011) (consent order).

286. For general discussion on FTC settlements and jurisprudence, see Solove & Hartzog, *supra* note 26.

287. SEC’Y’S ADVISORY COMM. ON GENETICS, HEALTH, & SOC’Y, U.S. DEP’T OF HEALTH & HUMAN SERVS., DIRECT-TO-CONSUMER GENETIC TESTING 40 (2010), https://osp.od.nih.gov/wp-content/uploads/2013/11/SACGHS_DTC_Report_2010.pdf [<https://perma.cc/ZL6J-PJVG>].

288. *Mobile Health App Developers: FTC Best Practices*, FED. TRADE COMM’N (Apr. 2016), <http://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-app-developers-ftc-best-practices> [<http://perma.cc/B97M-55FM>].

289. See Kyle G. French, *The Elderly and the Discriminatory Use of Genetic Information*, 5 ELDER L.J. 147, 167–70 (1997). Among the failed attempts, the notable include: the Human Genome Privacy Act, H.R. 2045, 102d Cong. (1991); the Genetic Privacy and Nondiscrimination Act of 1995, S. 1416, 104th Cong. (1995); H.R. 2690, 104th Cong. (1995); the Genetic Confidentiality and Nondiscrimination Act of 1996, S. 1898, 104th Cong. (1996); and the Genetic Privacy and Nondiscrimination Act of 1997, H.R. 341, 105th Cong. (1997).

One potential avenue is through modification of HIPAA. Since its enactment in 1996, HIPAA has gone through one major modification—the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009.²⁹⁰ On December 14, 2018, the HHS Office for Civil Rights (OCR) issued a Request for Information (RFI) seeking public input to make modifications to the HIPAA Privacy Rule.²⁹¹ Although the solicited comments are largely focused on promoting coordination of care,²⁹² it is possible that the next phase of modification of HIPAA could involve addressing the issue of the continued increase of non-HIPAA medical information including genetic information from DTC-GT. However, such modification would alter the nature of HIPAA and raise the line-drawing question of how much non-HIPAA information the modified HIPAA should cover.

The best solution to protect DTC-GT consumers' genetic privacy would be a comprehensive data privacy law. While it once seemed to be a far-fetched idea in the United States, a data privacy law might be more feasible than it used to be. Currently, there is mounting public pressure and political movement towards enacting a federal data privacy legislation.²⁹³ Among the bills introduced, the most notable is the draft Data Care Act of 2018 introduced by Senator Brian Schatz (D-HI) and joined by fifteen other Democratic senators.²⁹⁴ Upon scrutiny of the current text of the bill, however, it remains unclear whether the bill would be able to effectively regulate the data practices of DTC-GT companies. The draft Data Care Act imposes certain duties upon “online service providers” in terms of their data practices²⁹⁵ where an “online service provider” is defined as an entity that “is engaged in interstate commerce over the internet . . . and[,] in the course of business, collects individual identifying data about end users”²⁹⁶ While DTC-GT companies could qualify as “online service providers” under this definition, the bill constrains “individual identifying data” to personal data that is “collected over the internet or any other digital

290. Enacted as part of the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, §§ 13001–13424, 123 Stat. 115, 226–79.

291. Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, 83 Fed. Reg. 64,302, 64,302 (Dec. 14, 2018).

292. *Id.*

293. See, e.g., Cameron F. Kerry, *Will This New Congress Be the One to Pass Data Privacy Legislation?*, BROOKINGS (Jan 7, 2019), <https://www.brookings.edu/blog/techtank/2019/01/07/will-this-new-congress-be-the-one-to-pass-data-privacy-legislation/> [<http://perma.cc/3GUL-RZZT>]; Opinion, *Our Privacy Regime Is Broken. Congress Needs to Create New Norms for a Digital Age*, WASH. POST (Jan. 5, 2019), https://www.washingtonpost.com/opinions/our-privacy-regime-is-broken-congress-need-s-to-create-new-norms-for-a-digital-age/2019/01/04/c70b228c-0f9d-11e9-8938-5898adc28fa2_story.html [<http://perma.cc/H8UZ-XFMB>].

294. S. 3744, 115th Cong. (2018).

295. *Id.* § 3.

296. *Id.* § 2(4).

network . . .”²⁹⁷ Thus, the genetic information provided by the DTC-GT companies to the consumers would not qualify as individual identifying data protected under this draft Data Care Act. Moreover, while the bill provides additional protection for “sensitive data,”²⁹⁸ examples of sensitive data do not explicitly include genetic information despite listing biometric data and health information.²⁹⁹ Meanwhile, EU’s GDPR explicitly includes genetic information as one category of personal information to be protected under the regulation.³⁰⁰ Moving forward, we encourage the legislative activities towards a comprehensive data privacy law to consider the widening landscape of personal information and explicitly include genetic information as a category of personal data to be protected thereby recognizing the importance of the consumers’ genetic privacy.

CONCLUSION

In *The Right to Privacy*, Warren and Brandeis identified two major threats to privacy: the press and technology.³⁰¹ While much has changed since the days when Warren and Brandeis worried about the invasion of the press into the “sacred precincts of private and domestic life,”³⁰² one thing appears to be in common. The threat of technology is worsening as a myriad of novel technologies and industries collect and use an ever-increasing amount of personal information. While DTC-GT services have revolutionized the way we acquire genetic information and enhanced consumer autonomy, it has also presented unforeseen privacy problems. In addition to heightened privacy risks due to the sensitivity of genetic information itself, DTC-GT poses special privacy harms in the form of knowledge harms, harms to autonomy and trust, and data misuse harms. When analyzed through an exploitation-based framework, the DTC-GT companies’ privacy policies and data practices do not adequately protect the consumers’ genetic privacy from these harms. The unfairness of these transactions justifies a change in the already inadequate regulatory landscape surrounding the DTC-GT industry. While improving external regulation, in the form of laws and agencies, can protect the consumers’

297. *Id.* § 2(3).

298. *Id.* § 3.

299. *Id.* § 2(5)(E), (H). Similarly, in Senator Patrick Leahy’s proposed Consumer Privacy Protection Act of 2015, “sensitive personally identifiable information,” which is the data protected by the bill, did not explicitly include genetic information while including biometric data and health information. S. 1158, 114th Cong. § 3(10) (2015).

300. Regulation 2016/679, art. 4(1), 2016 O.J. (L 119) 1, 33.

301. See Warren & Brandeis, *supra* note 94, at 195 (“[N]umerous mechanical devices threaten to make good the prediction that ‘what is whispered in the closet shall be proclaimed from the house-tops.’”).

302. *Id.*

genetic privacy to a certain degree, DTC-GT companies should also reconsider their entire approach to data privacy. When companies consider themselves as data stewards (or trustees) rather than owners of the consumers' genetic information,³⁰³ we, as a society, would be able to bridge the trust-gap between DTC-GT services and consumers and further realize the potential of innovative technology and data.

303. See, e.g., David E. Winickoff & Richard N. Winickoff, *The Charitable Trust as a Model for Genomic Biobanks*, 349 NEW ENG. J. MED. 1180 (2003).