WHO KNOWS WHAT, AND WHEN?: A SURVEY OF THE PRIVACY POLICIES PROFFERED BY U.S. DIRECT-TO-CONSUMER GENETIC TESTING COMPANIES*

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Direct-to-consumer genetic testing (DTC-GT) companies have proliferated in the past several years. Based on an analysis of genetic material submitted by consumers, these companies offer a wide array of services, ranging from providing information about health and ancestry to identification of surreptitiously-gathered biological material sent in by suspicious spouses. Federal and state laws are ambiguous about the types of disclosures these companies must make about how the genetic information they obtain is collected, used, and shared. In an effort to assist in developing such laws, this Article reports a survey of the privacy policies these companies purport to follow. It canvasses ninety DTC-GT companies operating in the United States and provides a detailed analysis of whether and to what extent those policies inform consumers about how their genetic information will be used and secured, with whom it will be shared, and a host of other issues. Using the Federal Trade Commission's articulation of the Fair Information Practice Principles and the agency's proposed Privacy Framework as the baseline, we conclude that most policies fall well short of the ideal.

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INTRODUCTION

In the midst of a 2017 holiday season that saw deeply discounted direct-to-consumer genetic tests (DTC-GTs) at the top of online shopping lists for the second straight year,[1] Senate Minority Leader Charles "Chuck" Schumer (D-NY) convened a press conference to warn consum-

[1] Megan Molteni, *Ancestry's Genetic Testing Kits are Heading for Your Stocking This Year*, WIRED (Dec 1, 2017, 7:00 AM), https://www.wired.com/story/ancestrys-genetic-testing-kits-are-heading-for-your-stocking-this-year/.

ers of the potential risks associated with at-home DNA testing and called for increased government oversight.[2] Prompted by concerns about the adequacy and transparency of the privacy policies governing these services, Schumer asked the Federal Trade Commission (FTC) "to take a serious look at this relatively new kind of service and ensure that these companies have clear, fair privacy policies and standards for all kinds of at-home DNA test kits."[3] Schumer specifically referenced concerns that companies were disclosing sensitive consumer genetic data to unknown third parties without first obtaining adequate informed consent.[4]

Advertisements for DTC-GT services like 23andMe and AncestryDNA are commonplace on television, radio, the internet, and social media, increasing consumer awareness of genetic testing and contributing to the rapid growth of the industry over the last decade.[5] Americans now turn to DTC-GT companies in an attempt to translate their genetic data into insights into their health, ancestry and family relationships, lifestyle, as well as an ever-growing number of additional areas.[6] Companies now offer tests that purport to match consumers with the ideal romantic partner,[7] alcoholic beverage,[8] or even travel destination,[9] all allegedly based on their unique genetic makeup. These developments have been accompanied by fierce debate amongst scholars, medical professionals, and regulators about the benefits of utilizing these services,[10]

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2 Press Release, Charles E. Schumer, United State Senator for New York, Schumer Reveals: Popular At Home DNA Test Kits Are Putting Consumer Privacy At Great Risk, As DNA Firms Could Sell Your Most Personal Info & Genetic Data To All-Comers; Senator Pushes Feds To Investigate & Ensure Fair Privacy Standards For All DNA Kits (Nov. 26, 2017), https://www.schumer.senate.gov/newsroom/press-releases/schumer-reveals-popular-at-home-dna-test-kits-are-putting-consumer-privacy-at-great-risk-as-dna-firms-could-sell-your-most-personal-info-and-genetic-data-to-all-comers-senator-pushes-feds-to-investigate_ensure-fair-privacy-standards-for-all-dna-kits.

3 *Id.*

4 *Id.*

5 The market value of the US DTC laboratory and genetic testing industry grew from a humble $15 million in 2010 to over $210 million in 2017 and is projected to reach $350 million by 2020. *See The Market for Direct-to-Consumer Genetic Testing and Routine Laboratory Testing*, KALORAMA INFORMATION (Jan. 1, 2016) [hereinafter Kalorama Information Report], www.kaloramainformation. com/Direct-Consumer-DTC-9588755/; *Predictive Genetic Testing & Consumer/Wellness Genomics Market Worth $4.6 Billion by 2025*, GRAND VIEW RESEARCH, INC. (Feb. 2, 2017) [hereinafter Grand View Research Report], https://www.prnewswire.com/news-releases/predictive-genetic-testing—consumerwellness-genomics-market-worth-46-billion-by-2025-grand-view-research-inc-612533583.html.

6 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).

7 GENEPARTNER, http://www.genepartner.com (last visited Dec. 01, 2017).

8 VINOME, https://www.vinome.com (last visited Nov. 27, 2017).

9 DNA UNWRAPPED, https://www.dnaunwrapped.com (last visited Dec. 03, 2017).

10 Mauro Turrini & Barbara Prainsack, *Beyond Clinical Utility: The Multiple Values of DTC Genetics*, 8 APPLIED AND TRANSLATIONAL GENOMICS 4 (2016).

the validity of the tests involved,[11] and the privacy risks associated with surrendering genetic information to these companies.[12]

It is currently convenient and relatively straightforward for an American consumer to access DTC-GT testing services in the vast majority of states: a typical consumer places an order online (generally costing $50–$200, but up to $2,000 or more depending on the type of testing), is mailed an at-home collection kit by the company, and provides a DNA sample in the form of saliva, a buccal (cheek) swab, or, less commonly, blood.[13] Several weeks later, the consumer can access the test results online through the company's website. These transactions generally take place entirely in the comfort of the consumer's home and are governed by electronic agreements common to many e-commerce transactions.[14]

These agreements typically take the form of "click-wrap" (requiring the consumer to click "I agree" upon ordering the service or registering the kit) or "browser-wrap" (implying consent from the consumer's use of a company's website or product).[15] Under the current US self-regulatory "Notice and Choice" (or "Notice and Consent") framework, a company's privacy documents (usually denominated a Privacy Policy or Terms of Service) provide Notice of a company's data practices, while the consumer's actions (such as clicking "I agree" or utilizing the service) provide the Choice/Consent.[16] Citing concerns about adequate consumer awareness of the contents of these agreements and the resulting lack of informed consent, scholars have questioned the sufficiency of such an approach in the rapidly evolving online marketplace, where a typical consumer is bombarded with countless such agreements.[17]

A few recent studies, relying on documents located on company websites, have attempted to ascertain whether, and to what extent, suffi-

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11 Rose Geransar & Edna Einsiedel, *Evaluating Online Direct-to-Consumer Marketing of Genetic Tests: Informed Choices or Buyers Beware?*, 12 GENETIC TESTING 13 (2008); Tanya Agurs-Collins et al., *Public Awareness of Direct-to-Consumer Genetic Tests: Findings from the 2013 US Health Information National Trends Survey*, 30 J. CANCER EDUC. 799 (2015).

12 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).

13 U.S. Fed. Trade Comm'n, Direct-to-Consumer Genetic Tests, *available at* https://www.consumer.ftc.gov/articles/0166-direct-consumer-genetic-tests.

14 Andelka M. Phillips, *Reading the Fine Print When Buying Your Genetic Self Online: Direct-to-Consumer Genetic Testing Terms and Conditions*, 36 NEW GENETICS & SOC'Y 273 (2017).

15 *Id.* at 278.

16 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 (2014).

17 *Id.*

cient information is provided to consumers of DTC-GT services.[18] One survey of thirty companies marketing health and ancestry testing to American consumers found that companies failed to "consistently meet international transparency guidelines related to confidentiality, privacy, and secondary use of data."[19] However, this study did not evaluate companies that primarily offer paternity and other family relationship testing, which make up a substantial segment of the DTC-GT industry in the United States.[20] Another study of eighty-six DTC-GT companies marketing to Canadian consumers found that, "[w]ith some notable exceptions, these companies provided little or none of the information required for consumers to make informed decisions about their privacy. . . [including the] privacy implications of genetic testing, disclosing health information, and third parties gaining access to an individual's genetic information."[21] Again, this study focused primarily on companies offering health-related testing.[22]

This Article expands upon previous work in an effort to gain a more comprehensive understanding of the information US-based DTC-GT companies provide to a typical consumer across *all* categories of genetic testing, with a focus on the collection, use, and sharing of consumers' genetic data with third parties. The goal of this study is not to assess compliance of these DTC-GT companies with United States regulations but rather to characterize what information is provided to consumers under the current self-regulatory framework. The results presented in this Article should be helpful in determining what additional regulation, if any, might be appropriate in this arena.

I. THE LEGAL LANDSCAPE

In the United States, the DTC-GT industry is not governed by comprehensive legislation, but rather it operates against the backdrop of a patchwork of federal and state laws that govern various aspects of genetic testing and the resulting genetic data.[23] Prominent examples include the federal Genetic Information Nondiscrimination Act of 2008

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18 Phillips, *supra* note 6; Phillips, *supra* note 14.

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

20 *Id.* at 514.

21 Christofides & O'Doherty, *supra* note 12, at 117.

22 *Id.* at 102.

23 *See* GENETICS & PUB. POL'Y CTR., JOHN HOPKINS UNIV., *Survey of Direct-to-Consumer Testing Statutes and Regulations* (2007), https://repository.library.georgetown.edu/handle/10822/511162 [hereinafter Survey of DTC Statutes and Regulations]; *See, e.g.*, Kayte Spector-Bagdady & Elizabeth R. Pike, *Consuming Genomics: Regulating Direct-to-Consumer Genetic and Genomic Information*, 92 NEB. L. REV. 677, 697 (2014).

(GINA)[24] and the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[25] with its Privacy Rule,[26] that regulates the collection, use, and sharing of genetic data in the research and clinical settings. However, these laws generally do not directly implicate the bulk of the DTC-GT industry: GINA prohibits only the discriminatory use of genetic information by employers and health insurance companies, and the vast majority of DTC-GT companies do not qualify as "covered entities" under HIPAA.[27] A small number of states (e.g., New York and Maryland) place limitations on DTC-GT, such as requiring that certain genetic tests be ordered through a physician or placing additional requirements on laboratories that perform the testing, but DTC-GT remains largely unregulated in the majority of jurisdictions.[28]

In the absence of comprehensive legislation, the DTC-GT industry is primarily regulated, to differing degrees, by three federal administrative agencies: the Centers for Medicare and Medicaid Services (CMS) via the Clinical Laboratory Improvements Act (CLIA),[29] the Food and Drug Administration (FDA),[30] and the FTC.[31] CMS and CLIA are concerned primarily with ensuring the analytical validity of certain tests, including genetic tests, performed by a laboratory[32] that analyzes "materials derived from the human body for the purpose of providing

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24 *See* Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. § 2000ff (2008) [hereinafter GINA].

25 *See* Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified in various titles of the U.S.C.) [hereinafter HIPAA].

26 *Id.* at § 5(b).

27 GINA, *supra* note 24, at §202.

28 Helen C. Dick, *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 (2012); *See* Survey of DTC Statutes and Regulations, *supra* note 23.

29 Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, 102 Stat. 2903 (codified at 42 U.S.C. § 263a); Centers for Medicare & Medicaid Services, Clinical Laboratory Improvement Amendments (CLIA), Regulations and Guidelines (April 5, 2017), https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html.

30 Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1939) (codified at 21 U.S.C. ch. 9 § 301); Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified at U.S.C. §360c-360k); *see also* Institute of Medicine and National Research Council, *Current Legislative and Regulatory Framework in the United States, in* DIRECT-TO-CONSUMER GENETIC TESTING: SUMMARY OF A WORKSHOP (2011) (offering a brief overview of the federal laws at work for direct-to-consumer genetic testing), https://www.ncbi.nlm.nih.gov/books/NCK209639/.

31 Federal Trade Commission Act of 1914, ch. 311, §5, 38 Stat. 719 (codified as amended at 15 U.S.C. §§ 41-58) [hereinafter FTCA]; *see A Brief Overview of the Federal Trade Commission's Investigative and Law Enforcement Authority,* U.S. Fed. Trade Comm'n, https://www.ftc.gov/about-ftc/what-we-do/enforcement-authority (last updated July 2008).

32 Under CLIA, a laboratory is defined as "a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include proce-

information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" (a definition that excludes many types of DTC-GT).[33] In addition, CLIA does not grant CMS the authority to assess the clinical validity or utility of the tests being performed, nor does it regulate the information that companies must convey to consumers regarding those tests.[34]

The FDA has relatively broad authority to regulate DTC-GT but has thus far exercised "enforcement discretion," limiting its regulation to companies offering certain "health-related" genetic tests.[35] This category includes tests that purport to reveal carrier status[36] or to predict one's genetic predisposition to disease[37] or response to a particular pharmaceutical drug, but does not include the majority of non-health-related genetic tests currently on the market (e.g., ancestry and family relationships tests).[38] Therefore, when it comes to the type of information that DTC-GT companies must convey to consumers, the industry is largely left to self-regulation, so long as companies do not engage in practices that the FTC finds to be "unfair" or "deceptive," a concept discussed below.

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dures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body." 42 C.F.R. § 493.2.

33 42 U.S.C. § 263a(a).

34 *See id.*

35 There have been several important regulatory developments in the DTC-GT industry recently, driven largely by 23andMe and the FDA. The FDA authorized 23andMe to offer a direct-to-consumer carrier status test for Bloom Syndrome in February 2015, subsequently authorized it to carry out Genetic Health Risk (GHR) tests for ten diseases in April 2017, and mostly recently, authorized a test that reports on three mutations in BRCA genes in March 2018. As part of the pre-market approval process for GHR tests, 23andMe was required to demonstrate the analytical validity of their tests as well as adequate consumer understanding of the sample collection process and the resulting genetic reports. Going forward, the FDA "intends to exempt additional 23andMe GHR tests from the FDA's premarket review, and GHR tests from other makers may be exempt after submitting their first premarket notification . . . allow[ing] other, similar tests to enter the market as quickly as possible and in the least burdensome way, after a one-time FDA review." Press Release, Fed. Drug Admin., FDA Allows Marketing of First Direct-to-Consumer Tests that Provide Genetic Risk Information for Certain Conditions (April 6, 2017), *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm551185.htm; *See also infra* note 36 (containing references to the FDA press releases that describe the approval process for 23andMe's Bloom syndrome and BRCA tests).

36 Press Release, Fed. Drug. Admin., FDA Permits Marketing of First Direct-to-Consumer Genetic Carrier Test for Bloom Syndrome (Feb. 23, 2015), *available at* https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm435003.htm; Press Release, Fed. Drug Admin., FDA Authorizes, with Special Controls, Direct-to-Consumer Test that Reports Three Mutations in the BRCA Breast Cancer Genes (Mar. 6, 2018), *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm599560.htm.

37 Press Release, Fed. Drug Admin., FDA Allows Marketing of First Direct-to-Consumer Tests that Provide Genetic Risk Information for Certain Conditions (Apr. 6, 2017), *available at* https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm551185.htm.

38 *See id.*

The FTC has broad authority to police false or misleading advertising practices under the Federal Trade Commission Act (FTCA) of 1914.[39] Under the authority granted in Section 5 of the Act, the agency has targeted ". . . a wide range of anti-consumer practices where it can demonstrate that a consumer was deceived, or where a business practice is objectively "unfair" because it (1) causes significant consumer harm that (2) is not avoidable by consumers and (3) is not offset by countervailing benefits."[40] Section 12 of the Act also grants the FTC the authority to police false advertising of health care products.[41] However, the agency has only applied these provisions to the DTC-GT context on two occasions, otherwise limiting its actions in this area to the issuance of consumer bulletins regarding DTC-GT and its risks and limitations.[42]

The most prominent example of FTC action against a DTC-GT company occurred in January 2014, when the agency filed an administrative complaint against Genelink, Inc. and its subsidiary, Foru International Corporation, makers of an at-home genetic test kit that purported to match consumers to products in its line of dietary and skincare supplements.[43] The FTC took issue with Genelink's representations "that genetic disadvantages identified through the companies' DNA assessments [were] scientifically proven to be mitigated by or compensated for with the companies' nutritional supplements."[44] The FTC also claimed that "the companies' acts and practices related to data security were unfair and deceptive" because, in contradiction to the companies' posted privacy policies, it had "failed to provide reasonable and appropriate security for consumers' personal information," including genetic information and social security, credit card, and bank account numbers.[45] Genelink ultimately entered into a consent agreement with the FTC to settle the complaint, which required the company to "have at least 2 [randomized human clinical trials] before making disease prevention, treatment, and

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39 FTCA, *supra* note 31.

40 Justin Brookman, *Protecting Privacy in an Era of Weakening Regulation*, 9 HARV. L. & POL'Y REV. 355, 358 (2015); *See* 15 U.S.C. § 45.

41 *See* 15 U.S.C. § 52.

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

43 *See* Complaint, In re GeneLink, Inc. & Foru Int'l Corp., No. 112-3095 (F.T.C. Jan. 7, 2014), https://www.ftc.gov/system/files/documents/cases/140512genelinkcmpt.pdf [hereinafter Genelink Complaint].

44 *Id.* at 10.

45 *Id.* at 12.

diagnosis claims,"[46] "prohibited [the company] from misrepresenting [its] privacy and security practices," and required the company to "establish and maintain comprehensive data security programs and submit to security audits by independent auditors every other year for twenty years."[47]

The increasing diversity of direct-to-consumer genetic tests on the market, combined with the expansion of companies offering analysis of pre-existing genetic data,[48] promises to continue to raise unique privacy concerns and regulatory challenges.[49] For instance, the same genetic data that a consumer intended to be used for a particular purpose (i.e. to explore ancestry or physical traits) can, in many cases, reveal sensitive health and other personal information about not only the individual, but also the individual's relatives.[50] The problem is compounded by the fact that consumers are typically encouraged to provide additional sensitive information about themselves or their family in order to maximize the utility of the genetic test being offered. For example, "self-reported" information might include personal and family medical history, ethnicity, physical traits, or details about the consumer's lifestyle and habits.[51] Disclosure of this information could have potentially harmful consequences for both the individual and their loved ones, such as discrimination in the employment or insurance context.[52]

These privacy concerns are further accentuated in an environment where consumer genetic data is becoming an increasingly valuable asset for many genetic testing firms.[53] Two of the largest US DTC-GT compa-

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46 Statement of Chairwoman Edith Ramirez and Commissioner Julie Brill In the Matter of GeneLink, Inc. and foru International Corporation (Jan. 7, 2014), https://www.ftc.gov/sites/default/files/documents/cases/140107genelinkstatementbrill.pdf.

47 Press Release, Fed. Trade Comm'n, FTC Approves Final Consent Orders Settling Charges that Companies Deceptively Claimed Their Genetically Modified Nutritional Supplements Could Treat Diseases (May 12, 2014), *available at* https://www.ftc.gov/news-events/press-releases/2014/05/ftc-approves-final-consent-orders-settling-charges-companies.

48 Lauren Badalato et al., *Third Party Interpretation of Raw Genetic Data: An Ethical Exploration*, 25 EUR. J. HUM. GENETICS 1189 (2017).

49 Margaret Curnutte, *Regulatory Controls for Direct-to-Consumer Genetic Tests: A Case Study on How the FDA Exercised its Authority*, 36 NEW GENETIC SOC'Y 209, 210–12 (2017).

50 Jean E. McEwen et al., *The Ethical, Legal, and Social Implications Program of the National Human Genome Research Institute: Reflections on an Ongoing Experiment*, 15 ANN. REV. OF GENOMICS AND HUM. GENETICS 481 (2014).

51 *See e.g.*, 23andMe, Privacy Highlights, *available at* https://www.23andme.com/about/privacy/ (last visited June 8, 2018) (defining "self-reported" information as "information you provide directly to us, including your disease conditions, other health-related information, personal traits, ethnicity, family history, and other information that you enter into surveys, forms, or features while signed in to your 23andMe account").

52 Robert C. Green et al., *GINA, Genetic Discrimination, and Genomic Medicine*, 372 NEW ENG. J. MED. 397 (2015).

53 *See* Grand View Research Report, *supra* note 5.

nies, AncestryDNA and 23andMe, have assembled massive databases containing the genetic data of over five million and two million customers, respectively.[54] The sale of data generated by DTC-GT to third parties, such as pharmaceutical companies and academic institutions, generally in de-identified and aggregated form, can serve as an important revenue stream for some companies, and the data can be used to illuminate genetic components of disease or to facilitate drug development.[55] In addition, DTC-GT companies themselves are beginning to engage in peer-reviewed research using their databases.[56] Taken together, the increasing dissemination of direct-to-consumer genetic data may exacerbate privacy harms, most obviously because of the heightened risk, demonstrated by recent studies, that an individual might be re-identified from the de-identified datasets commonly used by companies and researchers.[57]

All of these risks are less likely to be understood in the direct-to-consumer setting than in the clinical and research settings, which generally provide enhanced legal protections and additional opportunities for patients or participants to obtain more information about a test and its implications, both before and after undergoing testing, and thus a more meaningful opportunity to provide informed consent. In contrast, consumers of DTC-GT are unlikely to receive consultation from a healthcare provider or genetic counselor unless they choose to seek out such assistance, something which studies indicate occurs infrequently.[58] Taken together, these potential harms illustrate the importance of providing a consumer with sufficient information to make an informed decision about whether to purchase DTC-GT or analysis services, including, as in the clinical setting, adequate descriptions of how data will be collected and used internally by the company and whether and how it will shared

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54 Press Release, Ancestry Corporate, Ancestry Surpasses 5 Million People in DNA Database, Giving Customers Even More Opportunities to Discover Who They Are and How They Connect to One Another (Aug. 9, 2017), *available at* https://www.ancestry.com/corporate/newsroom/press-releases/ancestry-surpasses-5-million-people-dna-database-giving-customers-even-more; *Estimating the Sizes of the Genealogical at DNA Databases,* THE DNA GEEK BLOG (Apr. 17, 2017), http://thednageek.com/estimating-the-sizes-of-the-genealogical-atdna-databases/.

55 *See* Grand View Research Report, *supra* note 5.

56 *See, e.g.,* Kelly Servick, *Can 23andMe Have it All?,* 349 SCI. 1472 (2015); Eunjung Han et al., *Clustering of 770,000 Genomes Reveals Post-Colonial Population Structure of North America,* 8 NATURE COMM. 14238 (2017).

57 Melissa Gymrek et al., *Identifying Personal Genomes by Surname Inference,* 339 SCI. 321, 321–24 (2013); Bradley Malin & Latanya Sweeney, *Determining the Identifiability of DNA Database Entries,* PROC. AM. MED. INFORMATICS ASS'N SYMP. 547–51 (2000); Bradley Malin & Latanya Sweeney, *Re-Identification of DNA hrough an Automated Linkage Process,* PROC. AM. MED. INFORMATICS ASS'N SYMP. 423–27 (2001).

58 Diane R. Koeller et al., *Utilization of Genetic Counseling after Direct-to-Consumer Genetic Testing: Findings from the Impact of Personal Genomics (PGen) Study,* 26 J. GENETIC COUNSELING 1270 (2017).

with third parties. The current study was conducted to add to our knowledge about the extent to which DTC-GT companies provide such information.

II. RESEARCH DESIGN

A. *Internet-Based Search Strategy*

US-based companies offering DTC-GT or analysis services were located using an internet-based search strategy in February 2017.[59] We limited our analysis to companies that had a physical presence in the United States, such as corporate offices, headquarters, or laboratories. We also limited our analysis to companies providing services directly to the consumer without the involvement of a healthcare provider, which meant that we excluded companies that require physician approval to order testing or receive the results. Companies were then coded based on the type of genetic testing service(s) offered and sorted into four broad categories: health-related, ancestry and genealogy, family relationship, and lifestyle and wellness. It was common for a company to offer services from more than one category of testing.

B. *Collection of Policy Documents*

From each company so discovered, we sought documents describing its policy toward the collection, use, and sharing of genetic information. Common documents included Privacy Policies or Statements, Terms or Conditions of Use, Terms or Conditions of Service, and Consent documents (typically consent for third-party research). Web "cookie" and tracking policies, whether a separate document or a provision within another privacy document, were excluded from analysis.

All readily accessible policies were collected from company websites in February 2017 and saved as electronic documents, typically Adobe PDF. Links to these documents were typically located at the bottom of the main page of a company's website but were occasionally found in "FAQ" or "Legal" subsections. In order to track the fate of companies on our list and to examine the extent to which privacy documents change over time, this process was repeated in October 2017.

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[59] A Google search was performed utilizing a combination of the following terms: genetic, genome, DNA, test, screen, sequencing, profile, analysis, home, order, kit, service, report, direct-to-consumer, ancestry, health, personal, nutrition, aging, paternity, infidelity, family relationship, talent, lifestyle, drug response, carrier, forensic, methylation, telomere. In order to replicate how a typical consumer might locate a company, DTC-GT companies located on pre-existing lists of companies or via relevant sponsored links and advertisements were included on the list.

C. *Correspondence with DTC-GT Company Representatives*

During document collection, it became evident that some companies might have additional policy documents that were not readily accessible on their websites but appeared relevant to their genetic data practices (i.e. documents that were only available upon registering for the service or upon ordering the test kit). To ascertain the extent to which companies utilized non-readily accessible policy documents, companies were contacted using the email address, web-based contact form, or phone number provided on the company website or within a company's policy documents. Company representatives were asked about the applicability of ambiguous policy documents, as well as the existence of any additional policy documents governing genetic data that might not be readily accessible on the company's website (i.e. those that might be included upon sign-up or account creation, at the point-of-purchase, or within a test kit). These interactions were carried out from the standpoint of a prospective consumer, an approach that was reviewed and certified as "exempt" by the Vanderbilt Institutional Review Board (Application # 171439).

D. *Analysis of Policy Documents*

To assess what a typical consumer might learn from viewing a company's privacy documents, we developed an analysis instrument designed to assess the information these policies provided regarding the collection, use, and sharing of genetic data. The questions on the survey instrument were based on guidelines and policy statements issued by national and international professional organizations,[60] insights gained from recent surveys of consumers and prospective consumers of DTC-GT services,[61] as well as an analysis of the industry's most comprehensive policies. The survey was then circulated to an interdisciplinary working group consisting of a large group of scholars from the law, medicine, psychology, history, and humanities fields.[62] Finally, the analysis instrument was applied on a pilot basis to a small subset of policies, modified to address any areas of ambiguity, and ultimately applied to all policy documents by two independent legal research assistants. Material disagreements were resolved by a third party, a professor of law. All study data was collected and managed using REDCap (Research Elec-

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60 Laestadius et al., *supra* note 19, at 515; Heather Skirton et al., *Direct to Consumer Genetic Testing: A Systematic Review of Position Statements, Policies and Recommendations*, 82 CLINICAL GENETICS 210 (2012).

61 Christofides & O'Doherty, *supra* note 12.

62 The survey was circulated to investigators at The Center for Genetic Privacy and Identity in Community Settings (GetPreCiSe) at Vanderbilt University. A complete list of members is available at: https://medschool.vanderbilt.edu/getprecise/people/team.

tronic Data Capture)[63] tools hosted at Vanderbilt University and exported in Microsoft Excel format for subsequent analysis.

III. RESULTS

A. *Overview of US-based DTC-GT Companies*

We identified ninety US-based companies that provided genetic testing or analysis services directly to the consumer without the involvement of a healthcare provider at any step in the process. Companies were spread across the country, in a total of twenty-four states, with California (19), New York (11), and Texas (10) having the greatest number of companies.

1. Overview of Services Offered

Companies offered a diverse set of genetic testing or analysis services, which we broke into four broad categories: family relationship, ancestry and genealogy, lifestyle and wellness, and health. Many companies offered more than one genetic testing service and were therefore included in multiple categories.

We found that over half of US-based companies, 54 of 90, offered genetic testing or analysis for purposes of determining family relationships (e.g., most commonly paternity, but also maternity, sibling, aunt-uncle, and grandparent identification), making this the most prevalent category of testing. Thirty-four companies provided genetic testing for ancestry or genealogy purposes (e.g., analysis of paternal Y-DNA, maternal mtDNA, and autosomal DNA). The remaining companies largely fell into the diverse lifestyle and wellness category (e.g., genetic testing and analysis services for a variety of purposes, including: athletic ability and fitness, nutrition, diet and weight management, cosmetics, beauty and anti-aging), with twenty-five companies offering such services. Finally, 23andMe was the only company approved by the FDA to market health-related tests in the United States at the time of this study (e.g., carrier status and genetic health risk tests) and was therefore the sole company in this category of testing.[64]

The vast majority of companies, 84 of 90, performed genetic testing services of some kind, typically through the use of an at-home collection kit, as well as subsequent analysis of the resulting genetic data. However, six companies did not perform genetic testing services but rather allowed

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[63] Paul A. Harris et al., *Research Electronic Data Capture (REDCap) - A Metadata-driven Methodology and Workflow Process for Providing Translational Research Informatics Support*, 42 J. BIOMEDICAL INFORMATICS 377 (2009) (introducing REDCap, a secure, web-based application designed to support data capture for research studies).

[64] *See* FDA Press Release, *supra* note 37.

consumers to upload raw genetic data generated by other companies, usually for ancestry purposes, and then provided additional insights using that data.

A large subset of companies, typically in the family relationship category, allowed consumers to submit "non-traditional" samples, such as cigarette butts, hair, gum, used condoms, and even articles of clothing suspected of containing biological material. These surreptitious testing services were offered under several names, including "infidelity," "forensic," "discreet," and "special sample" testing. In total, we identified twenty-seven US-based companies that appeared to permit, or in some cases even encourage, consumers to submit the genetic material of others without their consent. These services were generally marketed alongside a variety of more traditional family relationship tests; only three companies exclusively offered surreptitious testing services, whereas roughly half of companies offering paternity testing also offered some form of surreptitious testing.

2. Overview of Policy Documents

The majority of companies had readily accessible privacy documents on their website, generally a Privacy Policy (PP) or Terms of Service (ToS) document, or both. Of the ninety companies identified, only nine (10%) had no readily accessible privacy documents. However, an additional twenty-six companies (29%) had PP or ToS documents that appeared to apply only to the use of the company's website (e.g., "cookie" and web-tracking policies), as opposed to the genetic testing or analysis services. These "web-only" policies lacked any references, either explicit or implicit, to genetic data or the testing services being offered. Combining these two groups, a total of 39% of companies (35 of 90) had no readily accessible policy applicable to genetic data on their website and were thus categorized as companies that provided no information about how genetic data was collected, used, or shared.[65]

With respect to the fifty-five companies with relevant policy documents, 53% (29 of 55) provided consumers with a single relevant document, usually a PP, while 47% (26 of 55) provided two or more relevant documents, usually both a PP and a ToS document. Five companies had additional "consent" documents, usually associated with participation in third-party research, as discussed in further detail below. As noted above, these figures do not reflect policy documents which may be subsequently

[65] Subsequent correspondence with company customer service representatives regarding the applicability of these "web-only" policies to genetic data generally did little to resolve the ambiguities, further supporting the decision to exclude this class of policies from detailed analysis. Company representatives were often unsure about the scope of these policies, or deflected questioning with broad reassurances about the confidentiality of test results.

included in a test kit but were not readily accessible on a company's website and thus, unless specifically requested by the consumer, would not be available to consumers until after they had decided to purchase a test kit.[66]

3. Changes to Privacy Documents and Consumer Notification

We found that two-thirds of companies (37 of 55) provided information regarding the effect of changes to privacy documents (either the PP or ToS), all of which reserved the right to modify their privacy documents. Surprisingly, very few companies provided for individualized consumer notification of any potential changes. Instead, the majority of companies simply stated that any changes to the policy would be reflected on their website, and in some cases, the consumer was encouraged to routinely re-read the policy documents in order to keep themselves apprised of the changes. Companies either stated that consumers would be bound by the new terms immediately or after a specified time period, generally around thirty days. A small minority of companies stated that a consumer *may* be personally notified of changes via email. However, this provision commonly included a qualifying statement that the consumer would only be notified of "material" or "substantial" changes to the policies, leaving open the possibility that notification via the website would be sufficient.

B. Collection of Genetic Information

1. Information Regarding the Testing Laboratory

We next examined what the documents told consumers about the collection of genetic information, with a focus on information regarding the testing laboratories, the fate of a consumer's physical sample, and retention of the resulting genetic data. We analyzed only the policies of those companies that offered genetic testing services of some kind (49 of 55). The remaining six companies offered only analysis of genetic data previously obtained from another company, usually for ancestry purposes, and were therefore excluded from this analysis.

Fifty-seven percent (57%) of companies (28 of 49) provided some information to the consumer about what information was shared with the laboratory or what procedure, if any, was used to safeguard the informa-

66 Subsequent correspondence with company representatives led to the provision of an additional thirteen policy documents that were not readily accessible on company websites. These documents were generally short consent forms included within the testing kit (generally seeking registration information alongside an acknowledgement that the consumer understood the terms and conditions associated with their utilization of the test) as opposed to substantive policy documents. Therefore, these documents were excluded from further analysis and are not included in the numbers presented in this study.

tion during this process. However, the quality and quantity of information varied greatly: the majority of companies simply provided vague commitments to security or confidentiality at the testing facilities (e.g., stating that the testing facility was secure or that laboratory employees were bound by confidentiality agreements). Only 39% of companies (11 of 28) stated that they took steps to remove personally identifiable information from a consumer's sample before sending the sample to an affiliated laboratory for testing (i.e. identifying the sample with only a unique barcode or by generating a fictitious surname for testing). The remaining companies appeared to send both the sample and at least some personally identifiable information to the testing laboratory. Twenty-nine percent (29%) of companies (8 of 28) made statements about using, or striving to use, only certified or accredited laboratories. This generally consisted of statements about compliance under CLIA or references to accreditation by organizations such as the American Association of Blood Banks (AABB) or the International Organization for Standardization (ISO).

2. Fate of a Consumer's Physical Sample

Only 49% of companies (24 of 49) addressed the fate of a consumer's physical sample (e.g., the buccal swab, saliva sample, and/or the extracted DNA) after it was tested by the company's laboratory. Of these companies, 50% (12 of 24) had a default policy of storing all samples after testing was completed; however, a majority (7 of 12) allowed consumers to opt-out of default sample storage by contacting the company and asking that the sample be destroyed. In contrast, 29% of companies (7 of 24) had a default policy to destroy all samples, although one company provided the consumer with the opportunity to opt-in if they wanted their sample stored indefinitely.

Many companies had policies that did not fit neatly into the above categories but contained caveats or provided additional information about their storage policies. For example, a subset of companies generally stated that although their default policy was to store or destroy the samples, such a step would be carried out according to the laboratory's standard operating procedures or as required by a certifying or accrediting agency. Of the companies that discussed the fate of a consumer's sample, very few distinguished between the physical sample (e.g., the submitted cheek swab or saliva) and the extracted DNA; however, three companies stated that they would destroy the consumer's physical sample but would maintain the extracted DNA indefinitely. One policy stated the company retained sole discretion over the fate of the sample.

3. Retention of Genetic Data

We also examined what information was provided regarding the fate of the genetic data derived from analysis of the physical samples (i.e. the resulting test results or reports). We found that 45% of policies (25 of 55) contained explicit language that indicated that genetic data would be retained indefinitely, or until the consumer requested deletion of the data, while 11% (6 of 55) stated that genetic data would be retained for a finite period of time, ranging from 2 weeks to 7 years. In contrast, 42% of policies (23 of 55) lacked explicit language about how long genetic information would be retained by the company after testing, although many seemed to imply that data would be retained, perhaps indefinitely (i.e. with language about how consumers could request copies of test reports and other information possessed by the company or continue to access this information through the company's website). Twenty-two percent (22%) of companies (12 of 55) provided information regarding the ability of consumers to export raw genetic data or test results possessed by the company.

4. Ability to Delete Retained Genetic Data

The finding that many companies appear to have a default policy of retaining genetic data indefinitely is perhaps not surprising given that many consumers may wish to have continued access to their test results and reports. However, we also examined whether policies provided consumers with the ability to request deletion of retained genetic data should they no longer wish to utilize the service. We found that 44% of companies (24 of 55) addressed consumers' ability to delete their genetic data that a company held in its possession: 71% of these companies (17 of 24) provided for consumers to delete *some* of the genetic data possessed by the company, 21% (5 of 24) explicitly stated that consumers would be able to delete *all* of the data possessed by the company, and one company explicitly stated that consumers would not be able to delete any of their genetic data. Reasons given for the inability to delete all genetic data included the fact that the data may have been previously shared with third parties or de-identified/aggregated for internal or external research activities, thereby making complete deletion difficult or impossible.

5. Provisions Regarding Minors

Scholars, medical professionals, and professional organizations have warned of the legal, ethical, and psychological concerns associated with genetic testing of children and adolescents.[67] We found that 65% of

[67] Jeffrey R. Botkin et al., *Points to Consider: Ethical, Legal, and Psychosocial Implications of Genetic Testing in Children and Adolescents*, 97 AM. J. HUM. GENETICS 6 (2015);

companies (36 of 55) had policy documents that contained specific provisions pertaining to the use of the service by minors. Of those companies, 44% (16 of 36) allowed a parent or guardian to consent to their child's use of the service, while 17% (6 of 36) explicitly stated that the service was not intended for minors, with or without parental consent. One-third (33%) of companies (12 of 36) contained ambiguous provisions that left unclear whether a parent or guardian could consent to the use of a service by a child, and two companies had policy documents that appeared to contradict each other on whether a parent or guardian could consent to the use of the service. Finally, those companies that had policies directed toward children were not consistent in their definition of minors, adopting different age cut-offs (e.g., 18, 16, or 13) for use of their services, either with or without a parent.

C. *Use of Genetic Information*

We next analyzed the information that companies provided to consumers regarding internal uses of the consumer's genetic data by the company. Seventy-one percent (71%) of companies (39 of 55) provided information that indicated a consumer's genetic data could be used internally by the company for purposes other than providing the results to the consumer, such as to analyze or improve the quality of the company's services or to develop new products or services. Sixty-two percent (62%) of companies with provisions regarding potential uses of a consumer's data (24 of 39) explicitly stated that a consumer's genetic data could be used for internal research and development activities.

1. Ownership and Commercialization of Genetic Data

Given the secondary value of genetic information (i.e. in third-party research and internal research and development), we also examined what information was provided regarding the ownership of submitted genetic material or the genetic data generated as a result of the genetic testing or analysis service, including who retained the rights to, and profits derived from, any commercialization of that genetic information. We found that the majority (73%) of policies (40 of 55) did not explicitly address ownership of genetic material or the resulting data, nor did they discuss licensing or commercialization of that data. However, 18% of companies (10 of 55) explicitly stated that *the company* retained the right to commercialize the consumer's genetic data, nine of which added that the consumer would not receive any personal benefit from this commercialization. Thirteen-percent (13%) of companies (7 of 55) explicitly stated

Ellen Wright Clayton et al., *Addressing the Ethical Challenges in Genetic Testing and Sequencing of Children*, 14 AM. J. BIOETHICS 3 (2014).

that *the consumer* retained ownership of their genetic material or the resulting data. However, five of these companies then went on to reserve the rights to any commercial products generated from that genetic material or the resulting data, generally through a nearly unlimited, transferrable license.

2. Security of Data, Data Breaches and Consumer Notification

Given the sensitive nature of genetic information and the possible consequences of unauthorized disclosure, we also wanted to find out what information was provided to consumers regarding the security of their genetic data. We found that 89% of companies (49 of 55) made broad or vague commitments to the security of a consumer's genetic data and 31% (17 of 55) made general references to encryption, but only a third provided a detailed description of the security protocols or procedures in place to safeguard a consumer's data. Surprisingly, 95% of companies (52 of 55) provided no information regarding how the company would deal with a security breach or whether an affected consumer would be notified. Of the 5% of companies (3 of 55) that provided for consumer notification in the event of a security breach, only two stated definitively that consumers *would* be notified, while one stated that consumers *may* be notified at the discretion of the company.

3. Discussion of Risks and Limitations of Genetic Testing

Only with an awareness of the risks and limitations of genetic testing can a consumer make an informed decision about whether to undergo such testing.[68] We found that two-thirds (67%) of companies (37 of 55) discussed potential risks to the consumer associated with utilizing their genetic testing or analysis services, while the remaining companies provided no information. Risks that were commonly discussed included the implications of disclosure of results to third parties and the potentially unwelcome information that genetic testing could reveal about a consumer or a consumer's family relationships. Only 20% of companies (11 of 55) discussed the potential risks of disclosure of genetic information to insurers or employers.

We found that two-thirds (67%) of companies (37 of 55) discussed the limitations of the genetic testing or analysis service(s) being offered. These disclosures generally took the form of broad disclaimers about the accuracy of the tests, their underlying analytical or clinical validity, or statements that the tests were not intended to diagnose or treat a particular disease. Eighteen percent (18%) of companies (10 of 55) did not dis-

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[68] Amanda Singleton et al., *Informed Choice in Direct-to-Consumer Genetic Testing (DTCGT) Websites: A Content Analysis of Benefits, Risks, and Limitations*, 21 J. OF GENETIC COUNSELING 433 (2012).

cuss either the potential risks or limitations of the genetic testing or analysis services being offered.

4. References to Federal or State Law

Nearly every company made vague references to potentially applicable laws in their policy documents (e.g., with phrases such as "all applicable laws") but only 55% (30 of 55) specifically referenced potentially relevant federal or state laws. The most commonly referenced federal laws were GINA (nine companies),[69] CLIA (three companies), HIPAA (two companies),[70] the Federal Arbitration Act (two companies), and the Federal Children's Online Privacy Protection Act of 1998 (two companies). The Department of Commerce's EU-US Privacy Shield Framework,[71] which governs the collection, use, and retention of personally identifiable information from the European Union, was the most frequently mentioned federal regulation (seven companies). In addition, one company made reference to regulation by the FDA, and one company made reference to regulation by the FTC.

With the exception of their treatment of GINA, most companies merely cited the above laws or agencies, providing little or no information regarding their scope or potential applicability to DTC-GT. In contrast, the majority of policies with references to GINA generally provided warnings of its uncertain scope and informed consumers that its protections did not apply to discrimination by life, disability, or long-term care insurance providers. A small subset of companies referenced state laws governing genetic data or DTC-GT:[72] four companies referenced state limitations on DTC-GT testing in New York, three referenced regulations in California, and one referenced limitations in the state of Alaska.

D. Sharing of Genetic Information

Finally, we examined what information was provided to consumers regarding the sharing of their genetic information with third-parties for commercial or research purposes (sharing with laboratories is addressed *supra* in the context of collection of genetic data). Twenty-three percent (23%) of companies (12 of 53) explicitly stated that genetic information would never be shared with third parties for any purpose, 27% of companies (15 of 55) contained similar language but with the caveat that the

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69 *See* GINA, *supra* note 24.

70 *See* HIPAA, *supra* note 25.

71 Martin A. Weiss & Kristin Archick, *US-EU Data Privacy: From Safe Harbor to Privacy Shield*, CONG. RES. SERV. REP. (May 19, 2016), https://fas.org/sgp/crs/misc/R44257.pdf.

72 *See, e.g., Survey of DTC Statutes and Regulations*, *supra* note 23 (providing an overview of laws and regulations governing direct-to-consumer genetic testing).

information would not be shared with a third party unless a consumer explicitly requested the information be shared or gave consent, and 9% of companies (5 of 55) provided no information regarding the sharing of genetic data with third parties. The remaining 42% of companies (23 of 55) provided at least some information regarding potential disclosures of a consumer's genetic information to third parties under certain circumstances, as discussed in additional detail below. However, policies varied considerably in the amount of details that were provided to the consumer regarding third-party sharing, and two companies had policy documents that appeared to provide conflicting information regarding whether data would be shared with third parties.

1. Sharing of Personally Identifiable Genetic Data and De-identified Genetic Data

Of the twenty-three companies with provisions permitting some third-party sharing, 70% (16 of 23) addressed sharing of personally identifiable genetic data (i.e., genetic data coupled with registration data). Such data was typically shared only with third-party partners or affiliates required to provide the services to the consumer. The provisions disclosing this limitation, however, were often vague or ambiguous; no company provided a specific or exhaustive list of exactly which third parties would receive access to the data, or for what specific purposes. These provisions may simply reflect a company's intention to share data with the entities required to deliver the test results to the consumer, such as testing laboratories or business partners which might assist in the subsequent analysis or storage of the data, but the scope of sharing was often unclear.

Seventy-eight (78%) of companies with data sharing provisions (18 of 23) provided for sharing of genetic data with third parties in de-identified (i.e., stripped of registration information) or aggregated form without additional consent from the consumer. In contrast to the sharing of personally-identifiable data, provisions governing sharing of data in de-identified or aggregated form were generally not accompanied by clauses indicating that sharing was limited to affiliates, subsidiaries, or third-party partners required to provide the services to the consumer.

2. Sharing with Third Party Researchers

Twenty-nine percent (29%) of companies (16 of 55) had policies regarding the sharing of genetic information with third-parties for external research use (internal research by the company is discussed *supra*). Companies that had such provisions primarily offered ancestry or lifestyle and wellness testing, as opposed to family relationship and paternity testing, which generate less comprehensive genetic profiles that typically

have limited utility in research.[73] Sixty-three percent (63%) of the companies (10 of 16) that discussed sharing with researchers required the consumer to opt-in for their data to be used for third party research, while 31% (5 of 16) stated that a consumer's data would be used for third-party research by default, and one company had an unclear policy. Two of the five companies that provided for default research sharing allowed consumers to opt-out, while the remaining three were unclear about whether a consumer could opt-out of research. Of the companies with provisions governing third-party research, 56% (9 of 16) discussed the risks to the consumer of participating in such research, 63% (10 of 16) discussed the societal benefits, and 38% (6 of 16) did not discuss either the risks or benefits.

3. Fate of Data in the Event of Sale or Bankruptcy

The DTC-GT industry is rapidly evolving: companies are constantly entering the market or going out of business, and mergers and acquisitions are common.[74] However, we found that only 36% of companies (20 of 55) had provisions regarding the fate of a consumer's data in the event of a sale, merger, or bankruptcy. All twenty companies stated that the consumer's data would, or may, be treated as an asset that would be transferred to the acquiring entity. Just over half of these companies (13 of 20) stated that the acquiring entity would be bound by the privacy practices in effect at the time of acquisition, as reflected in the companies' privacy documents.

4. Sharing with Law Enforcement or Governmental Agencies

Given the expanded collection and use of genetic data by law enforcement and other governmental agencies, we also examined the information companies provided about how they would deal with such requests. We found that over two-thirds (69%) of companies (38 of 55) addressed the sharing of information with law enforcement or other government authorities, but policies varied significantly in the amount of information provided to the consumer about the process. The majority of companies simply stated that personal information may be disclosed "as required by law" without further explanation. In addition, many policies did not limit disclosure to only lawful governmental requests, such as those required by subpoena, court order, regulation or statute, but also contained catch-all provisions that provided for disclosure to any third-party under broad circumstances, including: to protect the rights of the company, other users, or the public, or to enforce the company's terms

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[73] *What are the Types of Genetic Tests?*, NIH GENETICS HOME REFERENCE (last updated Jan. 23, 2018), https://ghr.nlm.nih.gov/primer/testing/uses.

[74] Phillips, *supra* note 6.

and conditions. Only 11% of companies with policies governing law enforcement disclosure (4 of 38) stated that they would attempt to notify the consumer if they were the subject of such a request, if such notification was permitted by law.

E. Eight-Month Follow-up: Modifications to Privacy Documents

This study revealed that nearly all DTC-GT companies retain the right to change their privacy documents at any time, often without individualized notice to the consumer. In an attempt to assess the frequency with which companies actually modify their privacy documents, we reexamined the readily accessible policy documents of those companies that were still operating eight months after our initial document collection. We found that six companies no longer appeared to be operating, or had temporarily ceased taking orders, as evidenced by inactive websites or inoperative email addresses and phone numbers. In addition, three companies were now operating under new names or had merged with another entity. Of the companies still in operation, we found that 22% (20 of 90) had made at least one change to their privacy documents. While many of the changes to these policies appeared to be relatively minor or insignificant, 13% of companies (12 of 90) had made substantial changes to their existing policies or had made additional policy documents available on their websites.

IV. AN ANALYSIS OF THE RESULTS UNDER THE FTC'S PRIVACY FRAMEWORK

Individuals contemplating use of DTC-GT and analysis services in the United States are confronted with a dizzying array of companies offering an ever-growing number of products, many of which provide little or no information to consumers regarding how their genetic data will be treated by the company.[75] The privacy concerns associated with the use of these services will only increase as genetic data becomes more ubiquitous: the current cost of sequencing an entire human genome is roughly $1,000, a bargain when compared to the 2006 price of $10 million, and it is expected to fall to roughly $100 within the next decade.[76]

Just weeks after Senator Schumer called on the FTC to increase its oversight of the DTC-GT industry, the agency released a December 2017 consumer bulletin titled, "DNA Test Kits: Consider the Privacy Implica-

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[75] *Direct-to-Consumer Genetics Tests*, FTC CONSUMER INFORMATION, https://www.consumer.ftc.gov/articles/0166-direct-consumer-genetic-tests.

[76] Erika Check Hayden, *The $1,000 Genome*, 507 NATURE 294 (2014); Matthew Herper, *Illumina Promises To Sequence Human Genome For $100—But Not Quite Yet*, FORBES (Jan. 9, 2017, 5:30 PM), https://www.forbes.com/sites/matthewherper/2017/01/09/illumina-promises-to-sequence-human-genome-for-100-but-not-quite-yet/#42c65be6386d.

tions."[77] The FTC recommended that consumers "comparison shop about privacy," "choose [their] account options carefully," and "recognize the risks" associated with undergoing DTC-GT in general.[78] The FTC also encouraged consumers to report a genetic testing company that "isn't living up to its promises" using their online Complaint Assistant, a portal that allows consumers to file complaints on topics ranging from identity theft to unwanted telemarketing calls.[79]

Senator Schumer is not the first to look to the FTC as a source of additional oversight for the DTC-GT industry. The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), established in 2002 "as a public forum for deliberation on the broad range of policy issues raised by the development and use of genetic tests," has also called for expanded oversight by federal agencies, including the FTC.[80] In its 2010 report on DTC-GT, the Committee identified gaps in the current regulatory framework and recommended, *inter alia*, that "[a] joint Health and Human Services (HHS)-Federal Trade Commission (FTC) task force should be established as soon as possible and convened as needed to provide the necessary expertise to develop guidelines for FTC to use as a basis to evaluate claims made by companies providing DTC genetic services."[81] The Committee also identified "other issues that need further study by SACGHS and/or other appropriate Federal agencies," including "[the] extent to which DTC services are being used for surreptitious genetic testing, the implications of DTC genetic testing for children, the psychosocial impact of DTC genetic testing, [and] research use of specimens and data obtained through DTC genetic testing . . . ."[82]

However, in the absence of comprehensive privacy legislation, the FTC has been left to operate within the current self-regulatory framework that governs much of the online commercial marketplace, including

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77 *See* FTC: *DNA Test Kits, supra* note 42.

78 *Id.*

79 *Id.*

80 Sec'y's Advisory Comm. on Genetics, Health, & Soc'y, U.S. Dep't of Health & Hum. Servs., U.S, System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services, 70 FR 17085 (2005), https://www.federalregister.gov/documents/2005/04/04/05-6614/secretarys-advisory-committee-on-genetics-health-and-society-office-of-the-secretary-hhs-request-for; *see also* Andrea Ferreira-Gonzalez et al., *U.S. System of Oversight for Genetic Testing: A Report from the Secretary's Advisory Committee on Genetics, Health and Society*, 5 PERSONALIZED MED. 5 521–528 (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2873211/.

81 SEC'Y'S ADVISORY COMM. ON GENETICS, HEALTH, & SOC'Y, U.S. DEP'T OF HEALTH & HUM. SERVS., DIRECT-TO-CONSUMER GENETIC TESTING (Apr. 2010), https://osp.od.nih.gov/wp-content/uploads/2013/11/SACGHS_DTC_Report_2010.pdf.

82 *Id.*

the DTC-GT industry.[83] In a 2000 report to Congress regarding privacy in the online marketplace in general, the FTC noted that "self-regulatory initiatives to date fall far short of broad-based implementation of effective self-regulatory programs [and] that such efforts alone cannot ensure that the online marketplace as a whole will emulate the standards adopted by industry leaders."[84] The FTC recommended that Congress enact legislation that would, "set forth a basic level of privacy protection for consumer-oriented commercial Web sites [and] basic standards of practice for the collection of information online," including a requirement that "[c]onsumer-oriented commercial Web sites that collect personal identifying information from or about consumers online . . . comply with the four widely-accepted[85] fair information practices," which it delineated as follows:

1. **Notice** - Web sites would be required to provide consumers clear and conspicuous notice of their information practices, including what information they collect, how they collect it (e.g., directly or through non-obvious means such as cookies), how they use it, how they provide Choice, Access, and Security to consumers, whether they disclose the information collected to other entities, and whether other entities are collecting information through the site.
2. **Choice** - Web sites would be required to offer consumers choices as to how their personal identifying information is used beyond the use for which the information was provided (e.g., to consummate a transaction). Such choice would encompass both internal secondary uses (such as marketing back to consumers) and external secondary uses (such as disclosing data to other entities).
3. **Access** - Web sites would be required to offer consumers reasonable access to the information a Web

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83 Christy Gamble et al., The Future of Our Roots: Direct to Consumer Genetic Testing & Privacy Implications for People of Color (unpublished comment), *available at* https://www.ftc.gov/system/files/documents/public_comments/2017/11/00041-141900.pdf.

84 U.S. FED. TRADE COMM'N, PRIVACY ONLINE: FAIR INFORMATION PRACTICES IN THE ELECTRONIC MARKETPLACE (2000) [hereinafter PRIVACY ONLINE], https://www.ftc.gov/sites/default/files/documents/reports/privacy-online-fair-information-practices-electronic-marketplace-federal-trade-commission-report/privacy2000.pdf.

85 While not legally binding, these principles form the basis of the privacy framework in the United States and are incorporated into several U.S. laws, including the Privacy Act of 1974, 5 U.S.C. § 552a (1974) and the Electronic Privacy Communications Act of 1986, 18 U.S.C. § 2510-22 (1986). The FTC has previously questioned whether it possesses the authority to force compliance with these principles in the form of mandated disclosures.

site has collected about them, including a reasonable opportunity to review information and to correct inaccuracies or delete information.

4. **Security** - Web sites would be required to take reasonable steps to protect the security of the information they collect from consumers.[86]

The Fair Information Practice Principles [FIPPs] have been articulated in numerous ways by various government agencies, with the FTC's four factor interpretation being among the most limited and concise.[87] However, in the years following the 2000 report, the FTC appeared to shift to a "harm-based approach": "[r]ather than emphasizing potentially costly notice-and-choice requirements for all uses of information, [the agency] targeted practices that caused or were likely to cause physical or economic harm, or "unwarranted intrusions in [consumers'] daily lives."[88] Ultimately, the FTC issued another major privacy report in 2012, in which it drew upon the FIPPs to craft an updated "Privacy Framework" that was "intended to articulate best practices for companies that collect and use consumer data" and "to assist Congress as it considers privacy legislation."[89] While noting that "the framework [was] not intended to serve as a template for law enforcement actions or regulations under laws currently enforced by the FTC,"[90] the agency urged companies to adopt the following three practices:

> **1) PRIVACY BY DESIGN** Companies should promote consumer privacy throughout their organizations

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86 *See* PRIVACY ONLINE, *supra* note 84, at iii.

87 A previous version of the FIPPs, articulated by the FTC in a 1998 report to Congress, included a fifth principle: "enforcement/redress." However, this principle was omitted in the agency's subsequent report to Congress in 2000, resulting in the four factor interpretation referenced in this study. U.S. FED. TRADE COMM'N, PRIVACY ONLINE: A REPORT TO CONGRESS 10 (1998) (including "enforcement/redress" as a fifth FIPP and stating that "[a]bsent an enforcement and redress mechanism, a fair information practice code is merely suggestive rather than prescriptive, and does not ensure compliance with core fair information practice principles."), *available at* https://www.ftc.gov/sites/default/files/documents/reports/privacy-online-report-congress/priv-23a.pdf; *See also* Robert Gellman, Fair Information Practices: A Basic History (unpublished manuscript), *available at* bobgellman.com/rg-docs/rg-FIPs history .pdf; Fred H. Cate, *The Failure of Fair Information Practice Principles*, *in* Consumer Protection in the Age of the Information Economy 341–78 (2006), https://ssrn.com/abstract=11569 72; Brookman, *supra* note 40, at 357.

88 U.S. FED. TRADE COMM'N, PROTECTING CONSUMER PRIVACY IN AN ERA OF RAPID CHANGE: PRELIMINARY FTC STAFF REPORT 9 (2010), *available at* https://www.ftc.gov/sites/default/files/documents/reports/federal-trade-commission-bureau-consumer-protection-preliminary-ftc-staff-report-protecting-consumer/101201privacyreport.pdf.

89 U.S. FED. TRADE COMM'N, PROTECTING CONSUMER PRIVACY IN AN ERA OF RAPID CHANGE (2012) [hereinafter PROTECTING CONSUMER PRIVACY], https://www.ftc.gov/sites/default/files/documents/reports/federal-trade-commission-report-protecting-consumer-privacy-era-rapid-change-recommendations/120326privacyreport.pdf.

90 *Id.* at vii.

and at every stage of the development of their products and services.

A. The Substantive Principles: Companies should incorporate substantive privacy protections into their practices, such as data security, reasonable collection limits, sound retention and disposal practices, and data accuracy.

B. Procedural Protections to Implement the Substantive Principles: Companies should maintain comprehensive data management procedures throughout the life cycle of their products and services.

2) SIMPLIFIED CONSUMER CHOICE Companies should simplify consumer choice.

A. Practices That Do Not Require Choice: Companies do not need to provide choice before collecting and using consumer data for practices that are consistent with the context of the transaction or the company's relationship with the consumer, or are required or specifically authorized by law.

B. Companies Should Provide Consumer Choice for Other Practices: For practices requiring choice, companies should offer the choice at a time and in a context in which the consumer is making a decision about his or her data. Companies should obtain affirmative express consent before (1) using consumer data in a materially different manner than claimed when the data was collected; or (2) collecting sensitive data for certain purposes.

3) TRANSPARENCY Companies should increase the transparency of their data practices.

A. Privacy notices: Privacy notices should be clearer, shorter, and more standardized to enable better comprehension and comparison of privacy practices.

B. Access: Companies should provide reasonable access to the consumer data they maintain; the extent of access should be proportionate to the sensitivity of the data and the nature of its use.

C. Consumer Education: All stakeholders should expand their efforts to educate consumers about commercial data privacy practices.[91]

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[91] *Id.* at vii–viii.

Although Congress never acted[92] on the FTC's recommendation to codify the FIPPs or the agency's proposed Privacy Framework, both frameworks nonetheless serve as a useful metric by which to analyze current practices in the DTC-GT industry. Given the lack of comprehensive privacy legislation and a history of reliance on companies operating online to self-regulate, it is perhaps not surprising that our analysis revealed a tremendous amount of variation in the complexity and scope of company privacy documents and that many companies do not do a good job meeting any of the four FIPPs or the FTC's proposed Privacy Framework. Indeed, we found that over 40% of companies either had no readily accessible policy documents or had policies that did not appear to govern genetic data. These "web-only" policies resembled those that might be found on any website and did not provide any additional information about the data practices that governed the company's genetic testing or analysis services. While some of these companies might provide additional information to consumers upon purchase of the test kit or upon signup for the service, this subsequent disclosure would not allow a consumer to make an informed decision before initiating a purchase.

Of those companies with policies governing genetic data, many fell short on each of the first three FIPPs (Notice, Choice, and Access) and also failed to meet the standards outlined in the FTC's Privacy Framework (Privacy by Design, Simplified Consumer Choice, and Transparency). Many did not provide detailed notice about their various practices, thus diminishing the extent to which consumer consent was informed, if consent was explicitly sought at all, and the extent to which consumers meaningfully participated in the decision as to what happens with their data.

Most importantly, with respect to transparency and providing adequate notice, we found that few companies provided information about testing laboratories or the fate of a consumer's sample after testing: only about one-fifth provided such information. This finding is consistent with a recent survey of Canadian consumers and prospective consumers of DTC-GT, which found that many consumers were unsure about the fate of their sample.[93] More troubling, the study also showed that consumers commonly expected that their sample would be destroyed after testing.[94] We found this expectation to be at odds with the policies we studied, as the majority of companies that addressed the fate of samples stated that they would store a consumer's sample by default.

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92 Natasha Singer, *Why a Push for Online Privacy is Bogged Down in Washington*, N.Y. TIMES, Feb. 28, 2016, https://www.nytimes.com/2016/02/29/technology/obamas-effort-on-consumer-privacy-falls-short-critics-say.html.

93 Christofides & O'Doherty, *supra* note 12, at 115–16.

94 *Id.*

Further, companies offering primarily family relationship testing, for example, paternity testing, typically provided even less information to consumers, a particularly troubling finding given the prevalence of companies offering this category of testing in the United States. This deficiency may be partially attributable to the limited genetic profile that is typically generated by family relationship tests, as compared to ancestry or lifestyle and wellness testing; indeed, previous studies have chosen to exclude this category of companies from analysis for this reason.[95] However, our analysis reveals that a number of companies offering primarily family relationship testing are expanding their services to include ancestry or lifestyle and wellness tests that tend to generate a much more expansive genetic profile.[96] Furthermore, as the price of sequencing continues to fall and the demand for genetic data increases, it is not inconceivable that the future value of genetic data may outweigh the costs associated with re-testing stored samples. Indeed, several companies examined in this study explicitly stated that they reserved the right to conduct additional testing on a consumer's sample as new technologies became available.

While we found that established industry leaders tended to have very comprehensive policies that provided consumers with a fairly complete picture of how their genetic data would be collected, used, and shared with third parties, their practice was the exception. Furthermore, even these fairly comprehensive policies were often difficult to understand or omitted specific details in some areas. For example, no company provided a specific, let alone exhaustive, list of the third parties with whom data would be shared and very few elaborated on the protocols in place to de-identify, aggregate, or secure genetic data.

Our study provides little information about how companies implement the fourth FIPP, Security, or comply with the charge of the FTC to ensure "Privacy by Design." However, we did find that many companies failed to provide meaningful information to consumers concerning the security of genetic data and how the company would deal with potential security breaches. While nearly every company that we examined made broad assurances about the security of a consumer's genetic data or referenced encryption, very few provided specific information regarding their security protocols or procedures: only 3 of 90 companies, less than 4%, provided information about the procedures governing breaches of a consumer's genetic data or provided for consumer notification in the event of a breach. The common failure to provide adequate information about this aspect of company practice suggests that, at the least, companies do not feel the need to provide consumers with information about these mat-

95 Laestadius, et al., *supra* note 19, at 514.

96 *See* NIH GENETICS HOME REFERENCE, *supra* note 73.

ters. At worst, it suggests that companies are lax about security, or perhaps lack robust protocols and procedures to deal with potential data breaches. Given the sensitive nature of genetic information and the possible consequences of unauthorized disclosure, the absence of this information represents a serious gap in current policies.

Another troubling area of the DTC-GT industry, highly relevant to the Notice, Choice, and Access FIPPs, is the emergence of companies providing surreptitious testing services.[97] Nearly one-third of the companies examined in this study appeared to permit, or even encourage, consumers to submit the genetic material of others without their consent, often providing these services alongside their family relationship tests. It is unclear how many individuals take advantage of these surreptitious testing services, and if they do, how often they first obtain consent from the person whose genetic material they submit. The overwhelming majority of companies offering surreptitious testing services did not have policies that discussed this type of testing or the submission of another's sample without their consent, and no company specifically referenced potentially applicable laws regarding the collection or analysis of another individual's genetic material without their consent.[98]

Also relevant to the Choice and Access FIPPs, as well as to the transparency aspect of the Privacy Framework, is whether providing additional information to consumers regarding the collection, use, and sharing of their genetic data would translate into better informed consumers or alter their behavior.[99] The majority of companies analyzed in this study had multiple privacy documents, with the company's privacy practices governing genetic data usually spread, sometimes arbitrarily, between the documents. It is unclear how many consumers take the time to read through a company's privacy documents before purchasing,[100] and even if they do, the extent to which they understand those documents.[101] Further, while two-thirds of companies (67%; 37 of 55) provided contact information in their privacy documents in the event of questions, our subsequent communication with customer service representatives revealed that, with the exception of industry leaders, these representatives

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97 *See* Nicole Strand, *Shedding Privacy Along with our Genetic Material: What Constitutes Adequate Protection against Surreptitious Genetic Testing?* 18 AMA J. ETHICS 264 (2016); Colin McFerrin, *DNA, Genetic Material, and a Look at Property Rights: Why You May Be Your Brother's Keeper*, 19 TEX. WESLEYAN L. REV. 967 (2012).

98 *Id.*

99 Aleecia M. Mcdonald et al., *A Comparative Study of Online Privacy Policies and Formats*, PROC. 9TH INT'L SYMP. ON PRIVACY ENHANCING TECH., (2009) at 37.

100 George R. Milne & Mary J. Culnan, *Strategies for Reducing Online Privacy Risks: Why Consumers Read (or Don't Read) Online Privacy Notices*, 18 J. INTERACTIVE MARKETING 15 (2004).

101 Lior Jacob Strahilevitz & Matthew B. Kugler, *Is Privacy Policy Language Irrelevant to Consumers?*, 45 J. LEGAL Stud. 69 (2016).

were generally poorly equipped to handle privacy-related inquiries. Thus, provision of more detailed explanations about practices regarding the collection, use, and sharing of genetic data might not necessarily improve consumer understanding or the consent process. At the same time, some research indicates that, "[w]hen such information is made available, consumers tend to purchase from online retailers who better protect their privacy . . . [and] that when privacy information is made more salient and accessible, some consumers are willing to pay a premium to purchase from privacy protective websites."[102]

Finally, relevant to the Transparency and Simplified Consumer Choice aspects of the Privacy Framework, as well as the Notice, Choice, and Access FIPPs, is our finding that even if consumers initially read and understand a company's privacy documents, the majority are subject to change at any time by the company. While over two-thirds of companies provided information about the procedure for modifying their privacy documents, very few provided for individualized notification of the consumer in the event of changes. Instead, the majority of companies stated that changes to the policy would be reflected only on their website and that the consumer would be bound by those changes either immediately or after a specified period of time. This practice raises serious concerns about expanded uses of a consumer's data that were not initially anticipated and the extent to which consumers understand and consent to those new uses.

It is important to note that, given the paucity of relevant law and the ambiguity of the law that does exist, the analysis criteria used in this study do not necessarily reflect US federal or state legal provisions governing DTC-GT companies. Although we framed our discussion in terms of the FIPPs and the FTC's proposed Privacy Framework and suggested that many policies did not adequately address them under the current regulatory landscape, a company may not be required to include in their privacy documents the information or provisions discussed in this study.[103] Furthermore, the information, or lack thereof, provided in policy documents might not necessarily reflect actual practices, which are difficult, if not impossible, to assess. However, this Article's description of the information that is provided to consumers in the absence of legal requirements should be helpful in determining what additional regulation, if any, may be appropriate in this arena.

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[102] Janice Y. Tsai et al., *The Effect of Online Privacy Information on Purchasing Behavior: An Experimental Study*, 22 INFO. SYS. RES. 254, 254 (2011).

[103] *See* PRIVACY ONLINE, *supra* note 84.

CONCLUSIONS

We observed tremendous variability across the DTC-GT industry in the quantity and quality of information provided to consumers concerning the collection, use, and sharing of their genetic data. The majority of companies that we surveyed failed to live up to the basic privacy principles embodied in the four Fair Information Practice Principles (Notice, Choice, Access, and Security) or Privacy Framework (Privacy by Design, Simplified Consumer Choice, and Transparency) endorsed by the FTC. Over one-third of companies had no policy documents or chose to rely on policies that were intended to govern access to the website but provided no additional information about the privacy practices that govern their genetic testing or analysis services. With a few exceptions, even policies that governed genetic data provided very little information regarding the collection and sharing of a consumer's genetic data. These results indicate that a typical consumer is likely not provided with sufficient information to make an informed decision regarding whether to undergo genetic testing with a particular DTC-GT company.

In the end, this study suggests that the privacy policies of genetic testing companies are evidence of a larger problem with e-commerce, big data, and the internet of things. Arguably all of these industries might benefit from enhanced consumer privacy protections. The question then becomes one of genetic exceptionalism: whether genetic data should garner more protection than other types of electronic data, such as a consumer's browsing habits, shopping patterns, or the plethora of location and lifestyle data generated by cell phone apps and fitness wearables. The goal should be achieving the right balance between consumer protection and informed consent so that privacy can be protected without unduly inhibiting the personal and research benefits that come from the free flow of genetic information.