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## Direct to Consumer or Direct to All: Home DNA Tests and Lack of Privacy Regulations in the United States

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THE UNITED  
STATES**

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Karen J. Kukla  
2023 – 2024

DIRECT TO CONSUMER OR DIRECT TO ALL: HOME DNA  
TESTS AND LACK OF PRIVACY REGULATIONS IN THE  
UNITED STATES

Karen J. Kukla

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## INTRODUCTION

While packing for a vacation, Heather Woock found out she had a half-sibling. Later, one half-sibling became two. Then three. As of 2019, more than fifty people were identified as Woock's half-siblings.<sup>1</sup> Thanks to today's direct-to-consumer genetic testing (DTC-GT), such as 23andMe and Ancestry.com, Woodstock and her siblings identified their common parent: fertility doctor Donald Cline.<sup>2</sup> Due to the ease of purchasing and taking a direct-to-consumer genetic test, Woodstock and her siblings were able to uncover their father's fertility fraud. More importantly, they were able to find each other.

DTC-GT is a revolutionized way for consumers to find insights based on their DNA without visiting a physician or genetic counselor. DTC genetic tests are advertised to consumers, through television, social media, the internet, etc. From identifying related family members to isolating future health risks, DTC-GT has a wide range of utility.

DTC-GT also provides law enforcement with a larger, more comprehensive genetic database. In 2016, a woman voluntarily submitted her DNA as part of a rape kit to San Francisco law enforcement.<sup>3</sup> Five years later, law enforcement used her submitted DNA, submitted only because of her rape, to bring a felony property charge against the woman.<sup>4</sup> While law enforcement maintains government genetic databases, they also use consumer genetic tests such as GEDmatch and FamilyTreeDNA to supplement missing data.<sup>5</sup>

Although the U.S. has some measures of privacy protection for genetic data, the lack of a comprehensive approach to protecting DTC-GT results in privacy violations for both consumers and their relatives. This

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<sup>1</sup> Kara Kenney, *Victims Hopeful New Law Will Protect Against Fertility Fraud*, WRTV INVESTIGATES (May 03, 2019), <https://www.wrtv.com/news/call-6-investigators/victims-hopeful-new-law-will-protect-against-fertility-fraud> [<https://perma.cc/P4Z9-L7A7>].

<sup>2</sup> Sarah Zhang, *The Fertility Doctor's Secret*, THE ATLANTIC (April 2019), <https://www.theatlantic.com/magazine/archive/2019/04/fertility-doctor-donald-cline-secret-children/583249/> [<https://perma.cc/63QZ-A3FR>] (Mar. 18, 2019, 5:23 PM).

<sup>3</sup> Emily Mullin, *A Rape Survivor Gave Police Her DNA. They Linked Her to Another Crime*, WIRED (Feb. 24, 2022, 8:00 AM), <https://www.wired.com/story/a-rape-survivor-gave-police-her-dna-they-linked-her-to-another-crime/> [<https://perma.cc/UZ7X-H6KP>].

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

essay explores the critical need for the U.S. government to address these privacy violations and argues that the U.S. should approach the problem and strategize a solution similar to the European Union's (EU) General Data Protection Regulation (GDPR). Part I identifies current United States law, both federal and state regulations that address DTC-GT and genetic privacy. Part II examines the lack of regulation surrounding current DTC-GT companies and the potential to abuse individuals' privacy. Finally, Part III explores various solutions to resolve genetic privacy issues in the U.S. and advocates for the federal government to adopt a comprehensive regulatory framework like the EU or California.

#### I. BACKGROUND: UNITED STATES' CURRENT LAW SURROUNDING GENETIC DATA PRIVACY

In the United States, numerous players and mechanisms regulate genetic data privacy. Instead of establishing an overarching set of privacy laws or a single comprehensive system, the U.S. regulates genetic data through separate, dissociated approaches. For example, courts are currently debating whether the Fourth Amendment may regulate law enforcement's use of genetic data provided by DTC-GT companies.<sup>6</sup> Another route involves establishing federal law or assigning power to federal agencies to directly regulate the gathering, analysis, and use of genetic information or to indirectly regulate DTC-GT companies.<sup>7</sup> Unless there is federal preemption, states can also supplement the federal system's laws and regulations.<sup>8</sup> Finally, common law privacy torts such as disclosure and intrusion torts may regulate genetic data privacy.<sup>9</sup> However, while the U.S. legal system addresses some genetic data privacy concerns, current U.S. laws fail to provide a cohesive and comprehensive approach to regulating DTC-GT and the use of genetic data.

##### A. DTC-GT Regulation Through the Fourth Amendment

As DTC-GT utilization expands beyond its initial purpose of identifying ancestry, more consumers are submitting their DNA to DTC-GT companies.<sup>10</sup> Consequently, databases containing users' genetic information

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<sup>6</sup> See *Genetic Information Privacy*, ELEC. FRONTIER FOUND. (2015), <https://www EFF.org/issues/genetic-information-privacy> [<https://perma.cc/DY8V-YDTE>] (last visited Oct. 17, 2022).

<sup>7</sup> See Samuel A. Garner & Jiyeon Kim, *The Privacy Risks of Direct-To-Consumer Genetic Testing: A Case Study of 23andMe and Ancestry*, 96 WASH. UNIV. L. REV. 1219, 1225–1230 (2019).

<sup>8</sup> *Id.* at 1231–32.

<sup>9</sup> *Id.* at 1233.

<sup>10</sup> Ayesha K. Rasheed, *Personal Genetic Testing and the Fourth Amendment*, 2020 U. ILL. L. REV. 1249, 1252 (2020).

are also expanding.<sup>11</sup> As of 2019, more than 26 million people worldwide submitted genetic information to genealogy databases.<sup>12</sup> Following the trend, law enforcement also increased its utilization of the growing pool of genetic information to identify criminals.<sup>13</sup> More importantly, before accessing the databases, law enforcement rarely requests a warrant to obtain the database's sensitive information.<sup>14</sup> While some DTC-GT companies attempt to combat law enforcement by refusing to comply, the Fourth Amendment provides stronger legal protection against unreasonable searches and seizures by the government.<sup>15</sup> Due to law enforcement's increased use of DTC-GT databases, the application of the Fourth Amendment to law enforcement's use of DTC-GT databases is currently being tested in the U.S. court system.<sup>16</sup> The outcomes of these cases may address how the Fourth Amendment directly protects U.S. citizens' genetic privacy from the government.<sup>17</sup> Furthermore, the outcomes may explain how the Fourth Amendment indirectly impacts DTC-GT companies' capacity to sell or provide genetic data to law enforcement.<sup>18</sup>

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<sup>11</sup> See *Genetic Information Privacy*, ELEC. FRONTIER FOUND. (2015), <https://www.eff.org/issues/genetic-information-privacy> [<https://perma.cc/DN6P-UNCE>] (last visited Oct. 17, 2022).

<sup>12</sup> Antonio Regalado, *More than 26 million people have taken an at-home ancestry test*, MIT TECH. REV. (Feb. 11, 2019), <https://www.technologyreview.com/2019/02/11/103446/more-than-26-million-people-have-taken-an-at-home-ancestry-test/> [<https://perma.cc/3RYX-SLQZ>].

<sup>13</sup> Jennifer Lynch, *Police May Not Need a Warrant to Rummage Through Your Trash, But Warrantless Collection of DNA Is Unconstitutional*, ELEC. FRONTIER FOUND. (Mar. 11, 2020), <https://www.eff.org/deeplinks/2020/03/police-may-not-need-warrant-rummage-through-your-trash-warrantless-collection-0> [<https://perma.cc/44D5-W6EU>].

<sup>14</sup> *Id.*

<sup>15</sup> See U.S. CONST. amend. IV.

<sup>16</sup> See Brief of Amici Curiae American Civil Liberties Union in Support of Defendant's Motion to Suppress DNA Extraction, Testing, and Sequencing, *South Dakota v. Bentaas*, No. 49CRI19-001657 (2020); Laurel Wamsley, *In Hunt for Golden State Killer, Investigators Uploaded His DNA to Genealogy Site*, NPR (Apr. 27, 2018, 7:31 PM ET) <https://www.npr.org/sections/thetwo-way/2018/04/27/606624218/in-hunt-for-golden-state-killer-investigators-uploaded-his-dna-to-genealogy-site> [<https://perma.cc/PUT9-5BV5>]; First Amend. Felony Compl., *People v. DeAngelo*, No. 18FE008017, 2018 WL 4051697 (Cal. Super. Ct. Aug. 21, 2018); Michael Balsamo et. al., *Police Using Genetic Sites Misidentified Oregon Man as Golden State Serial Killer Suspect in 2017*, CHI. TRIB. (Apr. 28, 2018, 9:39 AM), <https://www.chicagotribune.com/news/nationworld/ct-genealogy-site-serial-killer-20180427-story.html> [<https://perma.cc/7SQY-GWMF>].

<sup>17</sup> See Rasheed, *supra* note 9, at 1254.

<sup>18</sup> See *id.* at 1255.

*B. Federal Regulation: Statutes*

Throughout recent years, Congress passed several federal laws to regulate private and public collection, processing, use, and disposal of genetic information.<sup>19</sup> Due to the multiple uses of genetic information, current federal laws address genetic privacy in limited scenarios.<sup>20</sup>

For research studies or clinical trials, several laws protect participants and their corresponding genetic information. The U.S. Common Rule or the Federal Policy for the Protection of Human Subjects aims to protect participants from lack of informed consent. For example, the U.S. Common Rule requires participants to be informed that their genetic data will be used for research or commercial purposes.<sup>21</sup> Taking additional steps to protect participants' confidentiality, in 2016 Congress passed the 21st Century Cures Act.<sup>22</sup> The Act provides federal research subjects with a certificate of confidentiality, preventing researchers from leasing subjects' genetic data to government agencies.<sup>23</sup>

While these laws protect some genetic privacy in a research setting, the laws fail to address privacy issues associated with DTC-GT. The Common Rule and 21st Century Cures Act targets federally funded research,<sup>24</sup> whereas DTC-GT is “internal research.”<sup>25</sup> Furthermore, DTC-GT companies argue their research involves “people” and not “human subjects” under the Common Rule definition.<sup>26</sup> Unless DTC-GT companies use government funding or other techniques that change the status of their research, DTC-GT companies are not required to follow the informed consent requirements under the Common Rule.<sup>27</sup>

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<sup>19</sup> Garner & Kim, *supra* note 6, at 1224.

<sup>20</sup> Megan Molteni, *The US Urgently Needs New Genetic Privacy Laws*, WIRED (May 1, 2019, 8:00 AM), <https://www.wired.com/story/the-us-urgently-needs-new-genetic-privacy-laws/> [<https://perma.cc/E3Z2-VF3P>] (last visited Oct 17, 2022).

<sup>21</sup> Kevin C. Gilligan, *Protecting Consumers and Regulating Data: The Need for Comprehensive Federal Oversight of the Direct-to-Consumer Genetic Testing Industry*, 14 DREXEL L. REV. 207, 228–30 (2022); see Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149 (Jan. 19, 2017); 45 C.F.R. §§ 46.109(b)–(c) (2021).

<sup>22</sup> 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016).

<sup>23</sup> Molteni, *supra* note 19.

<sup>24</sup> Gilligan, *supra* note 20, at 229–31; see Molteni, *supra* note 19.

<sup>25</sup> *Protecting People in People Powered Research*, 23ANDME BLOG (July 30, 2014), <https://blog.23andme.com/23andme-research/protecting-people-in-people-powered-research/> [<https://perma.cc/4KHH-ND66>].

<sup>26</sup> Gilligan, *supra* note 20, at 231.

<sup>27</sup> *Id.*

Aside from research contexts, three federal statutes provide the bulk of the protection for patients' genetic privacy in clinical or insurance settings. However, "none [of these laws] truly protect[] privacy."<sup>28</sup> The first statute is the Health Insurance Portability and Accountability Act or HIPAA.<sup>29</sup> Under HIPAA, genetic data available to a patient's doctor is considered *identifiable* personal health information.<sup>30</sup> Under HIPAA, a patient's genetic privacy is protected from non-law enforcement agencies such as a patient's school or employer.<sup>31</sup> However, *without* a warrant, law enforcement agencies can access data under certain conditions.<sup>32</sup>

The second statute, the Affordable Care Act (ACA), protects patients from insurer discrimination (i.e., patient rejection, increased prices, etc.) based on genetic predisposition to health conditions.<sup>33</sup> Similarly, the Genetic Information Nondiscrimination Act (GINA) also protects patients from insurer discrimination based on genetic predisposition with several limitations.<sup>34</sup> Outside insurance, GINA regulates employment discrimination.<sup>35</sup> For example, an employer cannot "request, require, or purchase genetic information" of its employees or their family members.<sup>36</sup> Furthermore, an employer cannot discriminate against employees based on genetic information.<sup>37</sup>

Although HIPAA, ACA, and GINA provide a patient with some genetic privacy, the laws fail to comprehensively regulate DTC-GT. For example, genetic data from DTC-GT is considered aggregated, non-identifiable data and, therefore, is not protected under HIPAA.<sup>38</sup>

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<sup>28</sup> ELEC. FRONTIER FOUND., *supra* note 10.

<sup>29</sup> Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

<sup>30</sup> Molteni, *supra* note 19.

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Coverage for Pre-Existing Conditions*, HEALTHCARE.GOV, <https://www.healthcare.gov/coverage/pre-existing-conditions/> [<https://perma.cc/E7UW-6FKW>] (last visited Oct. 17, 2022).

<sup>34</sup> Molteni, *supra* note 19 (GINA only applies to pre-dispositions and not current diagnosis. GINA does not "apply to long-term-care insurance, life insurance, or disability insurance." *Id.*).

<sup>35</sup> ELEC. FRONTIER FOUND., *supra* note 10.

<sup>36</sup> Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 202, 122 Stat. 907 (2008) (codified as amended at 42 U.S.C. § 2000ff).

<sup>37</sup> *Id.* at 908.

<sup>38</sup> Robert Gellman, *Health Information Privacy Beyond HIPAA: A 2018 Environmental Scan of Major Trends and Challenges*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Dec. 13, 2017), [https://ncvhs.hhs.gov/wp-content/uploads/2018/05/NCVHS-Beyond-HIPAA\\_Report-Final-02-08-18.pdf](https://ncvhs.hhs.gov/wp-content/uploads/2018/05/NCVHS-Beyond-HIPAA_Report-Final-02-08-18.pdf) [<https://perma.cc/AK34-PGUJ>].



Additionally, DTC-GT companies are outside the “covered entities” or “business associate[s]” under HIPAA.<sup>39</sup> However, a DTC-GT company may be subject to HIPAA if the company partners with a covered entity.<sup>40</sup> Similarly, GINA does not specifically identify DTC-GT companies under the act’s third-party sharing regulations<sup>41</sup> and is limited to protection against discrimination.<sup>42</sup> Nonetheless, DTC-GT information falls under GINA protection.<sup>43</sup> Although an employee may voluntarily share their information, an employer cannot collect genetic information through DTC-GT or discriminate against an employee based on DTC-GT results.<sup>44</sup>

Analogous to ACA and GINA is the Americans with Disabilities Act (ADA). The ADA protects individuals with disabilities in employment, public accommodations, and government facilities.<sup>45</sup> An individual with a disability based on a genetic trait may be covered under ADA only if the trait visibly affects the individual.<sup>46</sup> Consequently, the ADA does not protect an asymptomatic individual with a disability from discrimination.<sup>47</sup> The ADA is also unclear regarding whether it protects an individual with a genetic trait that may increase the probability that a disability will manifest in the future.<sup>48</sup> Due to the lack of judicial interpretation, the ADA’s genetic privacy protection and its relation to DTC-GT companies is murky.<sup>49</sup>

From research to discrimination in the workplace, several federal statutes regulate genetic information. Similar to a slice of Swiss cheese, Congress’s approach to genetic privacy results in multiple gaps of unprotected uses or applications of genetic information. Because current

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<sup>39</sup> 45 C.F.R. § 160.103 (2021).

<sup>40</sup> A DTC-GT genetic testing company might collaborate with a HIPAA covered entity to expand genetic data collection and use. For example, in 2009, 23andMe partnered with a health care entity in California, gathering genetic data from the patients associated with the health care entity. Thus, 23andMe was subject to HIPAA. *See 23andMe and Palomar Pomerado Health Partner to Give PPH Members Access to Their Genetic Information*, 23ANDME (Apr. 27, 2009), <https://mediacenter.23andme.com/press-releases/23andme-and-palomar-pomerado-health-partner-to-give-pph-members-access-to-their-genetic-information/> [<https://perma.cc/M9Y7-J2HK>].

<sup>41</sup> Gilligan, *supra* note 20, at 241.

<sup>42</sup> *See supra* text accompanying note 33.

<sup>43</sup> Gilligan, *supra* note 20, at 238–39; *see generally* 42 U.S.C. § 2000ff(4).

<sup>44</sup> Garner & Kim, *supra* note 6, at 1226–28; *see Lowe v. Atlas Logistics Grp. Retail Servs. (Atlanta), LLC*, 102 F. Supp. 3d 1360, 1361 (N.D. Ga. 2015) (finding an employer can violate GINA when conducting genetic testing on its employees).

<sup>45</sup> *See* 42 U.S.C. §§ 12112, 12182.

<sup>46</sup> Gilligan, *supra* note 20, at 241–42.

<sup>47</sup> *Id.*

<sup>48</sup> Robert I. Field et. al., *Am I My Cousin's Keeper? A Proposal to Protect Relatives of Genetic Database Subjects*, 18 IND. HEALTH L. REV. 1, 25 (2021).

<sup>49</sup> Garner & Kim, *supra* note 6, at 1227–28.

laws lack clear protections and no laws directly regulate DTC-GT companies, many citizens' data remains vulnerable and unprotected.

*C. Federal Regulation: Administrative Agencies*

In addition to Congress's Swiss-cheese-like approach to statutory regulation of genetic privacy, three federal administrative agencies inadequately regulate DTC-GT: the Food and Drug Administration (FDA),<sup>50</sup> the Centers for Medicare and Medicaid Services (CMS) via the Clinical Laboratory Improvements Act (CLIA),<sup>51</sup> and the Federal Trade Commission (FTC).<sup>52</sup> The FDA's primary purpose is to protect "the public health by assuring the safety, effectiveness, quality, and security of . . . drugs, vaccines and other biological products, and medical devices."<sup>53</sup> Under the FDA, DTC genetic tests are regulated as "in vitro diagnostic devices."<sup>54</sup> Throughout the last decade, the FDA occasionally exercised its authority over DTC-GT companies.<sup>55</sup> However, the FDA's authority is extremely limited to only "health-related" DTC-GT, leaving a lack of regulation for DTC genetic tests for non-health-related purposes (e.g., genealogy, family relations, wellness, etc.).<sup>56</sup> Furthermore, the FDA regulates only the public health aspect of DTC-GT and offers no regulation for genetic privacy.<sup>57</sup>

Through the CLIA, CMS sets specific standards to ensure the validity of results and consistency among biological analyzing laboratories.<sup>58</sup> In particular, the CMS regulates laboratories that analyze "materials derived from the human body [to provide] information for the diagnosis, prevention, or treatment of any disease or impairment of, or the

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<sup>50</sup> Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399). The Federal Food, Drugs and Cosmetics Act provides FDA jurisdiction to regulate DTC-GTs as medical devices. *See* 21 U.S.C. § 321(h).

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

<sup>52</sup> Federal Trade Commission Act of 1914, Pub. L. No. 63-203, 38 Stat. 717 (codified as amended at 15 U.S.C. §§ 41–58).

<sup>53</sup> *FDA Fundamentals*, U.S. FOOD AND DRUG ADMIN, <https://www.fda.gov/about-fda/fda-basics/fda-fundamentals> [<https://perma.cc/X8BE-SAUR>] (Jan. 8, 2021).

<sup>54</sup> 21 C.F.R. § 809.3(a) (2023).

<sup>55</sup> *See* Garner & Kim, *supra* note 6, at 1228–29.

<sup>56</sup> James W. Hazel & Christopher Slobogin, *Who Knows What, and When?: A Survey of the Privacy Policies Proffered by U.S. Direct-to-Consumer Genetic Testing Companies*, 28 CORNELL J.L. & PUB. POL'Y 35, 41–42 (2018).

<sup>57</sup> Garner & Kim, *supra* note 6, at 1229.

<sup>58</sup> 42 C.F.R. § 493.1253(b)(2) (2023).

assessment of the health of, human beings.”<sup>59</sup> Under this definition, many types of DTC-GT are excluded.<sup>60</sup> Like the FDA, the CMS’s authority is limited to regulating health-related DTC-GT (e.g., diagnostic disease tests).<sup>61</sup> Thus, the CMS regulates a test’s analytical validity but not clinical validity nor utility.<sup>62</sup> The CMS also fails to regulate genetic privacy as well as provide guidance on how DTC-GT companies must convey information to consumers.<sup>63</sup>

Lastly, under the Federal Trade Commission Act (FTCA), the FTC broadly regulates “unfair” or “deceptive” business practices including false or misleading advertising practices.<sup>64</sup> The FTC has authority over DTC-GT, which is considered non-prescription medical device advertising.<sup>65</sup> In 2014, the FTC directly took action against DTC-GT companies.<sup>66</sup> The FTC alleged the companies contradicted its publicly available privacy policies.<sup>67</sup> The FTC stated the companies’ “acts and practices [related to data security were] . . . unfair or deceptive,” that companies “failed to provide reasonable and appropriate security for consumers’ personal information,” and that the companies created “unnecessary risks to personal information” including genetic information.<sup>68</sup> For the companies’ misdeeds, the FTC mandated updated data security programs and biennial security audits against the companies.<sup>69</sup> However, the FTC’s active involvement in the 2014 situation was rare.<sup>70</sup> Typically, the FTC limits its regulation over DTC-GT companies to “consumer bulletins.”<sup>71</sup>

Overall, federal administrative agencies partly address genetic privacy and DTC-GT, resulting in another Swiss-cheese approach. Both the FDA and the CMS regulate only “health-related” DTC-GT and fail to address DTC-GT. Although the FTC has broad authority to regulate non-health-related aspects of genetic privacy, history demonstrates the FTC favors a hands-off approach to regulating DTC-GT. Consequently, federal administrative agencies inadequately regulate DTC-GT.

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<sup>59</sup> 42 U.S.C. § 263a(a).

<sup>60</sup> Hazel & Slobogin, *supra* note 55, at 40–41.

<sup>61</sup> Garner & Kim, *supra* note 6, at 1229.

<sup>62</sup> *Id.*

<sup>63</sup> Hazel & Slobogin, *supra* note 55, at 41.

<sup>64</sup> Federal Trade Commission Act of 1914, Pub. L. No. 63-203, 38 Stat. 717 (codified as amended at 15 U.S.C. §§ 41–58).

<sup>65</sup> Garner & Kim, *supra* note 6, at 1229–30.

<sup>66</sup> Hazel & Slobogin, *supra* note 55, at 42.

<sup>67</sup> *Id.*

<sup>68</sup> Complaint at 12–14, *In re GeneLink, Inc.*, No. C-4456, (F.T.C. May 8, 2014).

<sup>69</sup> Garner & Kim, *supra* note 6, at 1229–30.

<sup>70</sup> *See id.*; *see also id.* at n. 70.

<sup>71</sup> Garner & Kim, *supra* note 6, at 1230; *see id.* at n.72.

*D. State Law*

In recent years, individual states attempted to fill the holes in the federal government's Swiss-cheese genetic privacy model. As of 2019, at least thirteen states effectively prohibit DTC-GT, and twelve states limit access to DTC-GT in certain aspects.<sup>72</sup> However, like the Federal Administrative regulations and federal laws, many of these effective regulations only limit when an entity uses DTC-GT to diagnose disease or health.<sup>73</sup> Consequently, the government generally fails to regulate DTC-GT's other services such as genealogy searches, lifestyle suggestions, etc.

In terms of genetic privacy and discrimination, more than half of states prohibit discrimination in employment and health insurance, including supplementing the unprotected areas in GINA.<sup>74</sup> More importantly, more than 80 percent of states provide some genetic information privacy to their citizens.<sup>75</sup> Some states approach genetic information as an individual's "exclusive" or "unique" property.<sup>76</sup> However, the limitations and definitions of these laws are often unclear.

California is the trailblazing state that supplements most of the federal genetic privacy framework's gaps. Due to its comprehensive and cohesive framework, California's laws are considered comparable to the European Union's General Data Protection Regulation (GDPR).<sup>77</sup> In 2011, California broke new ground by passing a forefront law: the California Genetic Information Nondiscrimination Act (CalGINA).<sup>78</sup> CalGINA extends federal discrimination protection from employment and health insurance to include discrimination involving medical services, housing, banking, education, etc.<sup>79</sup> In 2018, California passed the California Consumer Privacy Act (CCPA) protecting the rights of consumers whose data (not only genetic information) are collected by businesses.<sup>80</sup> Under CCPA, California citizens can request from businesses any data collected and bar businesses from selling their data.<sup>81</sup>

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<sup>72</sup> Garner & Kim, *supra* note 6, at 1231.

<sup>73</sup> *Id.*; *see id.* at nn.80–82.

<sup>74</sup> *Id.* at 1231–32; *see id.* at n.86.

<sup>75</sup> *Id.* at 1232.

<sup>76</sup> States include Alaska, Colorado, Georgia, and Florida. Jessica L. Roberts, *Progressive Genetic Ownership*, 93 NOTRE DAME L. REV. 1105, 1128 (2018).

<sup>77</sup> Garner & Kim, *supra* note 6, at 1232.

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*; *see id.* at n.88.

<sup>80</sup> CAL. CIV. CODE §§ 1798.100–1798.199 (West 2018).

<sup>81</sup> Gilligan, *supra* note 20, at 235–36.

The California Privacy Rights Act (CPRA) “closes loopholes from CCPA.”<sup>82</sup> This is the strongest privacy law in the United States and increases penalties, widens the scope of genetic information protection from large companies, and more strictly limits companies from collecting or selling consumer data.<sup>83</sup> Some consider CPRA as “likely to serve as the [new] standard for companies across the nation.”<sup>84</sup>

Effective January 1, 2022, California’s Genetic Information Privacy Act (GIPA) *directly* regulates DTC-GT companies, including those offering non-health-related services.<sup>85</sup> GIPA requires DTC-GT companies to be transparent about their genetic data practices, obtain written consent from consumers, establish and practice a framework that protects consumer’s genetic data, and allow consumers “to easily revoke consent, access their genetic data, delete their account and genetic data, and to have their biological sample destroyed.”<sup>86</sup> Consequently, GIPA protects individuals to a whole new level.

Unlike California’s GIPA, Florida’s genetic privacy law, the Protecting DNA Privacy Act, punishes violators with criminal penalties.<sup>87</sup> Without written consent, a business cannot intentionally analyze a person’s DNA through collection and retention, submit another person’s DNA sample for analysis, or disclose results to a third party.<sup>88</sup> Taking it a step further, Florida also prevents “sell[ing] or otherwise transfer[ring] another person’s DNA sample or analysis to a third party even if the DNA sample was originally collected with express consent.”<sup>89</sup>

Maryland and Montana lead the states in protecting genetic privacy against law enforcement. In 2021, Maryland and Montana passed the nation’s first laws “requiring judicial authorization to search consumer

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<sup>82</sup> *Id.* at 237.

<sup>83</sup> *Id.*; *see id.* at nn.197–201.

<sup>84</sup> Sam Dean, *California Voters Approve Prop. 24, Ushering in New Rules for Online Privacy*, L.A. TIMES (Nov. 4, 2020, 10:43 AM), <https://www.latimes.com/business/story/2020-11-03/2020-california-election-tracking-prop-24> [<https://perma.cc/2HQG-CPWU>].

<sup>85</sup> *See* Cal. Civ. Code § 56.18 (West 2021).

<sup>86</sup> Theodore Claypoole et. al., *California and Florida Introduce Two More Genetic Privacy Laws into the Mix*, JD SUPRA (Oct. 20, 2021), <https://www.jdsupra.com/legalnews/california-and-florida-introduce-two-1188777/> [<https://perma.cc/Y4VJ-K6LX>].

<sup>87</sup> FLA. STAT. § 817.5655 (2022).

<sup>88</sup> Claypoole et. al., *supra* note 85.

<sup>89</sup> *Id.*

DNA databases in criminal investigations.”<sup>90</sup> Following the Fourth Amendment’s purpose, Maryland’s and Montana’s laws prevent law enforcement from using DTC-GT databases and invading users’ sensitive data privacy to identify criminal suspects without a warrant.<sup>91</sup> Maryland’s law is more comprehensive and clearer than Montana’s law, limiting law enforcement’s request to use DTC-GT databases, providing judicial oversight of its use, and requiring written informed consent before collecting DNA samples from third parties.<sup>92</sup> Only two pages long, Montana’s law requires a warrant before law enforcement uses familial DNA or partial match search techniques as well as other kinds of searches on DTC-GT databases.<sup>93</sup>

As DTC-GT continues to grow and expand its services, the states need to protect their citizens from genetic privacy violations and plug the holes left by the federal system. While each state has its unique approach, California leads the efforts to fill the cheese holes. With several laws, California offers one of the more robust systems regarding discrimination and individual rights with companies. Other states such as Maryland and Montana focus on privacy from law enforcement.

#### *E. Common Law*

Like in many situations, a common law tort offers unclear, confusing, inadequate relief to victims of privacy violations. Out of current privacy torts established by Prosser,<sup>94</sup> the intrusion upon seclusion and public disclosure of private facts torts, in theory, could offer victims some relief.<sup>95</sup> For intrusion, DT-GT companies’ misuse of genetic information, or data breach may create a cause of action for the victim.<sup>96</sup> Similarly, disclosure may lead to a cause of action when a data breach occurs.<sup>97</sup> Additionally, a victim could argue emotional distress from a data breach or claim that a DTC-GT company failed its fiduciary duty.<sup>98</sup> Due to a lack of

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<sup>90</sup> Jennifer Lynch, *Maryland and Montana Pass the Nation’s First Laws Restricting Law Enforcement Access to Genetic Genealogy Databases*, ELEC. FRONTIER FOUND. (June 7, 2021), <https://www.eff.org/deeplinks/2021/06/maryland-and-montana-pass-nations-first-laws-restricting-law-enforcement-access> [https://perma.cc/8KZW-5VNG].

<sup>91</sup> *Id.*

<sup>92</sup> *See id.*; *see also* MD. CODE ANN., CRIM. PROC. §§ 17-101:02 (LexisNexis 2022).

<sup>93</sup> *See* Lynch, *supra* note 89; *see also* MONT. CODE ANN. § 44-6-104 (2021).

<sup>94</sup> *See generally* William L. Prosser, *Privacy*, 48 CALIF. L. REV. 383, 389 (1960).

<sup>95</sup> Garner & Kim, *supra* note 6, at 1233–34.

<sup>96</sup> *Id.*

<sup>97</sup> *Id.* at 1234.

<sup>98</sup> Gilligan, *supra* note 20, at 244.

legal precedent and the consumer's provided consent, whether privacy torts or other torts would provide adequate relief to victims remains unclear.<sup>99</sup>

## II. DEFINING THE PROBLEM: CURRENT FREEDOMS OF DIRECT-TO-CONSUMER GENETIC TESTING

As demonstrated in Part I, current U.S. federal laws, administrative agencies, and common law, fail to provide a comprehensive legal privacy framework. While some states attempted to fill in those gaps, consumers remain vulnerable to exploitation. Subsequently, the lack of consistent regulation results in DTC-GT companies' freedom to set inconsistent privacy and terms of service policies.

In the U.S., the most prevalent category of DTC-GT is determining family relationships.<sup>100</sup> Other services include ancestry, wellness category, and health-related identification.<sup>101</sup> Out of U.S.-based companies, 23andMe leads the forefront of innovating DTC-GT uses, offering a variety of services.<sup>102</sup> For example, 23andMe is the only DTC-GT company that includes FDA-authorized Genetic Health Risk, Cancer Predisposition, Carrier Status, and Pharmacogenetics reports.<sup>103</sup> However, the lack of comprehensive government regulation allows each DTC-GT company the freedom to create unique policies revolving around the collection, use, and sharing of genetic data.

### A. Policy Documents

The majority of U.S.-based DTC-GT companies share some policy documents, such as Privacy Policies or Terms of Service.<sup>104</sup> However, some companies' policy documents only relate to website privacy and not GT services.<sup>105</sup> Although many companies include policy documents on their websites, some companies only send policy documents after a user

<sup>99</sup> Garner & Kim, *supra* note 6, at 1234.

<sup>100</sup> Hazel & Slobogin, *supra* note 55, at 47.

<sup>101</sup> *Id.*

<sup>102</sup> See Garner & Kim, *supra* note 6, at 1234–35.

<sup>103</sup> Hazel & Slobogin, *supra* note 55, at 47; see *Who We Are*, 23ANDME FOR HEALTHCARE PROFESSIONALS (2020), <https://medical.23andme.com/company/#who-we-are> [<https://perma.cc/E9RC-W2UK>] (last visited Oct. 17, 2022); see *FDA Allows Marketing of First Direct-to-Consumer Tests That Provide Genetic Risk Information for Certain Conditions*, U.S. FOOD AND DRUG ADMIN. (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/KW3L-PKPS>].

<sup>104</sup> Hazel & Slobogin, *supra* note 55, at 48.

<sup>105</sup> *Id.*

purchases a test kit.<sup>106</sup> Most policy documents specify that DTC-GT companies reserve the right to modify their policy documents.<sup>107</sup> More importantly, many DTC-GT policies *lack a notification requirement* of any policy changes to individualized consumers.<sup>108</sup> Instead, the consumers are “encouraged to routinely re-read the policy documents” available on the companies' websites.<sup>109</sup> Furthermore, some companies require parent or guardian consent if consumers are minors, depending on state law.<sup>110</sup> However, the definition of a minor varies among companies, with some companies defining a minor as low as 13 years old and as high as 18 years old.<sup>111</sup>

23andMe's Terms of Service state that the company has sole discretion to make changes to its policy documents.<sup>112</sup> Once changes are published, “they are effective immediately.”<sup>113</sup> Furthermore, 23andMe may notify its users if the change is “material” (no definition of material provided) via a website notice or email.<sup>114</sup> A parent or legal guardian may submit a sample for a minor if the child is under 18 years old, and state law allows the submission.<sup>115</sup>

### *B. Genetic Data: Laboratory Use*

Similar to the inconsistency among DTC-GT companies' policy documents, many companies are unreliable in providing information to the consumer about genetic data privacy, laboratory use, and security. Some companies clearly assert their compliance with federal and local laws such as the CLIA but fail to share their confidentiality procedures with consumers.<sup>116</sup> Other companies mention the removal of some personally identifiable information (i.e., name of consumer) associated with genetic data sent to an affiliated laboratory for testing, whereas some companies provide no insight into masking identifiable information.<sup>117</sup>

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<sup>106</sup> *Id.* at 48–49; *see id.* at n.66.

<sup>107</sup> Hazel & Slobogin, *supra* note 55, at 49.

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> *Id.* at 51–52.

<sup>111</sup> *Id.* at 52.

<sup>112</sup> *Terms of Service, 23ANDME*, <https://www.23andme.com/about/tos/> [<https://perma.cc/NC9D-CQ5S>] (June 8, 2022).

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *See id.*

<sup>116</sup> *See* Hazel & Slobogin, *supra* note 55, at 49–50.

<sup>117</sup> *Id.* at 50.



More frighteningly, physical genetic sample destruction policies are unclear and inconsistent. The majority of companies indefinitely store all samples, although they allow consumers to request that a sample be destroyed.<sup>118</sup> Conversely, some companies automatically destroy samples but allow consumers to request their samples be stored.<sup>119</sup> However, with many companies, it is unclear whether disposal includes the sample and the extracted DNA or just the sample.<sup>120</sup> Furthermore, many companies offer consumers the option to delete their genetic data in the database.<sup>121</sup> However, only some companies indicate the consumer may delete *all* of the data possessed by the company.<sup>122</sup>

With 23andMe, a user must opt-in to have their sample stored by 23andMe.<sup>123</sup> However, 23andMe or its contractors may store the sample.<sup>124</sup> Storage may be at least one year to a maximum of 10 years at a CLIA-certified laboratory, but if re-analysis is required, 23andMe may notify the user.<sup>125</sup>

### III. GENETIC DATA: COMMERCIAL USE & SHARING

Many DTC-GT companies do not explicitly assert ownership of genetic data or information from analysis, including commercialization rights.<sup>126</sup> Conversely, some companies explicitly assert.<sup>127</sup> Another pattern includes a DTC-GT company claiming the consumer retains ownership of the genetic data, but after submission, the company holds commercialization rights.<sup>128</sup>

Companies have inconsistent policies on sharing data due to the lack of government regulation. Some companies' policies include absolutely no sharing of genetic data with third parties.<sup>129</sup> Other companies require consumer consent before sharing.<sup>130</sup> Others have certain circumstances in

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<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

<sup>121</sup> Hazel & Slobogin, *supra* note 55, at 51.

<sup>122</sup> *Id.*

<sup>123</sup> *What You Should Know About Privacy at 23andMe*, 23ANDME, <https://www.23andme.com/legal/privacy/> [<https://perma.cc/J86V-4AAM>] (Dec. 14, 2022).

<sup>124</sup> *Biobanking*, 23ANDME, <https://www.23andme.com/about/biobanking/> [<https://perma.cc/L8ZH-R6L8>] (last visited Oct. 16, 2022).

<sup>125</sup> *Id.*

<sup>126</sup> Hazel & Slobogin, *supra* note 55, at 52–53.

<sup>127</sup> *Id.*

<sup>128</sup> *See id.*

<sup>129</sup> *Id.* at 54–55.

<sup>130</sup> *Id.*

which the company can sell to third parties without consumer consent.<sup>131</sup> For example, personally identifiable genetic data may be shared with third parties to provide services to consumers.<sup>132</sup> Many companies with this limitation fail to mention which third parties can access the data, or what is considered “services to the consumer.”<sup>133</sup> Another example would be sharing genetic information with third parties for genetic research.<sup>134</sup>

23andMe strongly advocates that the consumer decides when, how, and to whom their genetic information is shared.<sup>135</sup> For example, a customer may provide consent to allow 23andMe researchers to use their genetic information and agree to complete surveys.<sup>136</sup> In addition to adding the opted-in users to its research databases, 23andMe shares de-identified data (e.g., DNA data, age, and ethnicity) with third parties (i.e., non-profits, pharmaceutical companies, and academic institutions).<sup>137</sup> Additionally, 23andMe *may* share information with its Institutional Review Board.<sup>138</sup>

At the bottom of its Terms and Services, 23andMe specifically adds further information about the commercialization of genetic data.<sup>139</sup> 23andMe’s “Product Development” activities that qualify for commercialization include, but are not limited to: “improving our [s]ervices and/or offering new products or services to you; performing quality control activities; conducting data analysis that may lead to and/or include commercialization with a third party.”<sup>140</sup> However, 23andMe claims it is “not responsible for how those third parties collect or use your information”<sup>141</sup> and “won’t be able to contact [an individual] every time [23andMe] would like to share [an individual’s] data.”<sup>142</sup> If there are any

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<sup>131</sup> Hazel & Slobogin, *supra* note 55, at 55.

<sup>132</sup> *Id.*

<sup>133</sup> *Id.*

<sup>134</sup> *Id.* at 55–56.

<sup>135</sup> See *What You Should Know About Privacy at 23andMe*, *supra* note 121.

<sup>136</sup> *Research Consent Document*, 23ANDME, <https://www.23andme.com/about/consent/> [<https://perma.cc/2589-YHBN>] (last visited Oct. 16, 2022).

<sup>137</sup> *Id.*

<sup>138</sup> *Id.*

<sup>139</sup> See *Terms of Service*, *supra* note 110.

<sup>140</sup> *Id.*

<sup>141</sup> *Other Things to Know About Privacy*, 23ANDME, <https://www.23andme.com/legal/privacy/#other-things-to-know/> [<https://perma.cc/5LQ4-5XTG>] (last visited Oct. 16, 2022).

<sup>142</sup> *Individual Data Sharing Consent*, 23ANDME, <https://www.23andme.com/about/individual-data-consent/> [<https://perma.cc/9KMJ-PLK7>] (last visited Oct. 16, 2022).

financial benefits from the research, none will be provided to the user.<sup>143</sup> Similarly, a user will not receive profits from any commercial products derived from an individual's information, despite the fact that "any information derived from [an individual's] sample remains [that individual's] information."<sup>144</sup>

Regarding sharing data with law enforcement, DTC-GT companies hold inconsistent policies, such as the type of information shared or with whom the information is shared. While the majority of companies state they will only share personal information "as required by law," "required by law" remains undefined.<sup>145</sup> Surprisingly, many companies fail to disclose whether they would inform the individual if they released personal information to law enforcement.<sup>146</sup> Also, many companies include a catch-all provision that allows the company to disclose to third parties when required "to protect the rights of the company, other users, or the public, or to enforce the company's terms and conditions."<sup>147</sup>

However, in response to recent law enforcement use of DTC-GT for criminal investigations in the past couple of years generating public outcry,<sup>148</sup> the more prominent companies (i.e., GEDmatch, 23andMe, etc.) have taken a stricter approach against sharing data with law enforcement.<sup>149</sup> For example, 23andMe explicitly declared its database was "highly unlikely to be useful to law enforcement," because 23andMe's procedures fail to meet law enforcement's chain of custody requirement.<sup>150</sup> Furthermore,

<sup>143</sup> *Research Consent Document*, *supra* note 133. <https://www.23andme.com/legal/terms-of-service/#requirements-and-conditions>

<sup>144</sup> *See* 2. *Using the Services*, 23ANDME, <https://www.23andme.com/legal/terms-of-service/#requirements-and-conditions/> [<https://perma.cc/H735-5N9T>] (last visited Oct. 16, 2022).

<sup>145</sup> Hazel & Slobogin, *supra* note 55, at 56.

<sup>146</sup> *Id.*

<sup>147</sup> *Id.* at 56–57.

<sup>148</sup> *See* Jocelyn Kaiser, *We Will Find You: DNA Search Used to Nab Golden State Killer Can Home in on About 60% of White Americans*, SCIENCE (Oct. 11, 2018), <https://www.science.org/content/article/we-will-find-you-dna-search-used-nab-golden-state-killer-can-home-about-60-white> [<https://perma.cc/9CBK-2T9F>]; *see also* Katelyn Smith, *Genealogy Database Privacy Change Creates Challenges for Investigators*, WGAL NEWS 8, <https://www.wgal.com/article/genealogy-database-privacy-change-creates-challenges-for-investigators/28945357> [<https://perma.cc/4288-2WCC>] (Sep. 9, 2019, 6:58 PM).

<sup>149</sup> *See, e.g.*, Eric Heath, *Your Privacy is Our Top Priority*, ANCESTRY BLOG (Nov. 8, 2019), <https://blogs.ancestry.com/ancestry/2019/11/08/your-privacy-is-our-top-priority/> [<https://perma.cc/7NZR-E77B>].

<sup>150</sup> Kate Black & Zerina Curevac, *23andPrivacy: Your Data and Law Enforcement*, 23ANDME BLOG (Mar. 16, 2016), <https://blog.23andme.com/23andme-and-you/privacy-and-law-enforcement/> [<https://perma.cc/H4VR-R2YG>].

23andMe “chooses to use all practical legal and administrative resources to resist requests from law enforcement,” requiring a “valid legal process.”<sup>151</sup> Also, 23andMe declares the company “retains sole discretion to not notify the user” if law enforcement *requests* information.<sup>152</sup> However, 23andMe fails to mention a user notification policy if law enforcement *obtains* information.<sup>153</sup>

#### IV. PROPOSED SOLUTIONS

As the threat to data privacy continues to grow, government officials and consumers suggest various approaches to address the concerns listed above. One example includes assigning intellectual property rights to a consumer who submitted their genetic data. While numerous suggestions exist, adopting comprehensive policy regulations, like the EU’s GDPR, would solve many current U.S. genetic data privacy concerns.

##### A. Ownership: Intellectual Property

Under United States patent law, natural DNA (i.e., DNA unaltered by a human) is usually not patentable. In *Association for Molecular Pathology v. the United States Patent and Trademark Office* (also known as the Myriad case), the Supreme Court held an isolated nucleotide sequence identifying a gene for breast cancer was not patent-eligible subject matter per se.<sup>154</sup> In particular, the court held that isolated DNA is a “product of nature.”<sup>155</sup> Otherwise, the patent holder of an isolated DNA sequence would have a limited monopoly over diagnostic tests for breast cancer caused by BRCA1 and BRCA2 genes.<sup>156</sup> The court also held DNA manipulated in a lab (i.e., cDNA) was patent-eligible subject matter because of human manipulation.<sup>157</sup> However, the loopholes in U.S. patent law and patents before Myriad remain valid, resulting in patents for nearly twenty percent of

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<sup>151</sup> *23andMe Guide for Law Enforcement*, 23ANDME, <https://www.23andme.com/law-enforcement-guide/> [<https://perma.cc/828L-BG5B>] (last visited Oct. 16, 2022).

<sup>152</sup> *Id.*

<sup>153</sup> *See id.*

<sup>154</sup> *Ass’n for Molecular Pathology v. U.S. Pat. and Trademark Off.*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010), *as amended* (Apr. 5, 2010), *aff’d in part, rev’d in part*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted, judgment vacated sub nom.* *Ass’n. for Molecular Pathology v. Myriad Genetics, Inc.*, 566 U.S. 902 (2012), and *opinion vacated, appeal reinstated*, 467 Fed. Appx. 890 (Fed. Cir. 2012)(unpublished), and *aff’d in part, rev’d in part*, 689 F.3d 1303 (Fed. Cir. 2012).

<sup>155</sup> *Id.* at 190.

<sup>156</sup> *See id.* at 232.

<sup>157</sup> *See id.* at 198–99, 222.

the human genome.<sup>158</sup> Thus, while some genomes are patentable, the 2013 U.S. court decision in *Myriad* suggests individuals cannot patent their DNA. Hence, consumers cannot claim patent rights against DTC-GT companies.

In theory, DNA may be copyrightable as a literary work. Under the U.S. Copyright Act, literary works are “works, other than audiovisual works, expressed in words, numbers, or other verbal or numerical symbols or indicia, regardless of the nature of the material objects . . . .”<sup>159</sup> For example, computer code such as object code is considered a literary work even though code consists of numbers.<sup>160</sup> Similar to computer code, DNA comprises a string of letters to recognize a sequence of nucleotides.<sup>161</sup>

The difficulty lies in arguing DNA is original with *de minimis* creativity.<sup>162</sup> Like computer code, DNA is functional. But natural DNA is not created by a human or influenced by a human. A person may have a stronger argument for obtaining a copyright for lab-created DNA. Professor Dan Burk argues that copyrighting natural or synthetic DNA would be a “bad idea” because long-term (i.e., 120 years) copyright protection conflicts with the rapid advancements with DNA.<sup>163</sup> Thus, like in U.S. patent law, an individual would face difficulty in copyrighting their natural DNA to protect themselves from DTC-GT companies.

Overall, intellectual property rights do not provide users of DTC-GT with any privacy protections or rights from DTC-GT companies. Although individuals naturally produce genetic material, the law does not grant them intellectual property rights in their natural DNA.

### B. European Union Harmonization

In Europe, privacy is interwoven with the concept of human dignity.<sup>164</sup> Specifically, “[b]eing European means the right to have your personal data protected by strong, European laws.”<sup>165</sup> Following these

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<sup>158</sup> Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 *SCIENCE* 239, 239 (Oct. 14, 2005)

<https://www.science.org/doi/10.1126/science.1120014> [<https://perma.cc/96PY-QPS5>].

<sup>159</sup> 17 U.S.C. § 101.

<sup>160</sup> See generally *Apple Comput., Inc. v. Franklin Comput. Corp.*, 714 F.2d 1240, 1247–49 (3d Cir. 1983).

<sup>161</sup> 17 U.S.C. § 117.

<sup>162</sup> See *Feist Publ'ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 363–64 (1991).

<sup>163</sup> Susie Neilson, *Copyrighting DNA Is a Bad Idea*, NAUTILUS (June 14, 2016), <https://nautil.us/copyrighting-dna-is-a-bad-idea-235984/> [<https://perma.cc/2SEG-XEAT>].

<sup>164</sup> Jean-Claude Juncker, President of the European Commission, State of the Union 2016 (Sept. 14, 2016), in *PUBL'N OFF. OF THE EUR. UNION*, 2016, at 10.

<sup>165</sup> *Id.*

values, the European Union (EU) enacted the General Data Protection Regulation (GDPR) in 2016.<sup>166</sup> GDPR is considered a “strong” European law because its application applies to both national and foreign companies performing business in the EU.<sup>167</sup> With the EU's goal of harmonizing privacy laws across Europe and providing EU citizens more control over their data, the GDPR is perceived as one of the most comprehensive privacy legislation in the world.<sup>168</sup>

In addition to regulating any type of company, including a DTC-GT company, that processes EU citizens’ data regardless of the company’s physical location, GDPR requires companies to process personal data “lawfully, fairly, and transparently.”<sup>169</sup> Under the GDPR, genetic information is defined as personal information.<sup>170</sup> For example, data collection must be for a specified and limited purpose, excluding several exceptions.<sup>171</sup> Next, data must be concurrent and accurate, with changes performed in a prompt, transparent manner.<sup>172</sup> Finally, companies must ensure that any processing of personal data is performed to preserve the data’s integrity and confidentiality.<sup>173</sup> This includes storing the identity of users only for a necessary amount of time, heavily influenced by the data processing purpose.<sup>174</sup> However, the company that is controlling the data processing determines the “necessary amount of time.”<sup>175</sup>

More importantly, GDPR requires consumer consent.<sup>176</sup> Any processing and/or use of genetic data is unlawful unless “the consumer

<sup>166</sup> See Commission Regulation 2016/679, of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation), 2016 O.J. (L 119) 1 [hereinafter GDPR].

<sup>167</sup> See *id.* at 2, 4.

<sup>168</sup> Mark Scott & Laurens Cerulus, *Europe's New Data Protection Rules Export Privacy Standards Worldwide*, POLITICO (Jan. 31, 2018), <https://www.politico.eu/article/europe-data-protection-privacy-standards-gdpr-general-protection-data-regulation> [https://perma.cc/7S9W-6BRR].

<sup>169</sup> Juan Pablo Sarmiento Rojas, *Direct-to-Consumer Genetic Testing: Rethinking Privacy Laws in the United States*, 14 HEALTH L. & POL'Y BRIEF 21, 36 (2020); see *id.* at n.139.

<sup>170</sup> GDPR, *supra* note 162, art. 4(1), at 33.

<sup>171</sup> Rojas, *supra* note 165, at 36; see *id.* at n.140; see also GDPR, *supra* note 162, art. 5(1)(b), at 35.

<sup>172</sup> Rojas, *supra* note 165, at 36; see *id.* at n.141; see also GDPR, *supra* note 162, art. 5(1)(d), at 35.

<sup>173</sup> Rojas, *supra* note 165, at 36; see *id.* at n.142; see also GDPR, *supra* note 162, art. 5(1)(f), at 36.

<sup>174</sup> Rojas, *supra* note 165, at 36; see *id.* at n.143; see also GDPR, *supra* note 162, art. 5(1)(e), at 36.

<sup>175</sup> See GDPR, *supra* note 162, art. 5(1)(e), at 36.

<sup>176</sup> See GDPR, *supra* note 162, ch. 2, art. 6–7, at 37.

consents or it is necessary for the performance of a contract, complying with legal obligations, protecting vital interests of the individual or a third-party, carrying out a public interest task, or carrying out legitimate interests when such interests are not outweighed by the interests of the consumer.”<sup>177</sup> Consent must be in a written declaration and the burden is upon the company to demonstrate the consumer consented.<sup>178</sup> Likewise, a consumer may repudiate consent at any time.<sup>179</sup>

An additional unique GDPR feature includes mandating companies to tell users who has access to the users’ data, including contact information.<sup>180</sup> Similarly, the burden is on the company to ensure its users have multiple legal routes to ensure privacy or provide relief if privacy is breached.<sup>181</sup> For example, if a user’s data is processed in another country, that country must provide the user with legal routes to privacy or seek damages if privacy is breached.<sup>182</sup> In sum, the responsibility or duty to protect privacy is given to the company that is collecting or processing personal data.

Like most laws, the GDPR is not perfect. There are many loopholes or exceptions which companies like DTC-GT companies manipulate to their advantage. For example, the GDPR requires that a company must perform business or “the processing” activities are related to “the offering of goods or services” in the EU for the GDPR to apply.<sup>183</sup> However, the “offering of goods or services” is vague and is subject to different interpretations. Hypothetically, a DTC-GT company could set up a marketing company in the EU which performs limited personal data processing, transferring the user to a non-EU business (in this scenario the DTC-GT company) and gathering more intrusive personal data.<sup>184</sup>

Furthermore, the phrase “processing activities” can be exploited as well. For example, “transfer[ring]” data by selling data to a non-EU

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<sup>177</sup> Rojas, *supra* note 165, at 36.

<sup>178</sup> Rojas, *supra* note 165, at 36; *see id.* at n.145; *see also* GDPR, *supra* note 162, art. 7(1)–(2), at 37.

<sup>179</sup> Rojas, *supra* note 165, at 36; *see id.* at n.146; *see also* GDPR, *supra* note 162, art. 7(3), at 37.

<sup>180</sup> Rojas, *supra* note 165, at 36; *see id.* at n.147–48; *see also* GDPR, *supra* note 162, art. 12–13(1)(a).

<sup>181</sup> Rojas, *supra* note 165, at 37–38.

<sup>182</sup> Rojas, *supra* note 165, at 37.

<sup>183</sup> GDPR, *supra* note 162, art. 3(2)(a).

<sup>184</sup> *See* Robert Madge, *Five Loopholes in the GDPR*, MEDIUM (Aug. 27, 2017), <https://medium.com/mydata/five-loopholes-in-the-gdpr-367443c4248b> [<https://perma.cc/386K-FGWR>].

company would be outside GDPR protection.<sup>185</sup> Since the transferring of data is not related to the offering of goods or services covered under GDPR, personal data is not protected.<sup>186</sup> The chain of transferring and identifying specific data would be difficult to monitor and control.<sup>187</sup>

These loopholes may be concerning as DTC-GT companies expand their global partnerships. For example, in 2015, 23andMe received funding from China's WuXi Healthcare Ventures.<sup>188</sup> In 2018, GlaxoSmithKline (GSK) and 23andMe partnered for drug target discovery programs.<sup>189</sup> Although headquartered in the United Kingdom, GSK can access 23andMe's databases and user-sensitive data.<sup>190</sup>

Another GDRP concern involves its exceptions. Gathering or processing data involving public interest (i.e., public health), research, or historical (i.e., statistical) purposes are common exceptions.<sup>191</sup> Furthermore, Article 9.1 of the GDPR states processing data related to sensitive categories, such as biometrics, genetics, race, etc., is prohibited unless under Article 9.2.<sup>192</sup> One of these exceptions includes a user providing explicit consent to the processing of sensitive personal data.<sup>193</sup> However, "explicit consent" is not defined.<sup>194</sup> Thus DTC-GT companies are at liberty to define explicit consent.<sup>195</sup>

In 2022, the EU's In Vitro Diagnostic Medical Device Regulation (IVDR) took effect.<sup>196</sup> Like many U.S. genetic data privacy laws, the IVDR focuses on regulating DTC-GT performed for health-related purposes.<sup>197</sup> But while IVDR provides additional protection, IVDR fails to address many of GDPR's identified problems.

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<sup>185</sup> *Id.*

<sup>186</sup> *Id.*

<sup>187</sup> *Id.*

<sup>188</sup> See Sara A. Mahmoud-Davis, *Direct-to-Consumer Genetic Testing: Empowering EU Consumers and Giving Meaning to the Informed Consent Process Within the IVDR and GDPR Frameworks*, 19 WASH. U. GLOB. STUD. L. REV. 1, 35 n. 173–74 (2020).

<sup>189</sup> *Id.* at n. 175.

<sup>190</sup> *Id.* at 35.

<sup>191</sup> GDPR, *supra* note 162, art. 5(1)(b),(e), at 35–36.

<sup>192</sup> *Id.* art. 9, at 38–39.

<sup>193</sup> *Id.*

<sup>194</sup> Mahmoud-Davis, *supra* note 185, at 26.

<sup>195</sup> *Id.*

<sup>196</sup> *Id.* at 13; *see id.* n. 46.

<sup>197</sup> Mahmoud-Davis, *supra* note 185, at 19–20.



Although the EU's GDPR and recently enacted IVDR fails to address all genetic data privacy concerns, its privacy framework provides a more comprehensive regulation than the U.S.'s federal Swiss-cheese guidelines. Similar to the EU in enacting the GDPR, the U.S. federal government's first step could be considering genetic information as personal information. Federal legislation could include genetic privacy as part of a more comprehensive privacy law, like the EU's GDPR which includes genetic data with other sensitive information. By incorporating genetics in a larger privacy framework, the number of loopholes would decrease, and this would also clarify responsibilities and regulations to both DTC-GT companies and consumers. To supplement loopholes or address areas of concern, the U.S. federal government could expand federal oversight of genetic regulation through agencies. For example, the FTC could play a larger role over DTC-GT companies by requiring companies to publicly share similar privacy policies.<sup>198</sup>

Although not a perfect solution, adopting a data privacy framework like that of the EU would provide more data control to DTC-GT consumers. With a baseline standard of privacy, consumers' rights to access, delete, or control the use of their data would be prioritized and upheld. The GDPR inspired California's baseline genetic data privacy regulation, the CCPA.<sup>199</sup> Observing and recording the success or failures of CCPA, California passed CPRA to address some of these changes.<sup>200</sup> California also created a new agency, the California Privacy Protection Agency, to implement and enforce these data privacy laws.<sup>201</sup> While CPRA enforcement will not begin until July 1, 2023,<sup>202</sup> the federal government should at least monitor the successes and failures of California's and the EU's respective comprehensive data privacy frameworks.

#### CONCLUSION

The lack of a comprehensive genetic privacy framework to protect U.S. citizens from privacy invasion is a significant problem. Instead of establishing general privacy laws or a single comprehensive system, the U.S. regulates genetic data through separate, dissociated approaches.

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<sup>198</sup> Garner & Kim, *supra* note 6, at 1261.

<sup>199</sup> See Liam Tung, *GDPR, USA? Microsoft Says US Should Match the EU's Digital Privacy Law*, ZDNET (May 21, 2019), <https://www.zdnet.com/article/gdpr-usa-microsoft-says-us-should-match-the-eus-digital-privacy-law/> [<https://perma.cc/P494-V7KN>].

<sup>200</sup> Gilligan, *supra* note 20, at 236–37.

<sup>201</sup> *California Consumer Privacy Laws*, BLOOMBERG LAW, <https://pro.bloomberglaw.com/brief/the-far-reaching-implications-of-the-california-consumer-privacy-act-ccpa/> [<https://perma.cc/YU6J-UWH9>] (last visited Oct 29, 2022).

<sup>202</sup> *Id.*

However, current U.S. federal laws, administrative agencies, and even the Constitution fail to adequately protect individuals from privacy violations. Some states attempt to fill the gaps, yet consumers remain vulnerable to exploitation. Additionally, the lack of consistent regulation results in DTC-GT companies' freedom to set inconsistent privacy and terms of service policies. Solutions such as granting intellectual privacy rights to consumers' natural DNA are often complicated and do not provide the needed protection. In order to combat the current Swiss-cheese privacy system, the federal government should adopt a comprehensive framework similar to GDPR or California's data privacy framework.