# Family Ties: The Familial Privacy Implications of Direct-to-Consumer Genetic Testing

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## ABSTRACT

Over the last fifteen years, direct-to-consumer genetic testing has evolved from an amusing consumer service to a legitimate source of health information. Modern genetic testing services collect and interpret a vast amount of personal health information, with results ranging from an individual's sweet versus salty taste preference to his or her genetic predisposition to develop certain diseases. However, not only do these services reveal the personal health information of the individual who provided his or her genetic sample, but it also implicitly reveals the personal health information of that individual's genetic family members, who may share up to fifty percent of the same genetic makeup. Even anonymous genetic information is potentially retraceable to its original owner using publicly accessible genetic testing services and databases. This Article addresses the lack of protections afforded to the family members of individuals who use direct-to-consumer genetic services in the event that their personal health information is implicitly disclosed by a genetic testing service through adhesion contracts, mergers, or a data breach. This Article specifically discusses common law causes of action available to third-party family members, including intrusion upon seclusion, rights as third-party beneficiaries to a contract, negligent infliction of emotional distress, and class action suits. In addition to these common law causes of action, the federal government should also address potential third-party privacy violations resulting from the implicit disclosure of a family member's genetic information. Specifically, direct-to-consumer genetic testing services should be regulated as a covered entity under the Health Information Portability and Accountability Act and the public disclosure of genetic information should be strictly prohibited, regardless of whether such information is considered "anonymous" or not.

## I. INTRODUCTION

Direct-to-consumer (DTC) genetic testing is a popular trend in the United States.[1] Millions of Americans have sent saliva samples to private companies, such as 23andMe, seeking to discover a long lost relative or from what country their ancestors

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[1] Megan Molteni, *Ancestry's Genetic Testing Kits Are Heading for Your Stocking This Year*, WIRED (Dec. 1, 2017), https://www.wired.com/story/ancestrys-genetic-testing-kits-are-heading-for-your-stocking-this-year/ [https://perma.cc/2N9W-UKUW].

emigrated.[2] Due to its multitude of informative features, these companies' consumer base has skyrocketed. DTC genetic testing companies have sold 26 million[3] genetic testing kits in the United States, with over 12 million people contributing their DNA to 23andMe alone.[4] However, the numerous benefits of the mass collection and digitalization of genetic data come with a comparable number of risks.

There are countless entities that could have an interest in the genetic data that has been collected and interpreted by 23andMe and other DTC testing companies. In 2014, the Federal Trade Commission issued a report that analyzed nine data brokers, or "companies that collect consumers' personal information and resell or share that information with others."[5] Social media giants, such as Facebook, have partnered with these data brokers to "allow precision advertising targeting of its users based on the activities they perform" while on and off their website.[6] What would happen if a data broker or private company known for accumulating data and information about its consumers were to obtain the genetic information of 23andMe's customers without consumer consent? This event could occur in the future through common occurrences, such as through merger and acquisitions, contracts of adhesion, or a data breach. This expansive violation of privacy will not only directly affect those who have voluntarily provided online genetic testing sites with their genetic information, but blood relatives who inherently share similar DNA will be implicitly affected as well.[7]

Modern genomics has now allowed researchers to "fill in the blanks" of a family tree based on one family member's genetic sequence.[8] A notable example that will be discussed in further detail involves the case of the Golden State Killer,[9] where

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[2] *About Us*, 23ANDME, https://mediacenter.23andme.com/company/about-us/ [https://perma.cc/T7QJ-MFBA].

[3] Jessica Bursztynsky, *More Than 26 Million People Shared Their DNA With Ancestry Firms, Allowing Researchers to Trace Relationships Between Virtually All Americans: MIT*, CNBC (Feb. 12, 2019), https://www.cnbc.com/2019/02/12/privacy-concerns-rise-as-26-million-share-dna-with-ancestry-firms.html [https://perma.cc/V49A-KVRG].

[4] *About Us*, 23ANDME, *supra* note 2.

[5] FED. TRADE COMM'N (FTC), DATA BROKERS: A CALL FOR TRANSPARENCY AND ACCOUNTABILITY ii (2014), https://www.ftc.gov/system/files/documents/reports/data-brokers-call-transparency-accountability-report-federal-trade-commission-may-2014/140527databrokerreport.pdf [https://perma.cc/M2PZ-HY9B]; *Id.* at 46 ("Data brokers collect data from commercial, government, and other publicly available sources. Data collected could include bankruptcy information, voting registration, consumer purchase data, web browsing activities, warranty registrations, and other details of consumers' everyday interactions. Data brokers do not obtain this data directly from consumers, and consumers are thus largely unaware that data brokers are collecting and using this information.").

[6] Kalev Leetaru, *The Data Brokers So Powerful Even Facebook Bought Their Data—But They Got Me Wildly Wrong*, FORBES (Apr. 5, 2018), https://www.forbes.com/sites/kalevleetaru/2018/04/05/the-data-brokers-so-powerful-even-facebook-bought-their-data-but-they-got-me-wildly-wrong/#3ae8ab5f3107 [https://perma.cc/4ZJT-TSWK].

[7] Carolyn Y. Johnson, *Even If You've Never Taken a DNA Test, a Distant Relative's Could Reveal Your Identity*, WASH. POST (Oct. 11, 2018), https://www.washingtonpost.com/science/2018/10/11/even-if-youve-never-taken-dna-test-distant-relatives-could-reveal-your-identity/ [https://perma.cc/AV4F-KE75]; Amy Dockser Marcus, *Researchers Identify Relatives from DNA Data Online*, WALL ST. J. (Oct. 11, 2018), https://www.wsj.com/articles/researchers-identify-relatives-from-dna-data-online-1539285736 [https://perma.cc/US4A-WHL8].

[8] Marcus, *supra* note 7.

[9] Avi Selk, *The Ingenious and 'Dystopian' DNA Technique Police Used to Hunt the 'Golden State Killer' Suspect*, WASH. POST (Apr. 28, 2018) https://www.washingtonpost.com/news/true-crime/wp/2018/

investigators were able to solve a cold case after uploading and cross-referencing the genetic material collected at the scene of the crime onto a free, public online genetic database, GEDmatch.[10] It was through the suspected killer's family member on the database that police were eventually able to track down their target.[11]

There have been various academic commentaries regarding the use of genetic information for discriminatory purposes by employers or health care providers, as well as discussions regarding the implications of the use of genetic information by state actors, such as law enforcement, in the pursuit of criminal justice.[12] These topics are not the sole focus of this Article. Rather, this Article seeks to focus on civil remedies and regulatory protections regarding privacy implications arising to familial third parties as a result of the access, sharing, or disclosure of an individual's genetic information.

There is currently a lack of regulatory safeguards to protect individuals from the nonconsensual use and/or obtention of their DNA, and an even further lack of protection when it comes to relatives whose right to genetic privacy will be indirectly affected by the actions of others. Current regulations and legislation, such as the Health Information Portability and Accountability Act (HIPAA), are inadequate in the rapidly evolving field of genomics and data sharing.

Part I of this Article will discuss the relevant federal regulations and laws governing genetic information. Parts II and III will provide background information detailing the origins and evolutions of DTC genetic testing, specifically the private company 23andMe. It will also provide insight in 23andMe's collection, analysis, and storage procedures regarding consumer submitted genetic samples. These sections will further explain how modern research has expanded the impact of the voluntary sharing of genetic information, as the information that is shared with consent by one family member provides information regarding that person's relative, a relative who did not provide consent to the access of his or her genetic information.

Part IV will discuss the potential methods in which individual consumers' genetic information may be made public without their consent, thereby affecting the genetic privacy of their relatives. Part V will discuss the scope of individuals who may claim an actionable harm for the nonconsensual use of their personal health information and DNA, as well as the feasibility of pursuing those claims.

Finally, Part VI will offer broad regulatory guidance under which HIPAA can be expanded to help protect millions of consumers' personal health information that will be implicitly impacted by the sharing and disclosure of genetic information.

## II. BACKGROUND

### A. *Relevant Federal Legislation and Agencies*

There has been a relatively smaller amount of legislation and regulations pertaining to genetic information than in other areas of health information. This may be owed to the controversial concept of "genetic exceptionalism," or the idea that genetic

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04/27/golden-state-killer-dna-website-gedmatch-was-used-to-identify-joseph-deangelo-as-suspect-police-say/ [https://perma.cc/E87D-L97G].

[10] *Id.*

[11] *Id.*

[12] *See infra* note 125.

information is a distinct subset of health information and therefore demands its own context of legislative and regulatory protection.[13] "Virtually all of the recent legislation enacted to deal with genetic privacy and genetic discrimination has been genetic-specific," and the traditionally narrow approach to legislating genetic information has ultimately led to gaps and issues falling outside of that scope.[14] The primary legislation and federal agencies that are relevant to the understanding of DTC genetic testing are the Health Information Portability and Accountability Act (HIPAA), the Genetic Information Nondiscrimination Act (GINA), the Food and Drug Administration (FDA), and the Federal Trade Commission (FTC).

### *i. HIPAA*

Among the several acts and regulatory agencies whose roles must be analyzed regarding the spread of genetic information over the internet, the first is the Health Insurance Portability and Accountability Act (HIPAA). The original purpose of this legislation was to simplify health insurance administration, prevent waste and fraud, and improve accessibility within the health insurance industry.[15]

Surprisingly, not all entities that obtain and control health information are covered subject to enforcement under HIPAA's provisions. HIPAA only applies to "covered entities," which primarily consists of four different types of institutions that deal with health information.[16] First are health care providers, such as doctors, clinics, nursing homes, and pharmacies.[17] The second type of institutions are health plans, such as health insurance companies and government health care programs.[18] The third institution are health care clearinghouses.[19] The last covered entities under HIPAA are business associates (nonmedical professionals who legally obtain and deal with protected health information).[20] Entities and programs not covered under HIPAA may include long term and workers' compensation insurance, gyms and fitness clubs, and

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[13] Ifeoma Ajunwa, *Genetic Testing Meets Big Data: Tort and Contract Law Issues*, 75 OHIO ST. L.J. 1225, 1258 (2014) ("While some argue that genetic information is not exceptional and therefore should not be awarded any special legal concessions, others argue that the diagnostic and predictive nature of genetic information puts it in a genre all by itself when it comes to personal information.").

[14] Ellen Wright Clayton, Barbara J. Evans, James W. Hazel & Mark A. Rothstein, *The Law of Genetic Privacy: Applications, Implications, and Limitations*, 6 J.L. & BIOSCIENCES 1, 8 (2019) ("One of the main reasons for this choice is that genetic-specific laws are necessarily narrower in scope and are thus more likely to garner political support.").

[15] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

[16] 45 C.F.R. § 160.102 (2020).

[17] *Id.* § 160.102(3); *Covered Entities and Business Associates*, U.S. DEP'T HEALTH & HUMAN SERVS., https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html [https://perma.cc/K2HN-HL2A] (last reviewed June 16, 2017).

[18] 45 C.F.R. § 160.103(1).

[19] *Id.* § 160.102(a)(2).

[20] *Id.* § 160.102(b), .103(1)(i)–(ii).

most schools and school districts.[21] DTC genetic testing companies are also among these uncovered entities.[22]

In 2003, three major rules were issued to implement the landmark legislation. The first was the Privacy Rule, which detailed individuals' rights regarding how "covered entities" can use their "protected health information" (PHI).[23] The second was the Security Rule, which established standards to protect electronic PHI.[24] The third rule was the Enforcement Rule, which established standards for compliance, investigations, and penalties upon the violation of either of the two previous rules.[25]

An important aspect of HIPAA is that "de-identified data," or data that has had its "18 specific identifiers removed . . . is not protected under the HIPAA Privacy Rules as PHI and covered entities can use and disclose it more widely."[26] Allowing protected health information to be shared after de-identification "mitigates privacy risks to individuals and thereby supports the secondary use of data for comparative effectiveness studies, policy assessment, life sciences research, and other endeavors."[27] This has become a questionable practice in the realm of genetic information, as it has become increasingly easy to re-identify "anonymous" genetic information.[28]

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[21] *Health Privacy: HIPAA Basics*, PRIVACY RIGHTS CLEARINGHOUSE, https://privacyrights.org/consumer-guides/health-privacy-hipaa-basics [https://perma.cc/6YDH-CK9D] (last updated Feb. 1, 2015); Robert Gellman & Pam Dixon, *Student Privacy 101: Health Privacy in Schools – What Law Applies?*, WORLD PRIVACY FORUM, https://www.worldprivacyforum.org/2015/02/student-privacy-101-health-privacy-in-schools-what-law-applies/ [https://perma.cc/AY8E-76CD] (last updated Jan., 2017) (This is not to say there are no laws or guidance policies regarding these unprotected fields. For instance, the Family Educational Rights and Privacy Act applies to the majority of health record held by schools. But "[w]hen FERPA does not apply, then the HIPAA exemption for records covered by FERPA does not apply. While this means that HIPAA may potentially apply, it is also possible that no privacy law applies. HIPAA does not actually apply to every healthcare record held by schools, even when FERPA does not apply. HIPAA only applies to certain types of businesses which are defined strictly under HIPAA as 'covered entities.'").

[22] ROBERT GELLMAN, CONTRACTOR FOR 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) at 2, https://ncvhs.hhs.gov/wp-content/uploads/2018/05/NCVHS-Beyond-HIPAA_Report-Final-02-08-18.pdf [https://perma.cc/H43M-3VQ5] ("Many but not all of the activities in the non-HIPAA category involve organizations that rely on health data as an element of a commercial activity, including data brokers, advertisers, websites, marketers, genetic testing companies, and others.").

[23] 45 C.F.R. § 164.522 (2020).

[24] *Id.* § 164.306.

[25] *The HIPAA Enforcement Rule,* U.S. DEP'T HEALTH & HUMAN SERVS., https://www.hhs.gov/hipaa/for-professionals/special-topics/enforcement-rule/index.html [https://perma.cc/S8Q6-TNSY].

[26] *What is Protected Health Information*, HIPAA JOURNAL (Jan. 10, 2018), [https://perma.cc/93VY-3P3U] (These identifiers may include names, social security numbers, email addresses, and even full-face photographic images.); 45 C.F.R. § 164.514(2)(i) (2020).

[27] OFF. FOR CIVIL RIGHTS, U.S. DEP'T HEALTH & HUMAN SERVS., GUIDANCE ON THE DE-IDENTIFICATION OF PROTECTED HEALTH INFORMATION IN ACCORDANCE WITH THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) PRIVACY RULE 5 (Nov. 26, 2012), https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#protected [https://perma.cc/X3NT-9FQ6].

[28] Peter Pitts, *The Privacy Delusions of Genetic Testing*, FORBES (Feb. 15, 2017), https://www.forbes.com/sites/realspin/2017/02/15/the-privacy-delusions-of-genetic-testing/#43ee0c1d1bba [https://perma.cc/9KGR-9XWH] ("Using this process, one MIT scientist was able to identify the people behind five supposedly anonymous genetic samples randomly selected from a public research database. It took him less than a day. Likewise, a Harvard Medical School professor dug up the identities of over 80% of the samples housed in his school's genetic database. Privacy protections can be broken.").

The Department of Health and Human Services implements and enforces HIPAA.[29] A violation of HIPAA is "a failure to comply with any aspect of HIPAA standards and provisions detailed in 45 C.F.R. Parts 160, 162, and 164."[30] Common violations of HIPAA include the impermissible disclosure, unauthorized access, and improper disposal of PHI.[31] These violations are often discovered through internal audits and employees who self-report potential violations committed by themselves or their co-workers.[32]

HIPAA violations are separated into a four-tier system. Each tier is distinguished based on the severity of negligence resulting in the disclosure of protected health information, as well as the existence of any attempt to correct the violation "within 30 days of discovery."[33] Based on the placement of the violation within the tier system, penalties range widely.

For instance, a tier-one violation occurs when a covered entity "did not know and, by exercising reasonable diligence, would not have known that the covered entity or business associate violated such provision."[34] This violation could result in a fine of \$100–\$50,000 per violation.[35] The most severe violation occurs in the event of "willful neglect" that was not corrected within thirty days from when the covered entity or business associate "knew, or, by exercising reasonable diligence, would have known that the violation occurred."[36] This violation could result in penalties of \$50,000 per violation (maximum \$1.5 million per year).[37] As discussed later in this Article, HIPAA should have an increased role in the realm of consumer protection regarding DTC genetic testing.

### *ii. GINA*

The Genetic Information Nondiscrimination Act of 2008 prohibits health insurance issuers from using one's genetic information in order to raise their insurance rates.[38] It also prohibits employers from making hiring, firing, and promotional decisions based on genetic information.[39]

However, there are significant gaps in this legislation, as it does not protect individuals with regard to their long-term care or disability insurance. This act will

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[29] Deborah F. Buckman, *Validity, Construction, and Application of Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Regulations Promulgated Thereunder*, 194 A.L.R. Fed. 133 (2004) ("Congress recognized the need to maintain strict privacy protection for health information and therefore authorized the Department of Health and Human Services to promulgate regulations . . . .").

[30] *What is a HIPAA Violation?*, HIPAA JOURNAL (Mar. 14, 2018), https://www.hipaajournal.com/what-is-a-hipaa-violation/ [https://perma.cc/8SZH-4B2D]; 45 C.F.R. §§ 160, 162, 164 (2019) (These regulations pertain to the General Administrative Requirements of HIPAA, as well as Security and Privacy regarding the standards for protection and notification procedures in the event of a breach of protected health information.).

[31] *What is a HIPPA Violation?*, *supra* note 30.

[32] *Id.*

[33] *Id.*

[34] 45 C.F.R. § 160.404(b)(i) (2020).

[35] *Id.*

[36] *Id.* § 160.404(b)(iv).

[37] *Id.*

[38] 29 U.S.C.A. § 1182(b)(3)(A) (2008).

[39] 42 U.S.C.A. § 2000ff-1(a)(1) (2008).

become increasingly relevant in the event that more and more people freely upload their genetic information onto social networking sites, or if their genetic information becomes available on the internet through data breaches and leaks.

#### *iii. FDA*

The U.S. Food and Drug Administration (FDA) is also a key regulator for DTC services. DTC genetic testing services, including 23andMe, must meet FDA guidelines.[40] FDA assesses the analytical validity, clinical validity, as well as the other claims made by a company regarding their DTC tests.[41] Analytical validity refers to whether the test can "accurately and reliably measure what it claims to measure."[42] Clinical validity refers to the company's ability to predict a specific health status.[43] Lastly, other claims may refer to various statements made by the company regarding the qualities and success of their product.[44] 23andMe has been operating under the approval of FDA since 2015.[45] FDA's history and role in relation with DTC genetic testing will be discussed further below.

#### *iv. Federal Trade Commission*

While it is not necessary to detail the background and overall role of the Federal Trade Commission (FTC) for the purposes of this Article, it is worth noting that direct-to-consumer genetic testing companies must also comply with FTC's rules and regulations prohibiting unfair or deceptive trade practices.[46] In an effort to ensure compliance, the FTC website provides guidance to entities selling genetic testing kits, offering specific advice, such as "explain third-party disclosures clearly" and "explain who can see what profile information – and let users know about important changes."[47]

### *B. Direct-to-Consumer (DTC) Testing*

#### *i. Origin*

DTC genetic testing, as the name implies, refers to the private transaction between consumers and genetic testing companies while taking the consumer's physician out

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[40] *Direct-to-Consumer Tests,* U.S. FOOD & DRUG ADMIN. (Dec. 20, 2019), https://www.fda.gov/medical-devices/vitro-diagnostics/direct-consumer-tests [https://perma.cc/Q84X-CME8] (last reviewed Dec. 20, 2019) ("Direct-to-consumer tests for moderate to high risk medical purposes, which may have a higher impact on medical care, are generally reviewed by the FDA to determine the validity of test claims.").

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *Id.*

[45] *23andMe and the FDA*, 23ANDME, https://customercare.23andme.com/hc/en-us/articles/211831908-23andMe-and-the-FDA [https://perma.cc/5L66-ZK5A].

[46] Elisa Jillson, *Selling Genetic Testing Kits? Read On*, FED. TRADE COMM'N (Mar. 21, 2019), https://www.ftc.gov/news-events/blogs/business-blog/2019/03/selling-genetic-testing-kits-read [https://perma.cc/U5AR-K663].

[47] *Id.*

of the equation.[48] Users could gather a variety of personal information ranging from lighthearted "infotainment"[49] to significant personal health risks.[50]

DTC genetic testing's popularity has risen in recent years. 23andMe alone boasts 12 million customers.[51] These tests have become a holiday gift trend as well with Ancestry, another DTC genetic testing company, selling approximately 1.5 million testing kits between Black Friday and Cyber Monday in 2017.[52]

DTC genetic testing brought a wave of revolutionary trends in numerous key aspects, such as: testing initiation, end use, pricing model, and return of information.[53] In DTC genetic testing, the patient initiates the test, rather than a health care worker.[54] In terms of end use, DTC genetic testing can be used for "multiple purposes e.g., ancestry, paternity, and health," which contrasts the traditional medical testing where the end use of genetic testing is to complement medical management.[55] The pricing model for DTC genetic testing is driven through more intense competition, which may lower product price more effectively than traditional medical testing's product price, which is "tied to the health care payment model."[56] Lastly, the return of DTC genetic test information is obviously given directly to the consumer, which often does not include any external services such as clinical support, counseling services, or any other services from a health care professional.[57]

### *ii. DTC 1.0*

While these unique aspects of DTC testing may easily be viewed as benefits, the first wave of DTC genetic testing to occur from 2005 to 2013, otherwise known as DTC 1.0, also came with its own set of shortcomings.[58]

One downside stressed by DTC opponents was the misleading language surrounding the return of health test results.[59] The language of the results were often returned in terms of a percent increase of risk, such as "40% more likely" to develop

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

[49] *Id.* at 114 ("Some tests include nonmedical 'infotainment' such as ear lobe attachment or the propensity to flush when drinking alcohol."); *Infotainment*, DICTIONARY.COM, https://www.dictionary.com/browse/infotainment [https://perma.cc/R8RC-T2FN] ("[F]actual material that is both informative and entertaining.").

[50] Allyse et al., *supra* note 48, at 114.

[51] *About Us*, 23ANDME, *supra* note 2.

[52] Molteni, *supra* note 1.

[53] *Id.* at 115.

[54] *Id.*

[55] *Id.*

[56] *Id.* at 114 ("In 2007, the cost of a DTC panel hovered around $1000. Three years later it dropped to between $300 and $400. By 2012, it dropped to $99 and 23andMe announced their goal of collecting 1 million users.").

[57] *Id.* at 115.

[58] *Id.* at 116–17.

[59] *Id.* at 115.

a certain condition, without offering any other details that may help the consumer interpret the results or further explanation as to how the result was reached.[60]

In 2006, FDA investigated the four largest DTC companies and found that the DTC's exaggerated value regarding their ability to improve personal health conditions constituted deceptive marketing.[61] In 2010, FDA notified the same DTC companies that their products "constituted medical devices that had not been submitted to the FDA for approval."[62] However, it was not until 2013 when FDA issued cease and desist letters to companies that were still noncompliant with FDA regulations that the companies began to take steps to improve their product.[63]

### *iii. DTC 2.0*

In the years following FDA's cease and desist letters, the agency began working with DTC companies to establish a new oversight mechanism for future genetic testing and a shift in focus from unregulated "infotainment" to distinct health information users can comprehend.[64] In 2017, FDA approved marketing for 23andMe's genetic health risk (GHR) tests, such as for Alzheimer's and Parkinson's disease, but instituted a separate regulatory framework for more diagnostic health-related information.[65]

There are several key features distinguishing DTC 2.0 from the previous model. First, for DTC 2.0 testing, FDA determines the eligibility of certain tests based on the scientific evidence on which those tests are provided and their outcomes.[66] Second, DTC 2.0 products focus more heavily on user comprehension by ensuring that "genetic information will be considered in the broader context of health, environment, and

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[60] *Id.* ("Without the interpretive help of a health care professional, critics of DTC products maintained that consumers were at risk of misinterpreting genetic test results and making health decisions on inaccurate or incomplete information. Of particular concern was the potential for decreasing health vigilance and the cessation of preventive health behaviors.").

[61] GREGORY KUTZ, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-847T, DIRECT-TO-CONSUMER GENETIC TESTS: MISLEADING TEST RESULTS ARE FURTHER COMPLICATED BY DECEPTIVE MARKETING AND OTHER QUESTIONABLE PRACTICES 1 (2010), https://www.gao.gov/assets/130/125079.pdf [https://perma.cc/XJV5-MVVV] ("GAO also found 10 egregious examples of deceptive marketing, including claims made by four companies that a consumer's DNA could be used to create personalized supplement to cure diseases. Two of these companies further stated that their supplements could 'repair damaged DNA' or cure disease, even though experts confirmed there is no scientific basis for such claims.").

[62] Letter from Alberto Gutierrez, Office of *In Vitro* Diagnostics & Radiological Health, to Anne Wojcicki, CEO, 23andMe, Inc. (Jun. 10, 2010), https://www.fda.gov/media/79205/download [https://perma.cc/KLV3-BPGA].

[63] Letter from Alberto Gutierrez, Dir., Office of *In Vitro* Diagnostics & Radiological Health, to Anne Wojcicki, CEO, 23andMe, Inc. (Nov. 22, 2013), https://quackwatch.org/cases/fdawarning/prod/fda-warning-letters-about-products-2013/23andme/ [https://perma.cc/RAQ9-Q3M7]; Megan Rose Dickey, *The FDA Wants 23andMe to Stop Marketing Its Genetic Testing Kits*, BUS. INSIDER (Nov. 25, 2013), https://www.businessinsider.com/fda-sends-warning-letter-to-23andme-2013-11 [https://perma.cc/34JK-Y485] (Original cease and desist letter text is no longer available on FDA's website. The full text of the letter is provided in this Article.).

[64] Allyse et al., *supra* note 48, at 118.

[65] News Release, U.S. Food & Drug Admin., FDA Allows Marketing of First Direct-To-Consumer Tests That Provide Genetic Risk Information for Certain Conditions (Apr. 6, 2017), https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-direct-consumer-tests-provide-genetic-risk-information-certain-conditions [https://perma.cc/DD95-45M9].

[66] Allyse et al., *supra* note 48, at 118.

behaviors."[67] DTC 2.0 also seeks to place a barrier between legitimate health information and entertainment.[68]

DTC 2.0 brought in a new wave of genetic testing, specifically greater regulatory oversight by FDA in an "attempt to strike a balance between the need to ensure consumer safety and the knowledge that personal genomic information is both highly desirable and potentially beneficial to some consumers."[69] Any future legislative or regulatory proposals should seek to maintain this balance.

### *C. 23andMe*

Founded in 2006, 23andMe's primary mission was to "help people access, understand and benefit from the human genome."[70] After launching its first product in 2007, its reputation grew in a matter of years.[71] In fact, "[i]n Silicon Valley, at the height of the dotcom boom, 23andMe was at the vanguard of a wave of interest in personal genomics."[72]

After working to meet compliance standards with FDA,[73] 23andMe recently introduced a new feature of health risk reports in which it could analyze customer DNA for health risks such as Parkinson's Disease, Alzheimer's, and other cancer risks.[74] The following section further details the information provided in 23andMe's user agreements, as well as the procedures regarding the collection, interpretation, and storage of its users' genetic information. While the policies and practices described below may not be unique to 23andMe, the company's interactions and cooperation with FDA make it an ideal model for the direct-to-consumer industry as a whole.

#### *i. Terms of Service*

Prior to using its services, 23andMe's customers must agree to its Terms and Conditions, which includes its Privacy Agreement.[75] The following are some of the key options users are given explicit control over regarding their acceptance of 23andMe's terms and conditions: the right to store or discard saliva samples after it has been analyzed, the right to decide which health reports to view and/or opt in to, the right to provide or decline consent to allowing your un-identified genetic data to be used by 23andMe for scientific purposes, and the right to delete your account and

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[67] *Id.*; *Terms of Service*, 23ANDME, https://www.23andme.com/about/tos/ [https://perma.cc/HNH5-JA67] (last updated Sept. 30, 2019) (23andMe's Terms of Service encourage their customers to "[m]ake sure to discuss your Genetic Information with a physician or other health care provider before [acting] upon the Genetic Information resulting from 23andMe Services.").

[68] Allyse et al., *supra* note 48, at 118.

[69] *Id.*

[70] *About Us*, 23ANDME, *supra* note 2.

[71] Allyse et al., *supra* note 48, at 114 ("[A]n early direct to-consumer (DTC) genetic testing company celebrated its launch with a Spit Party in which attendees danced, drank, and submitted DNA samples for sequencing. Within weeks, partygoers would have access to a comprehensive report, including their genetic preference for vegetables, whether their tongue curled, and their risk of developing breast cancer.").

[72] *Id.*

[73] Letter from Alberto Gutierrez, Office of *In Vitro* Diagnostics & Radiological Health, to Anne Wojcicki, CEO, 23andMe, Inc. (Mar. 25, 2014), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/23andme-inc-03252014 [https://perma.cc/5XXZ-QSL7].

[74] *23andMe and the FDA*, 23ANDME, *supra* note 45.

[75] *Terms of Service*, 23ANDME, *supra* note 67.

data.[76] Other terms of services pertaining to the risks, procedures, and effects of modifying the terms of service, mergers and acquisitions, and data breaches will be explored in a separate section of this Article. However, it is important to emphasize that the terms and services to which 23andMe and its consumers are bound will have direct consequences on the privacy interests of third parties as well.

### *ii. Collection*

After an individual purchases and registers with 23andMe, they are then provided with a 23andMe (saliva) Collection Kit.[77] Each kit contains the following items: a saliva collection tube, funnel lid, tube top, a plastic bio-specimen tube bag, instructions, and return shipping materials.[78] 23andMe recommends the customer provide approximately two milliliters of saliva.[79] Once the sample is received, "receiving personnel" remove any identifying information from the sample and replace that information with a unique barcode prior to sending the sample to the "testing personnel."[80]

### *iii. Interpretation and Results*

After these private companies have collected the genetic samples, they then analyze and interpret the genetic samples for relevant health and trait information of the consumer. For example, 23andMe's website offers the following predictive categories: Health Predisposition, Wellness, Traits, Ancestry, and Carrier Status.[81]

Health Predisposition refers to the genetic risk of developing certain diseases or health defects in one's lifetime.[82] Among the health predisposition recognition services recognized by the 23andMe report system are the genetic risks of adult-onset vision loss, anemia, dementia, and the newly revealed service of recognizing the health predisposition to Type 2 diabetes.[83] The Wellness category contains reports regarding weight, diet, and sleep cycles.[84] This category utilizes over 300 genetic variants that

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[76] *Id.* (This last user option is subject to limitations: "As stated in any applicable Consent Document, Genetic Information and/or Self-Reported Information that you have previously provided and for which you have given consent to use in 23andMe Research cannot be removed from completed studies that use that information. Your data will not be included in studies that start more than 30 days after your account is closed (it may take up to 30 days to withdraw your information after your account is closed).").

[77] *Items Included in a 23andMe Collection Kit,* 23ANDME, https://customercare.23andme.com/hc/en-us/articles/360037185053-Items-included-in-a-23andMe-Collection-Kit.\ [https://perma.cc/AY4K-ZFL3].

[78] *Id.*

[79] *Providing Saliva Sample for DNA Test Kit*, 23ANDME, https://customercare.23andme.com/hc/en-us/articles/202904530-Providing-Saliva-Sample-for-DNA-Test-Kit#:~:text=Collect%20the%20recommended%20volume%20of,just%20above%20the%20fill%20line [https://perma.cc/9YZY-HGVL].

[80] *Id.*

[81] *Reports Included in All Services*, 23ANDME, https://www.23andme.com/dna-reports-list/?vip=true&slideout=true&vip=true [https://perma.cc/BF8C-NEVW].

[82] *What Health-Related Information Can I Learn From 23andMe?*, 23ANDME, https://customercare.23andme.com/hc/en-us/articles/115013843028-What-health-related-information-can-I-learn-from-23andMe- [https://perma.cc/J8AH-B732].

[83] *Reports Included in All Services*, 23ANDME, *supra* note 81.

[84] *Id.*

influence how lifestyle will impact the previously mentioned factors.[85] The next category is Traits.[86] This includes personal traits such as sweet versus salty taste preferences and motion sickness.[87]

The Ancestry report "uses DNA you inherited from both sides of your family and tells you the proportion of your DNA that comes from each of 45 worldwide genetic populations, offering a detailed view of your ancestry from before ocean-crossing ships and airplanes were on the scene."[88] This report can be combined with Traits or with Health reports and also offers an opt-in DNA Relatives Feature that "allows you to find and connect with genetic relatives and see specific DNA segments you share with them."[89] Lastly, the Carrier Status report offers insight regarding "variants that may not affect your health, but could affect the health of your future family."[90] This category includes over forty reports that analyze gene variants for diseases such as Cystic Fibrosis and Sickle Cell Anemia.[91]

### *iv. Storage*

Among the agreements 23andMe's users must consent to prior to using its services, such as the Terms of Services and Privacy Agreement, is another agreement: a Biobanking Consent Document.[92] With this document, users have the ability to consent to 23andMe's storage of saliva samples for a minimum of one year and a maximum of ten years that may then be re-analyzed at a later date.[93] If an individual chooses to withhold consent to biobanking, then the "saliva sample and DNA are destroyed after the laboratory completes its work, subject to the laboratory's legal and regulatory requirements."[94] However, 23andMe will continue to maintain and store its users Personal Information until the user deletes the account.[95] Personal Information

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[85] *Genetic Variants Found to Influence Multiple Traits and Conditions*, 23ANDME: BLOG (Mar. 16, 2016), https://blog.23andme.com/23andme-research/study-shows-genetic-variants-that-influence-multiple-traits-and-conditions/ [https://perma.cc/VPG6-KZ2D].

[86] *Reports Included in All Services*, 23ANDME, *supra* note 81.

[87] *Id.*

[88] *What Ancestry Information Can I Learn From 23andMe?*, 23ANDME, https://customercare.23andme.com/hc/en-us/articles/115013846688-What-Ancestry-Information-Can-I-Learn-from-23andMe- [https://perma.cc/2QEL-YZGQ].

[89] *Id.*

[90] *About The 23andMe Health + Ancestry Service*, 23ANDME, https://customercare.23andme.com/hc/en-us/articles/115013683107-About-the-23andMe-Health-Ancestry-Service [https://perma.cc/3GAX-H8ES].

[91] *Reports Included in All Services*, 23ANDME, *supra* note 81.

[92] *Biobanking Consent Document*, 23ANDME, https://www.23andme.com/about/biobanking/ [https://perma.cc/6D6N-HHCK].

[93] *Id.*

[94] *Privacy Highlights*, 23ANDME, at § 2(b), https://www.23andme.com/about/privacy/ [https://perma.cc/A3J9-5WQM].

[95] *Id.* § 9(e)(ix) ("Unless you delete your account or delete certain Personal Information (i.e., User Content, etc.), we will store your Personal Information as long as your account is open.").

in this context includes, but is not limited to: Genetic Information,[96] Self-Reported Information,[97] and Sensitive Information.[98]

## III. THIRD-PARTY IMPLICATIONS

This Article is not primarily focused on those who voluntarily and willingly accepted the terms and conditions and privacy statement of DTC genetic testing companies. Although those individuals' genetic information would certainly be affected by a data breach or merger, "genetic information reveals inherently shared information between genetically related family members,"[99] therefore this Article seeks to focus on a much narrower group of individuals: the *relatives* of those companies' customers.[100]

### *A. Familial Identification*

The following explanation succinctly describes how family members may be identified from another's genetic sequence: "Each person has two sets of chromosomes, which are made up of DNA. . . . Segments of DNA are passed down from parents. . . . Researchers can look for shared DNA segments of people in databases, which indicate a genetic relationship. Longer lengths of shared DNA segments usually indicate closer relationships."[101]

Unfortunately, the "implications of genomic research for blood relatives have only recently attracted attention in scholarly literature on the ethics and law of genomic research."[102] With the rapid popularity of DTC genetic testing, the "[g]enetic information posted online can be used to identify relatives who never participated in the DNA testing or agreed to share their personal information."[103]

Yaniv Erlich, the leader of a study regarding the implicit disclosure of genetic information, provides the best analogy to further understand how impactful the use of private services such as 23andMe can be: "Each individual in the database is like a beacon of genetic information, and this beacon illuminates hundreds of individuals—

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[96] *Id.* § 1(4)(b) (information gathered from the saliva sample analysis regarding its users' genotype).

[97] *Id.* § 1(4)(c) (information provided to 23andMe from its users, such as family history and health related information).

[98] *Id.* § 1(4)(d) (a broad term that encompasses "information about your health, Genetic Information, and certain Self-Reported Information such as racial and ethnic origin, sexual orientation, and political affiliation").

[99] Samuel A. Garner & Jiyeon Kim, *The Privacy Risks of Direct-to-Consumer Genetic Testing: A Case Study of 23andMe*, 96 WASH. U. L. REV. 1219, 1241 (2019).

[100] *See, e.g.*, Dov Fox, Emily Spencer & Ali Torkamani, *Returning Results to Family Members: Professional Duties in Genomic Research in the United States*, 38 J. LEGAL MED. 201, 202 (2018) ("Genomic research, unlike any other discipline, makes medical information known not just about the deoxyribonucleic acid (DNA) source but also his or her kin, at least in probabilistic terms, with potentially serious consequences.").

[101] Marcus, *supra* note 7; Garner et al., *supra* note 99, at 1242 ("("[T]he 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.").

[102] Fox et al., *supra* note 100, at 202.

[103] Marcus, *supra* note 7.

distant relatives connected to this person via their family tree."[104] These distant relatives can even extend so far as one's second or third cousins.[105]

Jennifer Cacchio posited that the familial property interest of those who have shared their genetic information is analogous to those who have a joint ownership of tangible real estate property.[106] In the case of the latter, many jurisdictions seek to protect each individual's property interest by prohibiting one owner from transferring the property interest of the other.[107] One can only transfer his or her own property interest.[108] Similarly, in the case of familial genetic disclosure, "entire families have individual interests in the DNA 'property'" of their family member, as they share very similar genetic information.[109] However, unlike in the latter case, there is a clear lack of legal safeguards with regards to familial genetic privacy interests, as an "individual's property interest in her own genetic information is superseded by a contract between a curious (albeit naïve) family member and a corporate database."[110]

Cacchio's familial property proposal is not the only attempt within the academic community to reframe how we should view genetic privacy.[111] For instance, in the field of medical research, should a duty be imposed on researchers to "warn family members about results that bear on their own health or reproduction" upon the discovery of genetic medical risks found in their research participants?[112]

There are certainly a wide range of health and privacy implications for relatives of those who participate in modern genetic testing and research. These implications

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[104] Johnson, *supra* note 7.

[105] Yaniv Erlich, Tal Shor, Itsik Pe'er & Shai Carmi, *Identity Inference of Genomic Data Using Long-Range Familial Searches*, 362 SCIENCE 690 (2018); Garner et al., *supra* note 99, at 1242 ("The familial nature of genes also extends to relatives that one might have never encountered or lived with."); Julian Segert, *Understanding Ownership and Privacy of Genetic Data*, HARV. U. (Nov. 28, 2018), http://sitn.hms.harvard.edu/flash/2018/understanding-ownership-privacy-genetic-data/ [https://perma.cc/5DMN-8NPT].

[106] Jennifer Cacchio, *What You Don't Know Can Hurt You: The Legal Risk of Peering into the Gene Pool with Direct-to-Consumer Genetic Testing*, 87 UMKC. L. REV. 219, 232 (2018) ("Perhaps the most difficult for customers to understand, this provision hinges on the biological truth that even if one person has never used Ancestry or a similar testing service, if one of his relatives has done so, the company already owns identifiable portions of his DNA.").

[107] *Id.*

[108] *Id.*

[109] *Id.*

[110] *Id.*

[111] Michael Parker & Anneke Lucassen, *Genetic Information: A Joint Account?*, 329 BMJ 165, 166 (2004) (The authors of this article go so far as to propose that genetic information in the field of clinical research should be treated as a "joint bank account," with the account being analogous to a group of relatives who all deserve access to the genetic information of other relatives who are members of the account."); Carol McCrehan Parker, *Camping Trips and Family Trees: Must Tennessee Physicians Warn Their Patients' Relatives of Genetic Risks?*, 65 Tenn. L. Rev. 585, 588 (1998) (This article discusses a "physician's duty to warn third parties under Tennessee law and rationales that support extension of that duty to genetically at-risk relatives of patients."); Sonia M. Suter, *All in the Family: Privacy and DNA Familial Searching*, 23 HARV. J. L. & TECH. 309, 358 (2010) ("In addition to threatening the privacy interests of the partial match and his or her relatives, familial searching poses privacy threats to the family as a whole . . . . Under this view, family privacy is not simply privacy as it applies to the individual in making decisions about the family, but instead privacy that protects the integrity of the family as an entity unto itself.").

[112] Fox et al., *supra* note 100, at 203 ("Family members of research participants stand to benefit in important ways from discoveries that can inform their own health and reproductive risks.").

expand even further when analyzed in the criminal context. Law enforcement agencies have now seized the opportunity of utilizing public genetic databases, thereby narrowing down potential criminal suspects through partial matches with the suspect's family members.[113]

### *B. Familial DNA Searches in Criminal Context*

Familial DNA searches (FDS) have become a controversial practice among law enforcement agencies and the general public. DNA searches have traditionally been performed through the Combined DNA Index System (CODIS), which was "designed by the FBI to facilitate the sharing and searching of DNA profiles within and between jurisdictions across the country."[114] However, with the increase in free, public, online genetic databases, law enforcement have begun using a method of FDS to "detect and statistically rank a list of potential candidates in the DNA database who may be close biological relatives (e.g., parent, child, sibling) to the unknown individual contributing the evidence DNA profile."[115]

Two noteworthy examples of the extent to which DNA has an implicit effect on family members can be seen from the arrests of suspects in the cold cases of the Golden State Killer and the Canal Killer. The Golden State Killer was an unidentified individual who was responsible for the death of twelve people and forty-five separate rape incidents across the state of California between 1976 and 1986.[116] Despite obtaining DNA evidence during police investigations at the time, law enforcement was unable to find a match in the FBI's national DNA database of "convicts, offenders, and arrestees."[117]

It wasn't until the police decided to use GEDmatch, a free online genetic database used by individuals seeking similar results as those who used other DTC genetic testing sites.[118] Unlike with the FBI database, law enforcement were not limited to only receiving identical matches.[119] Despite the suspected individual not having his genetic information on the database, law enforcement were able to identify a partial match with a distant relative and "[i]nstantly, the pool of suspects shrank from millions of people down to a single family."[120] This finally lead to the arrest of Joseph James DeAngelo and, for the time being, an end to an over-three-decades-long investigation.[121]

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[113] MICHAEL B. FIELD, SANIYA SEERA, CHRISTINA NGUYEN & SARA DEBUS-SHERILL, ICF, STUDY OF FAMILIAL DNA SEARCHING POLICIES AND PRACTICES: CASE STUDY BRIEF SERIES 1–2 (2017), https://www.ncjrs.gov/pdffiles1/nij/grants/251081.pdf [https://perma.cc/CV9W-JQXS].

[114] *Id.*

[115] *Id.*

[116] Selk, *supra* note 9.

[117] *Id.*

[118] *Id.* ("Police said they checked the crime scene DNA against one of the genealogy sites that have lately become popular—databases filled with the profiles of people who have volunteered their genetic codes in the hope of discovering their relatives and ancestors.").

[119] *Id.*

[120] *Id.*

[121] *Id.* (DeAngelo was a "72-year-old former police officer who lived within a few miles of many of the attacks.").

A similar set of facts can be found with the Phoenix, Arizona case of the Canal Killer, an individual suspected of the violent killing and mutilation of two young women during the 1990's.[122] Investigators sought the help of genealogist Colleen Fitzpatrick.[123] After receiving the suspected killer's DNA sequence, Fitzpatrick used popular DNA databases, Family Tree DNA and Ancestry.com, and was able to provide Phoenix investigators with the last name: Miller.[124] This quickly led to the arrest of Bryan Patrick Miller as the individual responsible for the criminal acts.

These cases admittedly highlight the benefits of utilizing DNA databases, as these methods helped solve gruesome cold case murders. However, we should also be apprehensive about the intrusive nature of this technology, especially in the criminal context, as the practice of DNA familial searches through public databases and abandoned DNA has raised various Fourth Amendment concerns.[125] While a majority of states have not addressed the lack of guidelines for law enforcement's technique of familial DNA searches (FDS), others have taken action.[126] For instance, California has "unique practices such as the institution of an interdisciplinary committee to approve the use of FDS in individual cases, as well as conducting records research prior to release of the profile name to investigators."[127] Additionally, Maryland is the only state to pass legislation explicitly forbidding the use of FDS.[128] In 2008, Maryland's Governor's Office offered support for Senate Bill 211 (SB 211), which sought to allow for the collection of DNA samples from individuals "arrested for violent crimes and burglaries and upload those profiles into the state CODIS DNA database."[129] Working with a coalition of other lobbyists, the Maryland Black Caucus successfully led an effort to amend SB 211 to ban FDS.[130]

Due to the innovative nature of this investigative technique, there are still gaps and questions left to be addressed. Although Colorado was the first state to utilize FDS in 2009, as of 2017, they had yet to have any "FDS cases go to trial or any motions on it

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[122] Megan Cassidy, *Geneology Leads to Arrest in Canal Killer Case*, THE REPUBLIC (Nov. 30, 2016, 6:00 AM), https://www.azcentral.com/story/news/local/phoenix/2016/11/30/how-forensic-genealogy-led-arrest-phoenix-canal-killer-case-bryan-patrick-miller-dna/94565410/ [https://perma.cc/VFF4-Q67M].

[123] *Id.*

[124] Selk, *supra* note 9.

[125] 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, 975 (2013) ("Although DNA evidence provides a useful and effective tool for both identifying and convicting suspects guilty of criminal acts, the methods used in . . . serial murder cases create issues of genetic privacy, consent, and abandonment."); Claire Abrahamson, *Guilt by Genetic Association: The Fourth Amendment and the Search of Private Genetic Databases by Law Enforcement*, 87 FORDHAM L. REV. 2539, 2540 (2019) ("This Note therefore asserts that the third-party doctrine does not permit law enforcement to conduct warrantless searches for suspects on private DTC genetics databases under the Fourth Amendment."); Elizabeth E. Joh, *Reclaiming "Abandoned" DNA: The Fourth Amendment and Genetic Privacy*, 100 NW. U. L. REV. 857, 874 (2006) ("If criminal procedure law imposes virtually no restrictions over the collection of abandoned DNA, the police may collect it from anyone about whom they have only a vague suspicion, or none at all.").

[126] FIELD ET AL., *supra* note 113, at 2.

[127] *Id.*

[128] *Id.* at 32 (Although Maryland is the only state to take such action, the District of Columbia passed legislation in 2009 that similarly banned the practice of FDS.).

[129] *Id.*

[130] *Id.* at 33.

litigated."[131] Regardless, those who voluntarily released their genetic information have unknowingly become "genetic informants,"[132] illuminating their family tree[133] and exposing relatives who did not voluntarily release their genetic information.

## IV. FUTURE EXPOSURE TO THE PUBLIC FORUM

The extensive collection and interpretation of customer DNA into specific and manageable categories increases the value and potential use of these DNA test results by outside actors. There are three major ways in which third-party entities may potentially access the genetic information of millions of consumers, and by extension their family members. Genetic information may be shared: voluntarily, but unknowingly, through contracts of adhesion; by way of company mergers and acquisitions; and through data breaches. Once this data is shared beyond the initial transaction between 23andMe and its user, third-party issues will likely arise from individuals who share extremely similar genetic information that is then being publicly exposed without their permission.

### *A. Shared Voluntarily, but Unknowingly*

The first way in which outside entities may access the private genetic information from consumers is when it is shared freely under the Terms and Conditions of the initial agreement. Tech giants and private companies may gain access to 23andMe's users' personal information with their consent through "contracts of adhesion," or contracts drafted by a party in a stronger position offered to a party in a weaker position.[134] The contract is nonnegotiable, and the weaker party must either "take it or leave it."[135] A popular form of a contract of adhesion are "terms and conditions/service" of many major companies and services.

Many consumers agree to these terms and conditions out of convenience, as they are usually multiple pages long and contain technical terms and language. California Western School of Law professor, Nancy S. Kim, and Valparaiso School of Law professor, D.A. Jeremy Telman, describe the questionable actions tech giants have taken in the realm of data mining:

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[131] *Id.* at 9 ("Once FDS evidence is allowed, stakeholders were less clear of the role it would play during the trial. One interviewee noted that it would not come up at all as it is simply an investigative lead that helped police arrive at the suspect and has nothing to do with the trial. One stakeholder with a legal background noted that while the defense bar prefers to keep CODIS out of trials so the jury does not think of the defendant as a convicted felon, they were unclear as to how the defense would prefer to treat someone's relative being in the database. Another posited that FDS might come into play to lend further weight to the DNA comparison sample match. Ultimately, the treatment of FDS at trial is untested in Colorado, but these perspectives demonstrate some of the considerations for this stage.").

[132] Ashley May, *Took An Ancestry DNA Test? You Might Be A 'Genetic Informant' Unleashing Secrets About Your Relatives*, USA TODAY (May 1, 2018, 11:31 AM), https://www.usatoday.com/story/tech/nation-now/2018/04/27/ancestry-genealogy-dna-test-privacy-golden-state-killer/557263002/ [https://perma.cc/6TQH-CNW8] (quoting Steve Mercer, the chief attorney for the forensic division of the Maryland Office of the Public Defender).

[133] Erlich et al., *supra* note 105.

[134] *Adhesion Contract*, BLACK'S LAW DICTIONARY (11th ed. 2019) ("A standard-form contract prepared by one party, to be signed by another party in a weaker position, usu. a consumer, who adheres to the contract with little choice about the terms").

[135] *Id.*

> The Internet giants disclose in those [Terms of Service] that they engage in data mining, or at least that they have the right to do so. As a result, the argument goes, nobody should be outraged that the Internet giants engage in mining the data provided by the customers because the customers have consented to such use.[136]

There is an illusion of true consent, as millions of consumers have blindly accepted the nonnegotiable terms and conditions of popular goods and services. This is an increasing problem, as a Deloitte survey of 2,000 consumers revealed that up to 97% of young adults between the ages of 18–34 agree to the legal terms and conditions without ever reading them.[137] The surveyed group was also aware that their information was likely being shared as a result of their agreement to the terms and conditions.[138] Currently, 80% of 23andMe's users have "opted-in" to participate in genetic research.[139] With this consent, there are also concerns that 23andMe's customers "may not fully understand the health implications of the information they receive."[140] If 23andMe were to include in their terms and services that 23andMe would be given permission to share genetic predispositions to third-parties, millions of users would have unknowingly agreed to those terms.

Furthermore, major online corporations and services facilitate this epidemic of consumer ignorance to the terms and conditions to which they agree through a means called "clickwrap agreements" and "browse-wrap agreements." Clickwrap agreements are means of consenting to the terms and conditions of a product or service by "clicking a button displayed next to or below a statement asking the user to accept or agree to the proposed contract (and in some cases also requiring the user to check a box and/or scroll through the entire agreement before being allowed to click the button)."[141] Federal and state courts have consistently upheld these types of agreements as long as the agreements are not obscure, unclear, or complex in their presentation.[142]

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[136] Nancy S. Kim & D.A. Jeremy Telman, *Internet Giants as Quasi-Governmental Actors and the Limits of Contractual Consent*, 80 MO. L. REV. 723, 729 (2015).

[137] Caroline Cakebread, *You're Not Alone, No One Reads the Terms of Service Agreements*, BUSINESS INSIDER (Nov. 15, 2017, 7:30 AM), https://www.businessinsider.com/deloitte-study-91-percent-agree-terms-of-service-without-reading-2017-11?r=US&IR=T [https://perma.cc/6XEG-9A9V].

[138] *Id.*

[139] *About Us*, 23ANDME, *supra* note 2.

[140] Allyse et al., *supra* note 48 ("Furthermore, buried in these user agreement forms were provisions that allowed DTC companies to retain and use customer data with impunity. This meant that companies could sell aggregate data to third parties or use consumer's data for research without their awareness. These concerns were partially born out when 23andMe filed a patent request in 2012, and several users protested that they had no knowledge that 23andMe intended to profit from their genetic information.").

[141] Ian C. Ballon, *Express and Implied Assent: Click-Through and Browsewrap Agreements*, *in* E-COMMERCE AND INTERNET LAW 21.03[2] (2d ed. 2020).

[142] *See* Net2Phone, Inc. v. Superior Court, 109 Cal. App. 4th 583, 588–89 (2003) (holding a forum selection clause enforceable despite that contract term being accessible only by hyperlink); *but see* Cullinane v. Uber Technologies, Inc., 893 F.3d 53, 60–64 (1st Cir. 2018) (holding that an arbitration clause found in a hyperlink was not enforceable because the hyperlink was presented in gray and white text as opposed to its traditional blue and underlined format and therefore was not "reasonably conspicuous" under Massachusetts law).

On the other hand, browse-wrap agreements "do not require the user to expressly manifest assent, such as by clicking 'yes' or 'I agree.'"[143] Courts are generally less accepting of these agreements.[144] For instance, in *Rodman v. Safeway Inc.*, Safeway argued that they were not required to provide notice of any future changes to the terms of service after the customers' initial registration.[145] The court rejected this argument, asserting that Safeway did not have the "power to bind its customers to unknown future contract terms, because consumers cannot assent to terms that do not yet exist."[146]

23andMe offers the following disclaimer in their Privacy Statement regarding changes that may be made in the future and what may constitute assent to those new terms:

> 23andMe modifies this Privacy Statement from time to time. We recommend revisiting this page periodically to stay aware of any changes to this Privacy Statement. If we modify this Privacy Statement, we'll make it available through our website. Whenever *material changes* to this Privacy Statement are made, we will provide you with notice before the modifications are effective, such as by posting a notice on our website or sending a message to the email address associated with your account.

By continuing to access or use the Services after changes to this Privacy Statement becomes effective, you agree to be bound by the revised Privacy Statement. If any changes are unacceptable to you, you may stop using our Services and delete your account at any time.[147]

Aside from the concerning language as to what constitutes a material change, this agreement appears to be a hybrid of both clickwrap and browse-wrap agreements. Users provide explicit assent to the original terms (clickwrap) and are also notified that future use after changes are made constitute implicit assent to those amended terms (browse-wrap). Notice is a central issue in this field of law, as the Ninth Circuit asserts in *Nguyen v. Barnes and Noble, Inc.* that "the onus must be on website owners to put users on notice of the terms to which they wish to bind consumers."[148]

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[143] Christina L. Kunz, John E. Ottaviani, Elaine D. Ziff, Juliet M. Moringiello, Kathleen M. Porter & Jennifer C. Debrow, *Browse-Wrap Agreements: Validity of Implied Assent in Electronic Form Agreements*, 59 Bus. Law. 279, 280 (2003).

[144] *See* Rodman v. Safeway Inc., No. 11-cv-03003-JST, 2015 WL 604985 at *9 (N.D. Cal. Feb. 12, 2015) ("Courts are typically reluctant to apply browsewrap agreements against consumers who were not provided with sufficient notice that their use of a website would be construed as a manifestation of assent to the agreement's terms.").

[145] *Id.* at 9.

[146] *Id.* at 10; Logan Koepke, *"We Can Change These Terms at Anytime": The Detritus of Terms an Service Agreements*, MEDIUM (Jan. 18 2015), https://medium.com/@jlkoepke/we-can-change-these-terms-at-anytime-the-detritus-of-terms-of-service-agreements-712409e2d0f1 [https://perma.cc/3ZRR-6UJL] (Despite this court and the Ninth Circuit's contempt for browse-wrap agreements due to a lack of notice of the terms to which consumers must give consent, they are still a large part of many Terms and Conditions, such as with the major corporations of Best Buy, Walmart, and Target.).

[147] *Privacy Highlights*, 23ANDME, *supra* note 94, at §11 (emphasis added).

[148] Nguyen v. Barnes and Noble, Inc., 763 F. 3d 1171, 1179 (9th Cir. 2014) ("Given the breadth of the range of technological savvy of online purchasers, consumers cannot be expected to ferret out hyperlinks to terms and conditions to which they have no reason to suspect they will be bound.").

23andMe's use of email and website displays may satisfy this notice requirement. However, this practice may also raise general policy concerns regarding the sufficiency of mere email notice and website headings, especially in an industry that handles sensitive health information. If 23andMe were to alter or amend their privacy statement to allow the free sharing of genetic information with other entities for purposes other than altruistic medical research, consumers—and consumers' relatives—may not have legal recourse or means to remedy the unwanted disclosure of their genetic information.

### *B. Company Mergers*

Another potential avenue in which private companies can gain access to genetic information stored by 23andMe's customers would be through a merger or acquisition with 23andMe. The most realistic example would be a hypothetical scenario in which Facebook desired to acquire the genetic predispositions of its consumers in order to expand its efforts in targeted advertising.

Over its existence, Facebook has engaged in a variety of mergers and acquisitions with other companies in order to acquire both their "technologies and their teams."[149] Tech giants can, and often do, use mergers and acquisitions to obtain companies, their information, and more importantly, those companies' users. Since 2007, Facebook has acquired companies and businesses, such as: Instagram,[150] WhatsApp,[151] and Oculus VR.[152] Facebook's acquisitions not only benefit itself, but they also benefit third-party advertisers who now have access to previously inaccessible consumer information.

Facebook's current targeted advertising options allow a third-party advertiser to choose from a variety of personalized items in order to better reach their desired consumer, such as location, interests, and behavior.[153] Based on the specificity of genetic testing indicators, such as deep sleep and taste preferences, advertisers would have an entirely new method of reaching their desired audience. Companies like Lunesta and Lay's potato chips would be able to identify and target consumers who are genetically inclined to purchase their product.

If this hypothetical scenario seems far-fetched, we only have to look back to 2018 for a real-world example of a major corporation merging with a company that deals with sensitive consumer health information and ultimately acquiring said information. Amazon recently acquired PillPack, an American online pharmacy, for $753 million.[154] Amazon's entrance into the United States' $500 billion a year prescription

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[149] Adam Hayes, *Facebook's Most Important Acquisitions*, INVESTOPEDIA (Jun. 25, 2019), https://www.investopedia.com/articles/investing/021115/facebooks-most-important-acquisitions.asp [https://perma.cc/PZC7-MQDH].

[150] *Id.* (purchased in 2012 for $1 billion).

[151] *Id.* (This 2014 acquisition was valued at $19 billion. Despite WhatsApp being a free messaging service, its acquisition allowed Facebook to expand and capture a vast overseas audience.).

[152] *Id.* (Oculus VR was purchased in 2014 for $2 billion with the ultimate goal to "develop immersive VR gaming and then expand to include all sorts of virtual experiences, including social networking.").

[153] *Help Your Ads Find the People Who Will Love Your Business*, FACEBOOK FOR BUSINESS (last visited Feb. 5, 2020), https://www.facebook.com/business/ads/ad-targeting [https://perma.cc/FD3W-T3W9].

[154] Christina Farr, *The Inside Story of Why Amazon Bought PillPack in its Effort to Crack the $500 Billion Prescription Market*, CNBC (last updated May 13, 2019), https://www.cnbc.com/2019/05/10/why-amazon-bought-pillpack-for-753-million-and-what-happens-next.html [https://perma.cc/52BD-FW8G] (Pillpack is "a company that delivers most of the medications consumers can get from their local drugstore

medication industry[155] likely comes with its own set of concerns, as "[p]rescription drug information is highly personal information—it can tell if someone has cancer, if they have a sexually transmitted disease."[156]

According to the Centers for Disease Control and Prevention, "[r]oughly 60% of American adults have at least one chronic illness, such as heart disease, cancer or diabetes, and 40% have two or more."[157] These statistics not only represent the incentives as to why Amazon desired to take a share of such a lucrative market, but they also illustrate the vast amount of personal and health information that is now in the global corporate entity's control.[158] Continuing from the discussion in the previous section, there is also a policy concern with Amazon's use of controversial clickwrap agreements in the arena of prescriptions and public health in terms of customer protection.[159] Amazon not only has access to PillPack's current customers, but it is also actively promoting PillPack to its 100 million Amazon prime members.[160] There are undoubtedly benefits from the increased accessibility and convenience of online medication delivery to millions of Amazon's consumers, especially in light of the recent events surrounding the SARS-CoV-2 pandemic.[161] However, Amazon and other entities seeking to acquire sensitive health information must take "steps to ensure the entire business meets federal privacy standards, which govern everything from who has access to data to how user passwords are encrypted."[162]

If the information that has been collected and interpreted by DTC genetic testing sites can be used to better understand or influence consumer behavior, there should be no surprise in the event a third-party entity seeks to acquire such information. In fact, 23andMe is prepared if such an event were to occur. According to their privacy statement, 23andMe may share "some or all of your Personal Information with other companies under common ownership or control of 23andMe, which may include our

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packaged in convenient white packets so people will remember to take them, along with automatic refills and 24/7 customer support.").

[155] *Id.*

[156] Julie Spitzer, *Amazon's PillPack Acquisition Gives It Access to Sensitive Health Information*, BECKER'S HEALTH IT (July 2, 2018), https://www.beckershospitalreview.com/cybersecurity/amazon-s-pillpack-acquisition-gives-it-access-to-sensitive-health-information.html [https://perma.cc/MP3K-4Y9V] (quoting Julie Roth, a healthcare regulatory attorney with Spencer Fane LLP).

[157] Farr, *supra* note 154.

[158] Spitzer, *supra* note 156. ("Amazon already collects its customers' personal data by analyzing their purchasing behaviors—a practice that is legal among marketers. As it looks to mine data on its PillPack customers, Amazon will face tougher regulations. Laws like HIPAA ensure medical information is collected and stored in a highly secure manner, and gives patients the rights to their own health data. Its [sic] a federal regulation much stricter than Amazon is accustomed to.").

[159] *Id.* ("[S]ome argue patients may not realize what they are consenting to, since consent could be given by simply checking a box at the bottom of a privacy disclosure.").

[160] Farr, *supra* note 154.

[161] Angus Loten, *Digital Payments Soar Amid Coronavirus Restrictions*, WALL ST. J. (Mar. 23, 2020), https://www.wsj.com/articles/digital-payments-soar-amid-coronavirus-restrictions-11585005215 [https://perma.cc/YCD5-49E5] ("Digital-payment services are facing a surge in demand as efforts to stem the novel coronavirus pandemic result in housebound shoppers stocking up on groceries, prescription drugs, audiobooks and movies online.").

[162] Laura Stevens & Sharon Terlep, *Amazon's PillPack Deal Gives It Access to Sensitive Health Data*, WALL ST. J. (Jul. 1, 2018), https://www.wsj.com/articles/amazons-pillpack-deal-gives-it-access-to-sensitive-health-data-1530442800 [https://perma.cc/V3PD-XX6H].

subsidiaries, our corporate parent, or any other subsidiaries owned by our corporate parent . . . ."[163] Recall in an earlier section of this Article pertaining to 23andMe's storage procedures, that "Personal Information" may include Genetic Information, Self-Reported Information, and Sensitive Information,[164] all of which would become accessible to the corporate parent in the event of a merger or acquisition.

### *C. Data Breach*

In today's interconnected society, reliance on the internet in storing and sharing sensitive information has increased heavily. In 2016, a LexisNexis Risk Solutions survey found that 35% of people electronically store records containing personally identifiable information.[165] This has exposed an immense amount of personal information to a series of massive and frequent data breaches resulting from either a leak due to poor security or hacking by malicious parties. Notable companies affected by leaks/data breaches include: Yahoo, First American Financial Corp., Facebook, Marriott International, and Friend Finder Networks.[166] These leaks/hacks resulted in over 5.8 billion records affected combined.[167]

In attempt to curb liability, 23andMe's privacy statement offers a disclaimer warning its potential and current customers under the heading: "Risks and Considerations," that "[i]n the event of a data breach it is possible that your data could be associated with your identity, which could be used against your interests."[168] As mentioned previously, anonymity is an illusion in the realm of genetic information. Even if anonymous data was released in a breach, it has become increasingly easier to identify previously anonymous DNA. In fact, Linda Avey, a cofounder of 23andMe, has "explicitly admitted that 'it's a fallacy to think that genomic data can be fully anonymized.'"[169]

Regardless of how data is breached through leaks and hacks, once it is out on the web, it can end up anywhere. If sites like 23andMe were to suffer a massive data breach affecting the majority, if not all, of their twelve million users, then those users' genetic information would essentially be accessible on the web. Tech giants, employers, insurers, family, friends, coworkers, and malicious websites would then be able to freely access that data.

Fortunately, GINA would offer consumers protection from repercussions by their employer or health insurer in the event that they obtained your genetic information as

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[163] *Full Privacy Statement*, 23ANDME, https://www.23andme.com/about/privacy/ [https://perma.cc/S7FT-DE84] (last visited Feb. 5, 2020).

[164] *Id.* (section 1(4)).

[165] *LexisNexis Risk Solutions-Sponsored Survey Finds More Than One-Third of Americans Store Tax, Bank, Health and Other Sensitive Records in Email, Cloud and Electronic Systems*, CISION PR NEWSWIRE (Oct. 3, 2016), https://www.prnewswire.com/news-releases/lexisnexis-risk-solutions-sponsored-survey-finds-more-than-one-third-of-americans-store-tax-bank-health-and-other-sensitive-records-in-email-cloud-and-electronic-systems-300338041.html [https://perma.cc/89FK-KUSW].

[166] Kenneth Kiesnoski, *5 of the Biggest Data Breaches Ever*, CNBC (Jul. 30, 2019), https://www.cnbc.com/2019/07/30/five-of-the-biggest-data-breaches-ever.html [https://perma.cc/F8S8-8NYN].

[167] *Id.*

[168] *Privacy Highlights: Risks and Considerations*, 23ANDME, https://www.23andme.com/about/privacy/ [https://perma.cc/69D8-7D8F] (last visited Feb. 5, 2020).

[169] Pitts, *supra* note 28.

a result of a data breach or hack.[170] However, there are other risks and considerations mentioned in 23andMe's Privacy Highlights to which GINA would not apply, such as the possibilities that you may learn distressing information about yourself with regard to your health or your familial status with your relatives.[171] Moreover, due to the internet's reach, if one's embarrassing or distressing genetic information also reached one's family, coworkers, and peers, it would certainly contribute to additional emotional distress and social anxiety.[172]

Ultimately, there are a variety of methods in which the unwilling, or unknowing, disclosure of personal genetic information may occur. If the use of DTC genetic testing services were an isolated transaction between DTC companies and its users, the issues raised in this Article would be moot. However, as a result of each of these potential avenues of third-party access, these privacy concerns affect not only those who used a DTC company's services, but their relatives as well.

## V. POTENTIAL CIVIL REMEDIES

In the event that the genetic information collected by 23andMe were to be disclosed and shared willingly or unwillingly with third-party entities, what cause of action would immediate or distant relatives of the owners of DNA have against 23andMe or other DTC genetic testing services for the public disclosure of their genetic information? For instance, what if the DNA shared of the original owner revealed that his or her family members were at an increased risk for developing a serious medical condition such as Alzheimer's or Parkinson's disease?

Even if DTC genetic testing were covered under HIPAA, third parties would not be able to bring a private cause of action under HIPAA. In *Acara v. Banks*, a patient brought suit against her physician for disclosing her protected health information while attending a deposition.[173] The Fifth Circuit held, after concluding a consensus amongst numerous trial court rulings on the topic, that enforcement of HIPAA was limited to the Secretary of Health and Human Services, and "HIPAA does not contain any express language conferring privacy rights upon a specific class of individuals."[174] Instead, "it focuses on regulating persons that have access to individually identifiable medical information and who conduct certain electronic health care transactions."[175]

Because DTC genetic testing services do not qualify as "health care providers" under HIPAA, the most effective way for an individual to seek a remedy may be through civil action. There are several potential civil causes of action that an individual may take against private companies that contribute to the revelation of their genetic information. First, a cause of action may arise under the concept of an invasion of privacy, such as intrusion upon seclusion. A second cause of action for relatives of 23andMe's consumers is to bring a claim for a breach of contract as a third-party

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[170] Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (2008).

[171] *Id.*

[172] Ajunwa, *supra* note 13, at 1229–31.

[173] Acara v. Banks, 470 F.3d 569, 570 (5th Cir. 2006).

[174] *Id.* at 571.

[175] *Id.* ("Because HIPAA specifically delegates enforcement, there is a strong indication that Congress intended to preclude private enforcement.") (citing Alexander v. Sandoval, 532 U.S. 275, 286–87 (2001)) ("The express provision of one method of enforcing [a statute] suggests Congress intended to preclude others.").

beneficiary. Third, the nonconsensual disclosure of sensitive genetic information by 23andMe could result in the unwanted third-party discovery of personal health risks and other distressing information. Therefore, a cause of action may arise under the negligent infliction of emotional distress. Lastly, due to the familial shared nature of genetic information, a class action suit may solve the issue of scope and efficiency in the realm of nonconsensual genetic disclosure.

The following discussion of civil remedies is a great starting point to represent the task of balancing one's personal autonomy to do with one's body, blood, and genes as they wish, while also considering the privacy implications to third-party relatives.[176] Because every individual is the sole proprietor of their own unique genetic information, they deserve the ability to consensually learn from their genetic information, even if that means sharing it with DTC companies. However, once that information is disclosed and used in a manner not contemplated, and consented to, by the original consumer at the time of the disclosure, such as through altered terms of service, mergers, or data breaches, third-party relatives may then be implicated and therefore have a cause of action for the invasion of their genetic privacy. Balancing these interests is vital while considering each civil remedy discussed in this Article.

### *A. Invasion of Privacy*

Mark A. Rothstein's article, *Genetic Stalking and Voyeurism: A New Challenge to Privacy*, explores the realm of genetic stalking with regard to abandoned celebrity DNA.[177] The article specifically deals with the publication of abandoned genetic information without the consent of its original owner.[178] While the circumstances differ from the context of this Article, the result (the public disclosure of private and personal health information) is the same nevertheless.

One possible claim under the tort of invasion of privacy would be intrusion upon seclusion. A claim for the intrusion upon seclusion may arise when "one who intentionally intrudes, physically or otherwise, upon the solitude or seclusion of another or his private affairs or concerns, is subject to liability to the other for invasion of his privacy, if the intrusion would be highly offensive to a reasonable person."[179] As explained in the article, applying this tort to a set of facts in which there is not a physical act of intrusion presents an obstacle to recovery.[180] The intrusion would have to be viewed as "a 'dignitary' as opposed to 'property' view of intrusion, independent of any physical intrusion or the widespread disclosure of the test results . . . ."[181] This

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[176] Law Offices of Stimmel, Stimmel, and Roeser, *The Legal Right to Privacy*, STIMMEL LAW https://www.stimmel-law.com/en/articles/legal-right-privacy [https://perma.cc/S9W3-CXUM] (last visited Feb. 5, 2020) ("Privacy is not sacrosanct, however, being balanced with the needs and wants of the other citizens and the person's own actions in perhaps pursuing exposure or encouraging it.").

[177] Mark A. Rothstein, *Genetic Stalking and Voyeurism: A New Challenge to Privacy*, 57 U. KAN. L. REV. 539 (2009).

[178] *Id.* at 543.

[179] RESTATEMENT (SECOND) OF TORTS § 652B (AM. LAW INST. 1977); Rothstein, *supra* note 177, at 550 (Rothstein asserts that in the realm of genetic stalking, the requirement that the "intrusion must be highly offensive to a reasonable person" would be the easiest requirement to fulfill. This conception likely extends to nonconsensual familial genetic disclosure.).

[180] Rothstein, *supra* note 177, at 549.

[181] *Id.* (A dignitary view in these types of cases "is based on the sensitive nature of the information revealed by the DNA testing.").

mindset embraces the ideology that the "common law tort of intrusion upon seclusion should protect people not places."[182] Intrusion upon seclusion as a result of the nonconsensual disclosure of genetic information can have detrimental effects on many aspects of third-party relatives' lives.[183] Damages may arise for "loss of reputation or community status," for "harm to the plaintiff's 'interest in privacy,'" and for the "consortium loss by the spouse of the subject."[184]

Rothstein also asserts that "the courts have not developed a consistent doctrine for when medical testing beyond the bounds of consent constitutes intrusion upon seclusion."[185] For instance, in *Doe v. High-Tech Institute Inc.*, the Colorado Court of Appeals held that intrusion was warranted when an unauthorized test for HIV on a student's blood sample, which was originally submitted for the purpose of rubella testing, yielded positive, and the positive HIV test result was subsequently disclosed to the state health department.[186] But the court also underscored the distinction between initial consent for an authorized action and further consent required for any additional action or procedures. In other words, "a person has a privacy interest in his or her blood sample and in the medical information that may be obtained from it," and "an *additional, unauthorized test* . . . can be sufficient to state a claim for relief for intrusion upon seclusion."[187]

This is where third-party relatives and immediate family members may run into an obstacle. Not only would third-party relatives not have consented to the "additional, unauthorized test" or other nonconsensual use of their genetic information in the event of unread or altered terms of service or a merger, but the relatives didn't even consent to the original agreement between the consumer and 23andMe to provide genetic information for the purposes associated with DTC genetic testing. Should a third-party relative be able to file suit against 23andMe, or even the sharing family member, for the disclosure of their DNA without the consent of every family member who may be affected by the disclosure?

As stated in the landmark Supreme Court decision *Moore v. Regents of California*: "[i]n deciding whether to create new tort duties we have in the past considered the impact that expanded liability would have on activities that are important to society, such as research."[188] In *Moore*, the court was hesitant to establish a cause of action for conversion for a physician's nonconsensual use of a patient's biological samples for personal gain, as the "extension of conversion law into this area will hinder research by restricting access to the necessary raw materials."[189]

In the case of a third-party relative seeking a remedy for the nonconsensual disclosure of their genetic information under intrusion upon seclusion, courts should

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[182] Doe v. High-Tech Inst., Inc., 972 P.2d 1060, 1068 (Col. Ct. App. 1998) (citing Hamberger v. Eastman, 106 N.H. 107 (1964)).

[183] Ajunwa, *supra* note 13, at 1229–31.

[184] Law Offices of Stimmel, Stimmel, and Roeser, *supra* note 176; 2 AM. LAW OF TORTS § 8:22 (2020) ("The term 'consortium' is usually defined as encompassing the services and financial support of the spouses, and the variety of intangible relations that exist between spouses living together in marriage.").

[185] Rothstein, *supra* note 177, at 550.

[186] *Id.* (citing *Doe*, 972 P.2d at 1067).

[187] *Doe*, 972 P.2d at 1068 (emphasis added).

[188] Moore v. Regents of University of California, 51 Cal. 3d 120, 146 (1990).

[189] *Id.* at 144.

similarly be hesitant to broaden the scope of liability to the point where any individual who legitimately discloses his or her genetic information and the entities that receive it (such as with DTC companies, clinical studies, medical researchers, etc.), may then be liable to every immediate family member who possesses an appreciable amount of the same genetic sequence.

### B. *Third-Party Beneficiary Argument*

A second applicable and potentially successful claim for relatives affected by the nonconsensual disclosure of their genetic information may lie under a breach of contract claim as a third-party beneficiary. To succeed under this claim, it would be imperative to establish that the relatives of 23andMe's consumers are an intended beneficiary, and not incidental beneficiary.[190] There are four elements one must establish to recover as an intended third-party beneficiary.[191]

First, there must be a contract between the parties.[192] For the purposes of this Article, a contract exists between the consumer and 23andMe upon the execution of payment in exchange for health and genetic test results. Second, there must be a "'clear' or 'manifest' intent of [the parties] that the contract primarily and directly benefit[s] the third party (or class of persons to which that party belongs)."[193] This element will be the most difficult to prove. Although 23andMe's privacy statement does refer to potential implications of genetic test results to family members, there is no question that the primary, intended beneficiary of the genetic testing lies with the individual that submitted their saliva sample and paid to obtain the results from said sample. The best argument that can be made is that the relatives are among the "class of persons to which that party belongs"; in other words, they are a member of the same class (i.e., family) as the consumer.

The third element may also have difficulty being met, as there must be a breach of the contract by either of the parties.[194] 23andMe has taken extensive precautions through contractual disclaimers to preclude itself from liability as a result of the disclosure of genetic information through a data breach, merger, or altered terms of service. Therefore, it may be difficult to assert a breach of contract for terms to which both parties technically provided consent. The last requirement is "damages to the third-party resulting from the breach."[195] However, this last prong is meaningless unless the relatives of the consumers can meet the first three required elements.

### C. *Negligent Infliction of Emotional Distress*

The third potential claim may arise under negligent infliction of emotional distress. Many courts have imposed a variety of requirements and obstacles to achieve recovery under this cause of action. For instance, there are discrepancies as to whether physical

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[190] RESTATEMENT (SECOND) OF CONTRACTS § 302 cmt. e (AM. LAW INST. 2019) ("Performance of a contract will often benefit a third person. But unless the third person is an intended beneficiary as here defined, no duty to him is created.").

[191] *Incidental Beneficiary Law and Legal Definition*, USLEGAL, https://definitions.uslegal.com/i/incidental-beneficiary/ [https://perma.cc/GT94-ATRU] (last visited Feb. 5, 2020).

[192] *Id.*

[193] *Id.*

[194] *Id.*

[195] *Id.*

injuries must manifest in order to recover damages.[196] Additionally, some courts "emphasize that in order to recover, the emotional distress is compensable only when it is the direct—not merely the consequential—result of the defendant's breach of duty."[197]

The success of this claim hinges on the question of whether a duty should be imposed on 23andMe to both their consumer *and their consumers' family members*. "Whether a defendant owes a duty of care depends upon the foreseeability of the risk and a weighing of policy considerations for and against imposition of liability."[198] As discussed previously, the academic community has recognized the foreseeable risks to third-party relatives associated with genetic testing, because with "the ability of genetic testing to infringe upon the privacy of related individuals, there is also a valid concern that public data may reveal a hidden disease risk that also pertains to a relative who would rather not know."[199]

In fact, 23andMe views these risks as foreseeable, as they warn their consumers to "make sure you have permission from the family member" before you disclose information about that family member.[200] However, while the harm of emotional distress to the relatives of 23andMe's consumers may certainly be foreseeable, there are understandable policy arguments against imposing such a broad scope of liability on DTC genetic testing, especially as the development of "DTC 2.0" has shifted genetic testing into the realm of legitimate medical research.[201]

### D. *Class Action*

Due to the number of third-party relatives who may wish to obtain a civil remedy for the nonconsensual disclosure and use of their genetic information, and due to the issue of broad liability and potentially repetitive litigation, the most efficient method for recovery would be through a class action suit. Class action suits are governed by Federal Rules of Civil Procedure Rule 23.[202] "The purposes of class actions are to (1) avoid multiplicity of actions and (2) enable persons to assert small claims that could not be litigated individually because the costs would far outweigh any recovery."[203] There are four requirements to establishing a class action suit: numerosity, commonality, typicality, and adequacy of representation.[204]

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[196] STUART M. SPEISER, CHARLES F. KRAUS & ALFRED W. GANS, AMERICAN LAW OF TORTS § 16:12 (Monique C.M. Leahy ed., 2019).

[197] *Id.*

[198] 46 Cal. Jur. 3d Negligence § 87 (2019).

[199] Erlich et al., *supra* note 10 ("There are many people who know that they may carry a genetic disease and choose not to be tested so that they can continue to live their lives without being defined by a diagnosis."); *see supra* notes 110–11.

[200] *Privacy Highlights*, 23ANDME, *supra* note 94, at § 2(a)(ii).

[201] Moore v. Regents of California, 51 Cal. 3d 120, 146 (1990) (recalling the court's hesitancy to burden the field of medical research with broad and intense civil liability).

[202] FED. R. CIV. P. 23.

[203] VIRGINIA A. PHILIPS & KAREN L. STEVENSON, FEDERAL CIVIL PROCEDURE BEFORE TRIAL ¶ 10:250 (2019).

[204] FED. R. CIV. P. 23(A).

### *i. Numerosity*

To satisfy numerosity, "the class is so numerous that joinder of all members is impracticable."[205] There are additional factors to consider when determining numerosity. First, class actions do not require an exact numerical cut-off number for plaintiffs, but the numerosity requirement "can be satisfied so long as there is a *reasonable basis* for the estimate provided."[206] This factor will be difficult for third-party relatives to establish. If 23andMe's entire twelve million customer database were affected by a merger or data breach, it would then be a guessing game at best as to how many mothers, fathers, brothers, and sisters were also affected by the nonconsensual disclosure of their genetic information. Second, class actions are suitable when the number of plaintiffs cannot be determined because the identity of the class's members remains unknown.[207] However, even though "the identity of the class members need not be known at the time of certification, class membership must be objectively ascertainable; i.e., it must be *possible for the members to identify themselves* as a member of the class."[208] This factor would only be workable for third-party relatives if there were a minimum threshold of shared genetic information requirement, e.g., 50% shared genetic information (the common percentage of shared genetic information between full siblings and between parents and their children).[209] With such a requirement, every immediate family member of those whose genetic information was dispersed through 23andMe could identify themselves as a member of the class.

### *ii. Commonality*

To meet commonality, there must be "questions of law or fact common to the class."[210] In 2010, the Supreme Court's decision in *Walmart Stores, Inc., v. Dukes* "expanded the significance of commonality"[211] by requiring that the plaintiff's "claims must depend upon a common contention of such a nature that it is capable of class wide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke."[212] Since the *Walmart Stores, Inc.* decision, lower courts have affirmed that "a plaintiff generally cannot satisfy the commonality requirement 'where the defendant's

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[205] *Id.*

[206] Feinman v. FBI, 29 F.R.D. 44, 49 (D.D.C. 2010) (quoting Kifafi v. Hilton Hotels Ret. Plan, 189 F.R.D. 174, 176 (D.D.C. 1999).

[207] PHILIPS & STEVENSON, *supra* note 203.

[208] *Id.* (emphasis in original) (citing DeBremaecker v. Short, 433 F. 2d 733, 734 (5th Cir. 1970) and Asiana v. Kashi Co., 291 F.R.D. 493, 500 (S.D. Cal. 2013)).

[209] *Average Percent DNA Shared Between Relatives*, 23ANDME, https://customercare.23andme.com/hc/en-us/articles/212170668-Average-percent-DNA-shared-between-relatives [https://perma.cc/K2KY-WUJN].

[210] FED. R. CIV. P. 23(A)(2).

[211] KEVIN M. LEWIS & WILSON C. FREEMAN, CONG. RSCH. S., R45159, CLASS ACTION LAWSUITS: A LEGAL OVERVIEW FOR THE 115TH CONGRESS 11 (2018), https://fas.org/sgp/crs/misc/R45159.pdf [https://perma.cc/EQ5D-X2WM].

[212] Walmart Stores, Inc. v. Dukes, 131 S. Ct. 2541, 2545 (2011).

allegedly injurious conduct differs from plaintiff to plaintiff.'"[213] In the case of a class action suit brought by third-party relatives of the consumers of 23andMe, the issue of whether 23andMe negligently or willfully disclosed the genetic information of its consumers would be an issue that is "central to the validity of each one of the" plaintiffs' claims.[214] While the harm or damages resulting from the injurious conduct (i.e., the wrongful disclosure of genetic information) may vary (i.e., invasion of privacy and emotional distress), there is still a common question as to whether the injurious conduct responsible for those damages was in fact the wrongful disclosure of 23andMe's consumers' genetic information.

### *iii. Typicality and Adequacy of Representation*

A plaintiff's claim is "typical if it arises from the same event or practice or course of conduct that gives rise to the claims of other class members and is based on the same legal theory as their claims."[215] When evaluating a class action suit for typicality, many courts "inquire whether the proposed class representative's claim 'arises from the same event or practice or course of conduct that gives rise to the claims of other class members.'"[216] Typicality appears to be a blend of commonality and adequate representation in that it inspects whether the plaintiff's claims arise from the same injurious conduct, and it also "seeks to ensure that representative parties 'adequately protect the interests of the class.'"[217]

Despite the many advantages of class action suits, they must inevitably be weighed against their accompanying disadvantages. First, the inherent nature of class action suits deprives millions of plaintiffs of their day in court by vesting all of their legal interest in the representative party.[218] While this downfall is ideally avoided when evaluating the adequacy of representation, this risk remains present throughout the course of litigation because the majority of "class members usually do not control or actively participate in the litigation."[219]

Another disadvantage of class action suits is "lawyer-driven litigation" resulting from the discrepancy between the expected award share for the class members and for legal counsel.[220] In other words, if "class counsel obtains a favorable result for the class in the $30 million fraud example described above, each class member may win a maximum of only $30, but class counsel could potentially receive a sizable award of attorney's fees."[221] This has created concern as to whether attorneys truly have an incentive to pursue the ideal award amount entitled by the members of the class as opposed to reaching a settlement.[222]

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[213] Lewis, *supra* note 214, at 12 (quoting Suchanek v. Sturm Foods, Inc., 764 F.3d 750, 756 (7th Cir. 2014)).

[214] *Walmart*, 131 S. Ct. at 2545.

[215] Rutter, *supra* note 206, at 10:289 (citing Rosario v. Livaditis, 963 F.2d 1013, 1018 (7th Cir. 1992)).

[216] Lewis, *supra* note 211, at 14 (quoting Oshana v. Coca-Cola Co., 472 F.3d 506, 514 (7th Cir. 2006)).

[217] *Id.* (quoting Gen. Tel. Co. of Sw. v. Falcon, 457 U.S. 147, 157 n.13 (1982)).

[218] *Id.* at 5.

[219] *Id.* at 6.

[220] *Id.*

[221] *Id.*

[222] *Id.* at 7.

Ultimately, individuals are not likely to succeed in bringing a civil action for the disclosure of their genetic information, especially because there is a lack of precedent regarding this particular realm of privacy. Due to the lack of case law and nebulous nature of modern genetics, there are substantial difficulties of recovering under these causes of action for even the original owner of the genetic information, let alone immediate family members.

## VI. RECOMMENDED FEDERAL ACTION

Although a variety of state laws[223] may "provide consumers with potential causes of action against DTC companies in certain circumstances, these efforts are complicated by the fact that consumers typically agree to terms and conditions that contain exclusion clauses that limit a company's liability or provisions that limit the remedies and damages available to the consumer."[224]

The undeniable implicit privacy implications of the disclosure of genetic information justify additional and specific federal guidance. The best solution to protect consumers, and especially third-party relatives, is expanding the Health Information Portability and Accountability Act to apply to DTC genetic testing. DTC genetic testing companies already have the ability to qualify as a business associate when it partners with a health care provider, such as the case when 23andMe partnered with Palomar Pomerado Health, the largest public health district in California.[225] Federal action should be taken, either through incentives or regulations, to facilitate partnerships between DTC genetic testing companies and health care providers to further ensure that the companies are subjected to HIPAA's restrictions on sharing protected health information.

Under this framework, the original sharer and 23andMe would not be liable for the initial disclosure, as they would be treated the same as the original sharer disclosing for medical research or at their doctor's office. 23andMe, however, would be liable when they share that information and be penalized under HIPAA. Additionally, third parties may have easier recovery for negligent disclosure since a HIPAA violation can potentially be used as evidence to establish the duty and breach elements of negligence or a breach of contract.[226]

Lastly, even if DTC genetic testing companies were to become a covered entity under HIPAA, genetic information must be precluded from HIPAA's de-identified

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[223] Elizabeth E. Joh, *DNA Theft: Recognizing the Crime of Nonconsensual Genetic Collection and Testing*, 91 B.U. L. Rev. 665, 686 n.136 (2011).

[224] Clayton et al., *supra* note 14, at 18.

[225] Garner et al., *supra* note 99, 1250 n.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 23andMewould be subject to HIPAA's Privacy Rule."); *23andMe and Palomar Pomerado Health Partner to Give PPH Members Access to Their Genetic Information*, 23ANDME, https://perma.cc/KW78-CPU8.

[226] Graves v. Health Express, Inc., No. 09-0277, 2009 WL 2835778, at *3 (W.D. La. Aug. 31, 2009) ("Moreover, due to the lack of a private cause of action under HIPAA, the significance of an alleged violation of the federal statute is limited merely to evidence that defendants may have violated a duty of care owed to plaintiff under state tort (or contract) law, provided the alleged violation of the statute was the legal cause of plaintiff's damages.") (citing Faucheaux v. Terrebonne Consol. Government, 615 So. 2d 289, 292-93 (La. 1993)).

data sharing exception. As stated earlier in the HIPAA section of this Article, protected health information may be shared freely once it is stripped of all identifying information, such as names, addresses, emails, phone numbers, and social security numbers.[227] However, anonymous DNA, even after all identifiers are removed, has the potential to be retraced and identified to the original owner with a surprising amount of ease and accuracy.[228] Therefore, genetic information, as defined by 45 C.F.R. § 160.103, must be precluded from secondary use to limit the possibility of future exposure to the public forum.[229]

## VII. CONCLUSION

Much like the exploration and research of outer space and the ocean floor, modern genetics has only begun to scratch the surface of unveiling its true potential. What was once considered infotainment has now become a major player in providing medical services to millions of consumers. The mass accumulation and interpretation of millions of Americans' genetic information has inevitably led to a legitimate risk of its mass disclosure. While the consumers of DTC services are indeed vulnerable to this risk, third-party relatives are just as vulnerable and are even further without any feasible civil remedies to recover damages resulting from the widespread dissemination of their genetic information. With the last groundbreaking federal legislation in the field of genomics being over a decade ago, state judicial systems will only be left with ineffective tort remedies to adjudicate claims regarding genetic privacy.

Third-party relatives cannot be subjected to various common law remedies varying by state. DTC genetic testing has evolved from a novelty service to a legitimate actor in the field of genetic and medical research. Due to the sensitive nature and health information of the data extracted from DNA samples, proper enforcement of its confidentiality and distribution should fall under HIPAA's protective umbrella, at least until the issues raised in this Article receive full legislative attention.

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[227] *What is Protected Health Information?*, *supra* note 26.

[228] Pitts, *supra* note 28.

[229] 45 C.F.R. § 160.103 (2020) ("Genetic information means: The individual's genetic tests; The genetic tests of family members of the individual; The manifestation of a disease or disorder in family members of such individual; or [a]ny 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.").