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# The Risks of Relying on Direct-to-Consumer Genetic Testing Service Agreements to Protect Genetic Information

*Brennan Canuteson\**

## ABSTRACT

A consumer's unique genetic code is their most intimate piece of personal data.<sup>1</sup> Many federal laws concerning the privacy and nondiscrimination of health data are outdated, and most are related to healthcare providers instead of commercial services.<sup>2</sup> To ensure that direct-to-consumer ("DTC") genetic testing companies do not misuse a consumer's unique genetic code, consumers rely on contractual agreements to protect their genetic information. DTC contractual protections are insufficient for several reasons: (1) consumers may not understand or read the agreement, (2) the company can modify the privacy statement, (3) the company could breach the agreement, and (4) new DTC companies may not include the same level of protection. Ultimately, the concern is that the DTC company may use the consumer's genetic information to be detrimental to the consumer or in a way the consumer did not intend when they provided that information. To address this, Congress should enact a comprehensive federal law for the protection of genetic information.

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1. Maggie Fox, *What you're giving away with those home DNA tests*, NBC NEWS (Nov. 30, 2017, 7:01 AM), <https://www.nbcnews.com/health/health-news/what-you-re-giving-away-those-home-dna-tests-n824776>.

2. Stephen Gandel, *Private Equity Wants to Own Your DNA*, CBS NEWS (August 7, 2020, 4:52 PM), <https://www.cbsnews.com/news/blackstone-private-equity-ancestry-com-dna/>.

## I. INTRODUCTION

Millions of people hand over their genetic code to direct-to-consumer (“DTC”) genetic testing companies.<sup>3</sup> These companies include Ancestry, 23andMe, and FamilyTreeDNA.<sup>4</sup> DTC genetic testing companies market genetic diagnostic tests directly to consumers “without the involvement of a health care provider.”<sup>5</sup> In most cases, DTC companies charge the consumer a fee,<sup>6</sup> and, in exchange, analyze a small sample of the consumer’s genetic code to produce a report about the person’s ancestry or predisposition for certain diseases.<sup>7</sup>

Our genetic code is known as DNA and consists of a distinct arrangement of nucleotides that act as an instruction manual for our cells.<sup>8</sup> This arrangement provides the instructions for our cells, which ultimately form the unique traits of each person.<sup>9</sup> For instance, the arrangement of nucleotides provides the necessary instructions for our cells to create and express eye color.<sup>10</sup> When a consumer sends their cheek swab to a DTC testing company, “[e]very cell on that cheek swab carries the full sequence of [the consumer’s] DNA, including the mutation pattern that makes it uniquely [theirs].”<sup>11</sup>

Analyzing genetic information can reveal an abundance of deeply personal information, such as a person’s risk of developing a disease or potential reactions to medications.<sup>12</sup> To discover this information, most DTC genetic testing companies analyze a person’s single nucleotide polymorphisms (“SNP”).<sup>13</sup> SNPs are mutations that occur when a single nucleotide in a person’s genetic code is substituted for a

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3. Antonio Regalado, *2017 Was The Year Consumer DNA Testing Blew Up*, TECHNOLOGY REVIEW (February 12, 2018), <https://www.technologyreview.com/s/610233/2017-was-the-year-consumer-dna-testing-blew-up/>.

4. See ANCESTRY, <https://www.ancestry.com> (last visited November 14, 2020); 23ANDME, <https://www.23andme.com/?nav2=true&sub=ver1> (last visited November 14, 2020); FAMILYTREEDNA, <https://www.familytreedna.com> (last visited November 14, 2020).

5. *Direct-to-Consumer Tests*, UNITED STATES FOOD AND DRUG ADMINISTRATION, <https://www.fda.gov/medical-devices/vitro-diagnostics/direct-consumer-tests> (last updated December 20, 2019) [hereinafter *Direct-to-Consumer Tests FDA*].

6. ANCESTRY, <https://www.ancestry.com> (last visited November 14, 2020); 23ANDME, <https://www.23andme.com/?nav2=true&sub=ver1> (last visited November 14, 2020); FAMILYTREEDNA, <https://www.familytreedna.com> (last visited November 14, 2020).

7. *Direct-to-Consumer Tests FDA*, *supra* note 5.

8. See RICHARD A. HARVEY & DENISE R. FERRIER, LIPPINCOTT’S ILLUSTRATED REVIEWS: BIOCHEMISTRY 395, (Richard A. Harvey ed., 5<sup>th</sup> ed. 2011); *Direct-to-Consumer Tests FDA*, *supra* note 5.

9. See HARVEY & FERRIER, *supra* note 8, at 395; *What is the Human Genome Project?*, NATIONAL HUMAN GENOME INSTITUTE <https://www.genome.gov/human-genome-project/What> (last visited November 14, 2020).

10. See generally *What is the Human Genome Project?*, *supra* note 9 (discussing how DNA arrangement provides instructions for many different attributes).

11. Fox, *supra* note 1.

12. See *Direct-to-Consumer Tests FDA*, *supra* note 5.

13. See *What Happens To My DNA Sample At The Lab?*, 23ANDME, <https://customer-care.23andme.com/hc/en-us/articles/202904590-What-Happens-to-My-DNA-Sample-at-the-Lab-> (“Samples that yield sufficient quantities of DNA are submitted for genotyping on our custom SNP chip.”);

*Select report category*, 23ANDME, <https://www.23andme.com/test-info/> (last visited November 14, 2020) (stating that the company’s reports reveal whether you carry a genetic variant).

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different nucleotide.<sup>14</sup> Most SNPs are common and do not have an effect on health or development, but some are of consequence.<sup>15</sup> Analyzing relevant mutations can “help[] scientists locate genes that are associated with disease” and provide personal information about the consumer.<sup>16</sup> Pharmacogenetics tests, one type of genetic test, can “provide information regarding the role genetics may play in an individual’s reaction to drugs.”<sup>17</sup>

Similarly, carrier screening tests can “determine whether a healthy person carries a genetic variant that could be passed on to their potential future child(ren).”<sup>18</sup> When a consumer selects a DTC company, they choose which tests to run on their genetic code.<sup>19</sup> For example, 23andMe includes ancestry reports with each of its packages but only includes carrier status reports with its “essential” and “premium” packages.<sup>20</sup>

Ancestry is a DTC company that has analyzed and retained the genetic information of more than 18 million people.<sup>21</sup> Earlier this year, Blackstone, a private equity firm, acquired a roughly 75% ownership stake in Ancestry for \$4.7 billion.<sup>22</sup> The purchase sparked conversations among privacy experts regarding how Blackstone might leverage Ancestry’s pool of unique genetic codes.<sup>23</sup> Despite Blackstone’s assurances that it will not share or sell Ancestry’s consumer data, concerns remain due to consumer reliance on outdated federal laws protecting their genetic information.<sup>24</sup>

## II. GENETIC EXCEPTIONALISM

Genetic exceptionalism is the idea that a consumer’s genetic code is worth more specialized protections than other health data.<sup>25</sup> Opponents of genetic exceptionalism argue that genetic information is not different from other kinds of health data.<sup>26</sup> Despite these arguments, “several important features of genetic information strongly support genetic exceptionalism.”<sup>27</sup>

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14. *Help Me Understand Genetics: Genomic Research*, UNITED STATES NAT’L LIBRARY OF MEDICINE: NAT’L INSTITUTES OF HEALTH 2, <https://medlineplus.gov/download/genetics/understanding/genomicresearch.pdf>.

15. *Id.*

16. *Id.*

17. *Direct-to-Consumer Tests FDA*, *supra* note 5.

18. *Help Me Understand Genetics: Genomic Research*, *supra* note 14.

19. *Two easy ways to discover you: Choose what’s right for you*, 23ANDME, <https://www.23andme.com/compare-dna-tests/?nav2=true&sub=ver4> (last updated December 20, 2019).

20. *Id.*

21. Heather Perlberg, *Blackstone Reaches \$4.7 Billion Deal to Buy Ancestry.com*, BLOOMBERG (August 5, 2020, 8:31 AM), <https://www.bloomberg.com/news/articles/2020-08-05/blackstone-said-to-reach-4-7-billion-deal-to-buy-ancestry-com>.

22. *Id.*

23. Gandel, *supra* note 2.

24. *Id.*

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

26. *Id.*

27. *Id.*

First, genetic information functions as a unique identifier.<sup>28</sup> Thus, a person's genetic information can be traced back to that person. Today, 60% of Americans of Northern European descent can be identified through DTC company databases.<sup>29</sup> In the next few years, this number is expected to climb to 90%.<sup>30</sup>

Second, genetic information is familial in nature. This means that one family member's genetic code can identify other family members.<sup>31</sup> As a result, many consumers are identifiable through DTC databases despite never giving consent to genetic testing.<sup>32</sup>

Third, an individual's genetic information can reveal existing medical conditions and the risk of developing new ones.<sup>33</sup> Because family members share genetic information, an individual's genetic information can also be used to diagnose and predict the medical conditions of family members.<sup>34</sup>

Fourth, consumers risk discrimination or stigmatization based on their genetic information.<sup>35</sup> Genetic information may reveal information that is not readily apparent, such as medical conditions.<sup>36</sup> There is growing concern that this information may be used to discriminate against Americans, specifically in the context of insurance.<sup>37</sup>

Finally, a company's retention of stored DNA creates the potential for long-term and transgenerational information risks.<sup>38</sup> DTC genetic testing companies can retain the genetic information they receive indefinitely.<sup>39</sup> Genetic information, unlike other forms of health data, can reveal new information over time.<sup>40</sup> The retention of genetic information, along with the potential to reveal new information, presents long-term information risks for the consumer and the consumer's family members. The unique features of genetic information warrant more specialized protections than those for other kinds of health data.

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28. See Heather Murphy, *Most White Americans' DNA Can Be Identified Through Genealogy Databases*, THE NEW YORK TIMES (Oct. 11, 2018), <https://www.nytimes.com/2018/10/11/science/science-genetic-genealogy-study.html>.

29. Erlich, et al., *Identity Inference of genomic data using long-ranged familial searches*, 362 SCIENCE, 690, 690 (2018).

30. Murphy, *supra* note 28.

31. *Id.*; *Infra* Section IV.A (noting that the police have already used genetic information provided by family members to solve some cold cases).

32. See Murphy, *supra* note 28.

33. Ronald M. Green & A. Mathew Thomas, *DNA: Five Distinguishing Features for Policy Analysis*, 11 Harv. J.L. & Tech. 571, 576 (1998).

34. See *id.*; Murphy, *supra* note 28.

35. *Id.* at 572, 584–85.

36. *Id.* at 576.

37. Gandel, *supra* note 2.

38. See Green & Thomas, *supra* note 33, at 577.

39. Consumers can request the deletion of their records. See ANCESTRY, <https://www.ancestry.com> (last visited November 14, 2020); 23ANDME, <https://www.23andme.com/?nav2=true&sub=ver1> (last visited November 14, 2020); FAMILYTREEDNA, <https://www.familytreedna.com> (last visited November 14, 2020).

40. See Green & Thomas, *supra* note 33, at 577.

### III. LEGISLATIVE PROTECTIONS

Most consumers believe they have exclusive control over their health data.<sup>41</sup> In reality, once a consumer hands their genetic code over to a DTC company, the company may use and share the genetic code in accordance with the law and the terms of the company's privacy statement.<sup>42</sup> To protect consumers, Congress enacted the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Genetic Information Nondiscrimination Act of 2008 ("GINA"), both of which limit the use of consumer genetic information in employment and healthcare contexts.<sup>43</sup>

#### *A. Health Insurance Portability and Accountability Act of 1996 ("HIPAA")*

In 1996, Congress enacted HIPAA,<sup>44</sup> which restricts the sharing of Protected Health Information ("PHI") by covered entities. Under HIPAA, genetic information is considered PHI.<sup>45</sup> In 2008, GINA amended HIPAA to prohibit genetic discrimination in health insurance.<sup>46</sup> Today, HIPAA prohibits covered entities from collecting or using genetic information to make health plan and insurance coverage decisions.<sup>47</sup> HIPAA also prohibits using genetic information to determine health insurance eligibility,<sup>48</sup> premiums, or contributions.<sup>49</sup> DTC testing companies, however, are outside HIPAA's scope because HIPAA only applies to healthcare providers and healthcare plans.<sup>50</sup>

#### *B. Genetic Information Nondiscrimination Act of 2008 ("GINA")*

In 2008, Congress expanded protections for genetic information by passing GINA.<sup>51</sup> GINA is divided into two parts. Title I of GINA amended HIPAA to

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41. See generally *Your Health Information Privacy Rights*, DEPARTMENT OF HEALTH AND HUMAN SERVICES: OFFICE FOR CIVIL RIGHTS, [https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/consumers/consumer\\_rights.pdf](https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/consumers/consumer_rights.pdf) (last visited November 14, 2020) (indicating how to check to see who has seen your private data).

42. See generally Health Insurance Portability and Accountability Act of 1996 (HIPAA) Pub.L. 104–191, Aug. 21, 1996, 110 Stat. 1936 [hereinafter HIPAA Act]; Genetic Information Nondiscrimination Act, Pub. L. No. 110-233, 122 Stat. 881 (2008) [hereinafter GINA Act] (providing background of the required protections of such information).

43. See HIPAA Act § 702, 110 Stat. at 1945; see GINA Act § 2, 122 Stat. at 882 ("Congress has been informed of examples of genetic discrimination in the workplace...Congress clearly has a compelling public interest in relieving the fear of discrimination and in prohibiting its actual practice in employment and health insurance.").

44. HIPAA Act Pub.L. 104–191, 110 Stat. at 1936.

45. 42 U.S.C. § 1320d-9 (2008).

46. See GINA Act § 2, 122 Stat. at 882; *Help Me Understand Genetics: Genomic Research*, *supra* note 14.

47. See 29 U.S.C. § 1182(a)(2) (2008).

48. 29 U.S.C. § 1182(a)(1).

49. 29 U.S.C. § 1182(b)(1).

50. 42 U.S.C. § 1320d-9 (restricting the use or disclosure of genetic information by covered entities only).

51. GINA Act, Pub. L. No. 110-233, 122 Stat. 881.

prohibit genetic discrimination in health insurance.<sup>52</sup> Title II of GINA prohibits genetic discrimination in the context of employment. Genetic discrimination occurs when a person is treated differently based on their genetic code.<sup>53</sup> GINA prohibits employers from “requesting, requiring, or purchasing genetic information” or using genetic information to make employment decisions, such as hiring and firing.<sup>54</sup> GINA also provides remedies for individuals whose genetic information is misused.<sup>55</sup>

The Equal Employment Opportunity Commission (EEOC) annually receives over 200 charges filed under GINA.<sup>56</sup> In the first GINA case to go to trial, *Lowe v. Atlas Logistics Grp. Retail Servs. (Atlanta), LLC*,<sup>57</sup> the United States District Court for the Northern District of Georgia upheld GINA’s protections and awarded a \$2.25 million verdict to the plaintiff.<sup>58</sup> In *Lowe*, the defendant, Atlas, provided transportation and storage services for grocery stores.<sup>59</sup> In 2012, an employee began defecating in the company’s warehouse, which eventually resulted in the destruction of grocery products.<sup>60</sup> To identify the culprit, the defendant required several employees, including the two plaintiffs in the case, to provide a cheek swab.<sup>61</sup> Atlas submitted the samples to a lab that compared them against the fecal matter.<sup>62</sup> The plaintiffs were exonerated but brought suit alleging that the employer’s conduct violated the plaintiff’s rights under GINA by requiring them to submit their genetic information.<sup>63</sup> Atlas denied this charge and argued that “‘genetic information’ refers only to information related to an individual’s propensity for disease.”<sup>64</sup> The district court rejected this argument, holding that the collection and analysis of employees’ genetic information violated GINA.<sup>65</sup> Though GINA provides significant protection in the context of genetic privacy and genetic discrimination,<sup>66</sup> its reach is limited to health insurance providers and employers.<sup>67</sup>

#### IV. GAPS IN FEDERAL PROTECTIONS

Congress enacted GINA and HIPAA to protect consumers, but these protections only apply in the context of health insurance and employment.<sup>68</sup> As a result, a

52. *Id.*; see also *Help Me Understand Genetics: Genomic Research*, *supra* note 14.

53. *Help Me Understand Genetics: Genomic Research*, *supra* note 14.

54. 29 C.F.R. § 1635.4 (2011).

55. 29 C.F.R. § 1635.10.

56. *Genetic Information Non-Discrimination Act Charges*, U.S. EQUAL EMPLOYMENT OPPORTUNITY COMMISSION, <https://www.eeoc.gov/statistics/genetic-information-non-discrimination-act-charges-charges-filed-eeoc-includes> (last visited November 14, 2020).

57. *Lowe v. Atlas Logistics Grp. Retail Servs. (Atlanta), LLC*, 102 F. Supp. 3d 1360 (N.D. Ga. 2015).

58. Garner & Kim, *supra* note 25, at 1227.

59. *Lowe*, 102 F. Supp. 3d at 1362.

60. *Id.*

61. *Id.* at 1361.

62. *Id.*

63. *Id.* at 1363.

64. *Id.* at 1364.

65. *Id.* at 1369.

66. *Privacy in Genomics*, NATIONAL HUMAN GENOME INSTITUTE, <https://www.genome.gov/about-genomics/policy-issues/Privacy> (last updated February 24, 2020).

67. *Id.*

68. See HIPAA Act Pub.L. 104–191, Aug. 21, 1996, 110 Stat. 1936; GINA Act, Pub. L. No. 110–233, 122 Stat. 881. (“Congress has been informed of examples of genetic discrimination in the

consumer's genetic code is not protected in many substantial areas such as life insurance decisions. Next, this article will explore the gaps in federal protection for consumer's genetic information. A consumer's unique genetic code can be used in the areas of law enforcement, disability, life, and long-term care insurance, research, and military personnel decisions.

### *A. Law Enforcement*

Currently, federal laws do not prevent private companies from sharing genetic information with law enforcement. In 2018, Joseph James DeAngelo, known as Golden State Killer, was arrested when police compared a crime-scene DNA sample to GEDMatch samples and matched DeAngelo to the crime.<sup>69</sup> This is one of many unintended consequences of shared genetic data.<sup>70</sup> Because law enforcement's use of this information involves separate considerations, including constitutional issues, we will not pursue those issues here.<sup>71</sup>

### *B. Disability, Life, and Long-Term Care Insurance*

GINA prohibits health insurance companies from using DTC test results to deny coverage or charge higher premiums.<sup>72</sup> But, "GINA does not apply to other forms of insurance."<sup>73</sup> Thus, non-health insurance providers, such as disability insurance, life insurance, and long-term care providers have the right to request the results of DTC tests and can use that information to make decisions about coverage and rates.<sup>74</sup> In 2016, a life insurance company denied coverage to a 36-year-old woman with no previous medical conditions because her application revealed that she had a positive BRCA1 gene, a gene associated with an increased risk for breast and ovarian cancer.<sup>75</sup> Still, it is unclear whether and to what extent insurance companies use genetic information to make insurance decisions. It is possible that insurance companies choose not to consider genetic information,<sup>76</sup> or that applicants have not submitted their genetic information for analysis.<sup>77</sup>

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workplace...Congress clearly has a compelling public interest in relieving the fear of discrimination and in prohibiting its actual practice in employment and health insurance.”)

69. Gina Kolata & Heather Murphy, *The Golden State Killer Is Tracked Through a Thicket of DNA, and Experts Shudder*, THE NEW YORK TIMES (April 27, 2018), <https://www.nytimes.com/2018/04/27/health/dna-privacy-golden-state-killer-genealogy.html>.

70. *Id.* (GEDmatch “was not intended to be used by law enforcement to identify suspects of crimes”).

71. For more information on this topic see Albert E. Scherr, *Genetic Privacy & the Fourth Amendment: Unregulated Surreptitious DNA Harvesting*, 47 Ga. L. Rev. 445, 447 (2013).

72. *Help Me Understand Genetics: Genomic Research*, *supra* note 14.

73. *Id.*

74. *Id.*

75. Christina Farr, *If You Want Life Insurance, Think Twice Before Getting A Genetic Test*, FAST COMPANY (Feb. 17, 2016), <https://www.fastcompany.com/3055710/if-you-want-life-insurance-think-twice-before-getting-genetic-testing>.

76. It is possible that many insurance companies do not consider genetic information to comply with state laws. See *infra*, Section V (explaining that some state laws prohibit the use of genetic information in insurance decisions).

77. See generally Michelle Andrews, *Genetic Tests Can Hurt Your Chances Of Getting Some Types Of Insurance*, NATIONAL PUBLIC RADIO (Aug. 7, 2018, 9:00 AM), <https://www.npr.org/sections/health-shots/2018/08/07/636026264/genetic-tests-can-hurt-your-chances-of-getting-some-types-of-insurance> (warning consumers that taking DTC tests could reduce their chances of finding insurance).



### C. Research

DTC companies frequently share genetic information with third parties for research.<sup>78</sup> In 2015, Ancestry entered into an agreement with Google to provide its consumer data for Google's "life extension spinoff Calico to study aging and longevity."<sup>79</sup> The partnership ended in 2018.<sup>80</sup> Later that year, GlaxoSmithKline, a pharmaceutical company, announced it would be acquiring a \$300 million stake in 23andMe.<sup>81</sup> The partnership allows GlaxoSmithKline to review 23andMe's consumer's genetic data to look for new drugs to develop and to inform their selection process of patients for clinical trials.<sup>82</sup>

### D. Military Personnel Decisions

GINA does not apply to service members in their capacity as employees of the US military.<sup>83</sup> Recently, the Department of Defense issued a memo warning service members that DTC genetic tests "expose[] sensitive genetic information to outside parties...[and]...pose[] personal and operational risks to Service Members."<sup>84</sup> Service members must disclose medical information that affects the member's readiness in accordance with the procedures established by the military department they belong to.<sup>85</sup> Information discovered during genetic testing could affect decisions about a member's readiness.<sup>86</sup>

## V. STATE LAW PROTECTIONS

In addition to federal protections, states regulate DTC genetic testing. Today, a majority of states allow some form of DTC testing.<sup>87</sup> For example, New York and Maryland state law effectively limit genetic testing kits to those approved by the Food and Drug Administration.<sup>88</sup> While some state laws focus on the products and services that can be marketed to citizens, as is the case in New York and Maryland,

78. See Erin Brodwin, *A collaboration between Google's secretive life-extension spinoff and popular genetics testing company Ancestry has quietly ended*, BUSINESS INSIDER (Aug. 1, 2018, 8:36 AM) <https://www.businessinsider.com/google-calico-ancestry-dna-genetics-aging-partnership-ended-2018-7> [hereinafter Brodwin, *Collaboration*]; Erin Brodwin, *DNA-testing company 23andMe has signed a \$300 million deal with a drug giant. Here's how to delete your data if that freaks you out*, BUSINESS INSIDER (July 25, 2018, 4:27 PM), <https://www.businessinsider.com/dna-testing-delete-your-data-23andme-ancestry-2018-7> [hereinafter Brodwin, *23andme*].

79. Brodwin, *Collaboration supra* note 78.

80. *Id.*

81. Brodwin, *23andme supra* note 78.

82. *Id.*

83. *Privacy in Genomics supra* note 66.

84. OFFICE OF SEC'Y OF DEF., DIRECT-TO-CONSUMER GENETIC TESTING ADVISORY FOR MILITARY MEMBERS, 1 (Dec. 20, 2019), [https://www.scribd.com/document/440727436/DOD-memo-on-DNA-testing#from\\_embed](https://www.scribd.com/document/440727436/DOD-memo-on-DNA-testing#from_embed). [hereinafter Direct-to-Consumer Genetic Testing Advisory for Military Members].

85. *Id.*; see also U.S. DEP'T OF DEF., INSTR. 6025.19, INDIVIDUAL MEDICAL READINESS, (June 9, 2014) <https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/DDI/issuances/dodi/602519p.pdf>.

86. Direct-to-Consumer Genetic Testing Advisory for Military Members *supra* note 84, at 1.

87. *Genome Statute and Legislation Database*, NATIONAL HUMAN GENOME INSTITUTE, <https://www.genome.gov/about-genomics/policy-issues/Genome-Statute-Legislation-Database> (last visited November 14, 2020); Garner & Kim, *supra* note 25, at 1231.

88. N.Y. COMP. CODES R. & REGS. tit. 10, § 58-1.8 (2015); see also MD CODE REGS. 10.10.01.02 (2019).

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most focus on how genetic information can be used or shared. In doing so, many states have closed some of the gaps left by federal law.

Regarding the use of genetic information, roughly 23 states expand federal non-discrimination laws by prohibiting genetic discrimination in life insurance, disability insurance, or long-term care insurance decisions.<sup>89</sup> For example, Florida law prohibits genetic discrimination by life insurers, long-term care insurers, and disability insurers.<sup>90</sup> The Florida House passed the law to address growing concerns that “insurers may discriminate against individuals who have genetic markers indicating a heightened risk of developing certain diseases or health conditions.”<sup>91</sup> Other states, such as Illinois, prohibit discrimination in some, but not all these areas.<sup>92</sup>

The most significant state law prohibiting the use of genetic information is the California Genetic Information Act (“CalGINA”).<sup>93</sup> Unlike GINA, CalGINA expands discrimination protections beyond employment and healthcare. CalGINA prohibits genetic discrimination in the following areas: education, housing, emergency medical services, state agencies, and state-funded programs.<sup>94</sup> Only California and Utah have expanded protection from genetic discrimination to education.<sup>95</sup> The residents of all other states are not protected from genetic discrimination in the context of education. For example, any person not a resident of California or Utah could legally have the results of a DTC test leveraged to discriminate against them in the context of education.<sup>96</sup> CalGINA makes genetic discrimination illegal in these additional areas. Despite its expansiveness, CalGINA falls short of sufficient protections because it does not address all aspects that make genetic information unique.

In addition to CalGINA is the California Consumer Privacy Act of 2018 (CCPA),<sup>97</sup> the most comprehensive privacy law in the United States.<sup>98</sup> The CCPA applies to California residents and grants the following protections to genetic information; (1) notices and information around rights, including a genetic information collection notice;<sup>99</sup> (2) the right to prevent the sale of genetic information,<sup>100</sup> (3) freedom from discrimination,<sup>101</sup> and (4) deletion rights.<sup>102</sup> A recent bill clarified that the CCPA does not apply to health data governed by HIPAA.<sup>103</sup> Because DTC companies are not subject to HIPAA, the CCPA still applies.<sup>104</sup> While the CCPA is

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89. See *Genome Statute and Legislation Database supra* note 87.

90. FLA. STAT. ANN. § 627.4301 (2020).

91. Florida House of Representatives Staff Analysis, H.B. 1189 (March 26, 2020).

92. See 410 ILL. COMP. STAT. 513/20(e) (2020) (“A company providing direct-to-consumer commercial genetic testing is prohibited from sharing any genetic test information or other personally identifiable information about a consumer with any health or life insurance company without written consent from the consumer”).

93. See CAL. CIV. CODE § 51(b) (2016).

94. See *id.*

95. *Id.*; See UTAH CODE ANN. § 53E-9-301(5)-(7) (2020).

96. The Americans with Disabilities Act of 1990 may bar genetic discrimination when it rises to the level of a disability; See *Chadam v. Palo Alto Unified Sch. Dist.*, 666 F. App’x. 615, 616 (9th Cir. 2016).

97. See CAL. CIV. CODE §§ 1798.100-1798.199 (2020).

98. Garner & Kim, *supra* note 25, at 1232.

99. CAL. CODE REGS tit. 11, § 999.304(b)-(c) (2020).

100. CAL. CIV. CODE § 1798.120(c)-(d) (2020).

101. CAL. CIV. CODE § 1798.125(a)(1)(A)-(D) (2020).

102. CAL. CIV. CODE § 1798.105 (2020).

103. See CAL. CIV. CODE § 1798.146 (2020).

104. *Id.*

the most comprehensive state privacy law, it is not the only state privacy law.<sup>105</sup> Forty-one states have laws that protect the privacy of genetic information, but these protections are more limited.<sup>106</sup>

Many states have enacted laws that expand HIPAA's and GINA's genetic privacy protections and genetic nondiscrimination laws.<sup>107</sup> These protections, however, do not apply to all United States citizens and fail to account for every gap in federal protections. For example, Illinois law prohibits DTC genetic testing companies from sharing consumer's genetic information with life and health insurers.<sup>108</sup> Despite these safeguards, however, an Illinois resident could still potentially be at risk of genetic discrimination regarding eligibility for disability insurance, contributions, or premiums.<sup>109</sup> In contrast, a California resident is protected from such usage.<sup>110</sup> Similarly, the CCPA includes expansive restrictions on the use and sharing of a California resident's genetic information.<sup>111</sup> A California resident has rights to protection under the CCPA and cannot waive these protections.<sup>112</sup>

## VI. CONTRACTUAL PROTECTIONS

To fill the gaps left by legal protections, consumers rely on contractual agreements.

### *A. Existing Contractual Protections of Ancestry, 23andMe, and FamilyTreeDNA*

When a customer purchases a testing kit from a DTC company, the company presents the terms and conditions, which include a privacy statement to the consumer.<sup>113</sup> The customer must consent to the terms and conditions to receive the kit and the company's services.<sup>114</sup> The customer also receives the company's informed consent document, which is voluntary and allows the company to use the consumer's genetic information for research purposes.<sup>115</sup> By consenting to the terms and conditions, the consumer gives the company consent to share the consumer's

105. See Gamer & Kim, *supra* note 25, at 1265.

106. *Id.*

107. See CAL. CIV. CODE §51; See generally *Genome Statute and Legislation Database* *supra* note 87.

108. 410 ILL. COMP. STAT. 513/20 ("A company providing direct-to-consumer commercial genetic testing is prohibited from sharing any genetic test information or other personally identifiable information about a consumer with any health or life insurance company without written consent from the consumer").

109. See 410 ILL. COMP. STAT. 513/20(e) (2020).

110. See CAL. CIV. CODE §51.

111. See CAL. CIV. CODE § 1798.192 (2018).

112. *Id.*

113. See e.g. *Sign Up*, ANCESTRY, <https://www.ancestry.com/account/create?signInReturnUrl=https%3A%2F%2Fwww.ancestry.com&returnUrl=https%3A%2F%2Fwww.ancestry.com%2Foffers%2Fsubscribe%3Fsub%3D1&rtype=113> (last visited November 14, 2020) [hereinafter *ANCESTRY-Sign Up*]; *Register your kit*, 23ANDME, <https://www.23andme.com/?nav2=true&sub=ver1> (last visited November 14, 2020) [hereinafter *23ANDME-Register*].

114. See e.g. *ANCESTRY-Sign Up*, *supra* note 112, *23ANDME-Register*, *supra* note 112.

115. See generally e.g. *23ANDME-Privacy Highlights*, *supra* note 115; *ANCESTRY-Your Privacy*, *supra* note 115.

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data with third parties to provide services as well as commonly owned entities.<sup>116</sup> Unlike the terms and conditions and enclosed privacy statement, a consumer is not required to sign an informed consent document to utilize the company's services.<sup>117</sup>

A recent survey of the privacy policies for Ancestry, 23andMe, and FamilyTreeDNA, revealed that the companies' terms and conditions limited the sharing of genetic information more stringently than required by federal law.<sup>118</sup> For example, Ancestry, 23andMe, and FamilyTreeDNA agree not to share the consumer's genetic information with insurance companies of any kind.<sup>119</sup> Additionally, according to each company's privacy policy,<sup>120</sup> they will only provide law enforcement with genetic information when required by law.<sup>121</sup> These requests are relatively rare.<sup>122</sup> For example, 23andMe has only "had a handful of inquiries over the course of 11 years."<sup>123</sup>

Ancestry, 23andMe, and FamilyTreeDNA still retain the right to use the consumer's genetic information in various ways. First, companies can use the consumer's saliva to generate consumer reports and match consumers to relatives.<sup>124</sup> Second, the companies can use individualized genetic information to conduct scientific, statistical, and historical research.<sup>125</sup> Third, Ancestry, 23andMe, and FamilyTreeDNA retain the right to share consumer's genetic information in certain situations. Ancestry and FamilyTreeDNA's privacy statements allow the companies to study and share de-identified, aggregate data with other entities.<sup>126</sup> Aggregate data is different from individual-level data and does not include "data about a single individual's genotypes, diseases or other traits/characteristics information."<sup>127</sup> Instead, "Aggregate Information may include a statement that '30% of our female users share a particular genetic trait,' without providing any data or testing results specific to any individual user."<sup>128</sup> All three companies can share aggregate and individual-level data with commonly owned entities.<sup>129</sup>

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116. See e.g. 23ANDME-Privacy Highlights, *supra* note 115; ANCESTRY-Your Privacy, *supra* note 115.

117. See e.g. ANCESTRY-Sign Up, *supra* note 112, 23ANDME-Register, *supra* note 112.

118. See generally e.g. 23ANDME-Privacy Highlights, *supra* note 115; ANCESTRY-Your Privacy, *supra* note 115 (showing the type of information collected.)

119. See e.g. 23ANDME-Privacy Highlights, *supra* note 115; ANCESTRY-Your Privacy, *supra* note 115.

120. See *FamilyTreeDNA Privacy Statement*, FAMILYTREEDNA, <https://www.familytreedna.com/legal/privacy-statement> (May 7, 2019) [hereinafter *FAMILYTREEDNA-Privacy Statement*] (FamilyTreeDNA allows law enforcement to create accounts and upload genetic information to identify the remains of a deceased individual or perpetrators of certain types of crimes. Users may opt out of law enforcement matching. If a user has opted out, FamilyTreeDNA will only share a consumer's genetic information with law enforcement when required by law.)

121. See e.g. 23ANDME-Privacy Highlights, *supra* note 115; ANCESTRY-Your Privacy, *supra* note 115.

122. Kolata & Murphy, *supra* note 69. (23andMe has only "had a handful of inquiries over the course of 11 years.")

123. *Id.*

124. See e.g. 23ANDME-Privacy Highlights, *supra* note 115; ANCESTRY-Your Privacy, *supra* note 115.

125. See e.g. 23ANDME-Privacy Highlights, *supra* note 115; ANCESTRY-Your Privacy, *supra* note 115.

126. See ANCESTRY-Your Privacy, *supra* note 115; FAMILYTREEDNA-Privacy Statement, *supra* note 121.

(showing that in contrast to Ancestry and FamilyTreeDNA, 23andMe will only use a consumer's individual data if the consumer "has consented to this use by completing a Consent Document.")

127. 23ANDME-Privacy Highlights, *supra* note 115.

128. *Id.*

129. See *id.*; ANCESTRY-Your Privacy, *supra* note 115; *FamilyTreeDNA Privacy Statement*, FamilyTreeDNA, FAMILYTREEDNA-Privacy Statement, *supra* note 121 ("Some or all of your information may be shared with other companies under common ownership or control of FamilyTreeDNA, which

At any time, consumers can request that the DTC genetic testing company delete the consumer's information.<sup>130</sup> For example, upon request, Ancestry will delete a consumer's genetic information from its "production, development, analytics, and research systems within 30 days."<sup>131</sup> If the consumer wants to request the destruction of the consumer's biological samples, however, the consumer must make a separate request that Ancestry destroy the sample.<sup>132</sup> Even after deletion and destruction of data, a consumer's previously shared genetic information remains with the parties with which the DTC genetic testing company once shared it.<sup>133</sup> Each company's terms and conditions and privacy policies include protections that go beyond those required by federal law. These extra protections are likely included to comply with state laws.<sup>134</sup>

### *B. How Informed is Consumer Consent?*

Consumers consent to the sharing and usage of their data by agreeing to the DTC genetic testing company's terms and conditions and informed consent document.<sup>135</sup> Unfortunately, many consumers are unaware of the sharing and usage they are accepting because many customers do not read a company's terms and conditions before providing consent. A 2017 study by Deloitte revealed that less than 10% of consumers read the terms and conditions.<sup>136</sup> The study focused on consumers' consent to a social media company's terms and conditions and did not directly study whether a consumer reads terms and conditions when they consent to DTC genetic testing.<sup>137</sup> It is likely reasonable, however, to rely on trend extrapolation.<sup>138</sup> This number was even lower for people between the ages of 18 and 34, which found that 97% of consumers consent to terms and conditions without reading.<sup>139</sup> A more

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may include our corporate parent, our subsidiaries, or any other subsidiaries owned by our corporate parent to provide you better service and improve user experience.”)

130. See e.g. 23ANDME-Privacy Highlights, *supra* note 115; ANCESTRY-Your Privacy, *supra* note 115.

131. ANCESTRY-Your Privacy, *supra* note 115.

132. *Id.*

133. *Id.* (“[W]e will not be able to remove your Genetic Information from active or completed research projects, but we will not use it for any new research projects.”); FAMILYTREEDNA-Privacy Statement, *supra* note 121 (“Self-Reported Information and/or Genetic Information that you have already provided and for which you have given consent to use in FamilyTreeDNA Research cannot be deleted from ongoing or completed studies that use the information. However, your information will not be used for any future research projects.”).

134. See Helen C. Dick, *Risk and Responsibility: State Regulation and Enforcement of the Direct-to-Consumer Genetic Testing Industry*, 6 St. Louis U.J. Health L. & Pol’y 167, 175 (2012) (noting that roughly twenty-three states prohibit genetic discrimination, in life, disability, and long-term care insurance).

135. See e.g. ANCESTRY-Sign Up, *supra* note 112, 23ANDME-Register, *supra* note 112.

136. Caroline Cakebread, *You're not alone, no one reads the terms of service agreements*, BUSINESS INSIDER, (November 15, 2017 6:30 AM), <https://www.businessinsider.com/deloitte-study-91-percent-agree-terms-of-service-without-reading-2017-11>.

137. *Id.*

138. See David Betts, et al, *Are consumers already living the future of health?*, DELOITTE (August 13, 2020), <https://www2.deloitte.com/us/en/insights/industry/health-care/consumer-health-trends.html> (Finding that consumers are willing to share their health data and that that willingness has increased since the pandemic).

139. Cakebread, *supra* note 136.

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recent study found that only 1% of customers read the terms and conditions before consenting.<sup>140</sup>

Customers do not read the terms and conditions because the language is often “too complex and long-winded for most.”<sup>141</sup> In many cases, the consumer feels comfortable accepting the risk “that the worst most companies will do is sell their name and email to a third party that wants to advertise to them.”<sup>142</sup> Unfortunately, the worst that a company can do with genetic information may be more significant. Regarding genetic information, risks include but are not limited to discrimination by disability, life, or long-term care insurers or unintended or detrimental effects to family members, such as use by law enforcement.<sup>143</sup>

### C. Strength of Contractual Protections

Ancestry, 23andMe, and FamilyTreeDNA currently include more stringent contractual protections than required by federal law. There are, however, three significant risks associated with reliance on contractual protection. First, Ancestry, 23andMe, and FamilyTreeDNA all retain the right to modify the privacy statement.<sup>144</sup> The company is only required to notify customers of “material changes to the statement.”<sup>145</sup> In the case of “non-material” changes, the company notes that “continued use of our Services after notice of non-material changes means that you consent to the updated Privacy Statement.”<sup>146</sup> Thus, the consumer must continue to inform themselves of the company’s changes to terms of the original agreement. Second, even if a consumer is aware and willing to accept the original and modified privacy terms, there is also the potential that the companies could breach the contract terms.<sup>147</sup> Third, as new companies enter the market, the companies may not provide the same caliber of protection currently offered by Ancestry, 23andMe, and FamilyTreeDNA’s contracts.

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140. Tim Sandle, *Report finds only 1 percent reads ‘Terms and Conditions’*, DIGITAL JOURNAL (January 29, 2020), <http://www.digitaljournal.com/business/report-finds-only-1-percent-reads-terms-conditions/article/566127>. This study explored whether a consumer read terms and conditions when they purchased an item or engaged a service, but did not directly study whether a consumer reads terms and conditions when they consent to DTC genetic testing.

141. Cakebread, *supra* note 136.

142. *Id.*

143. *See supra* Section IV.

144. *See e.g.* 23ANDME-*Privacy Highlights*, *supra* note 115; ANCESTRY-*Your Privacy*, *supra* note 115.

145. ANCESTRY-*Your Privacy*, *supra* note 115 (“We will provide prominent advance notice of any material changes to this Statement, such as posting a notice through the Services, on our websites, or sending you an email, to provide you the opportunity to review the changes and choose whether to continue using the Services.”).

146. *Id.*

147. A breach is unlikely, but not unheard of. DTC companies have faced lawsuits before. In 2014, a class action arbitration was submitted against 23andMe. Claimants alleged that 23andMe’s Personal Genome Service was based on inaccurate or misleading information and was not sold in compliance with applicable federal and state laws. The case was settled in arbitration. *See generally* 23andMe, Inc. v. Davis-Hudson, No. 5:15-CV-01323-PSG, 2015 U.S. Dist. LEXIS 141370 (N.D. Cal. Oct. 16, 2015) (deciding on the legitimacy of 23andMe’s arbitration clause).

## VII. PROPOSED SOLUTION

The main concern is that companies will use collected data in a way that is detrimental to or unintended by the consumer.<sup>148</sup> This is especially concerning given that a majority of consumers do not read the company's terms and conditions,<sup>149</sup> and the risks associated with genetic information are substantial.<sup>150</sup> When it comes to genetic information, the risk of misuse has the potential to be "unjust, unfair, or outright discriminatory."<sup>151</sup>

Congress should reduce reliance on uncertain contractual protections by passing more robust and comprehensive genetic information protection laws. Comprehensive federal laws would be more efficient than a network of state laws and would simplify compliance with varying state laws by DTC companies that offer their services nationwide.<sup>152</sup> The goal of any federal law should be to ensure "that everyone [can] enjoy [the] protection of his or her genetic information from unauthorized collection, processing, use and distribution, and that certain uses of genomic data...be forbidden because they impact data subjects in ways that are [harmful]."<sup>153</sup>

Returning to the concept of genetic exceptionalism, there are unique features of genetic information that make it worthy of more specialized protections than other health data.<sup>154</sup> These features include: the long-term information risks associated with a DTC company's retention of genetic information; the informational nature of genetic information and the role of genetic information as a unique identifier; genetic information's familial nature;<sup>155</sup> and genetic information's ability to reveal existing medical conditions or the risk of development of a medical condition.<sup>156</sup> New federal laws should address the unique features of genetic information.<sup>157</sup>

Genetic information functions as a unique identifier and can reveal existing medical conditions or the risk of developing a medical condition.<sup>158</sup> Accordingly, Congress should enact tighter privacy protections around the sharing and usage of genetic information. These could include several protections guaranteed in the CCPA, such as notices and information around rights, including a genetic information collection notice.<sup>159</sup> Because of the fear of genetic discrimination,<sup>160</sup> federal law should expand genetic discrimination protections beyond those provided by GINA. Disability, life, and long-term care insurers should be unable to discriminate on the basis of genetic information. Congress should also expand genetic discrimination protections to military members and should consider possible uses of genetic

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148. See Gandel, *supra* note 2.

149. See *supra* Section V.B.

150. See *supra* Section IV.

151. Garner & Kim, *supra* note 25, at 1245.

152. See generally *id.*

153. *Id.* (citing Tobias Haeusermann et al., *Genes Wide Open: Data Sharing and the Social Gradient of Genomic Privacy*, 9 AJOB EMPIRICAL BLOETHICS 207 (2018)).

154. *Id.* at 1241.

155. Green & Thomas, *supra* note 33, at 572.

156. *Id.* at 576.

157. Garner & Kim, *supra* note 25, at 1241.

158. Green & Thomas, *supra* note 33, at 576.

159. See CAL. CODE REGS tit. 11, § 999.304.

160. See GINA Act §2, 122 Stat. 881, 882 ("Congress has been informed of examples of genetic discrimination in the workplace...Congress clearly has a compelling public interest in relieving the fear of discrimination and in prohibiting its actual practice in employment and health insurance.").

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information by law enforcement and researchers.<sup>161</sup> Federal laws should also address the long-term informational risk associated with a DTC company's retention of genetic information. This could include a maximum period of time for DTC companies to run new tests on genetic information.<sup>162</sup> Lastly, Congress should address the familial nature of genetic information to ensure consumers who have not consented to genetic information do not suffer consequences for a familial member's disclosure.

These protections may not necessarily mean the end of the usage and sharing of genetic information. Stricter laws would likely forbid some uses,<sup>163</sup> but other uses may simply require a genuine expression of informed consent.<sup>164</sup> A robust and comprehensive federal statutory scheme could protect a consumer's genetic information against unauthorized use or discriminatory conduct.<sup>165</sup>

## VIII. CONCLUSION

Limited legislative protections raise concerns about how companies may use genetic information. Some consumers are deterred from seeking genetic testing. Consumers fear that companies will disclose test results in a manner not permitted by law or use test results in a discriminatory manner.<sup>166</sup> Contractual agreements between the DTC genetic testing company and consumers fill the gaps left by legal protections.

These protections are insufficient because terms and conditions and informed consent documents can be modified, companies can breach the terms of the agreements, and as new companies enter the market, the companies may not provide the same protections currently offered by existing DTC genetic testing companies.

Congress should pass federal laws that address the unique risk posed by the use and sharing of genetic information. This would address consumer fear and reduce consumer reliance on contractual agreements for the protection of genetic discrimination,

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161. See Fox, *supra* note 1.

162. See Green & Thomas, *supra* note 33, at 572.

163. See Garner & Kim, *supra* note 25, at 1245 (citing Tobias Haeusermann et al., *Genes Wide Open: Data Sharing and the Social Gradient of Genomic Privacy*, 9 *AJOB EMPIRICAL BLOETHICS* 207 (2018)).

164. Elizabeth B. Cooper, *Testing for Genetic Traits: The Need for A New Legal Doctrine of Informed Consent*, 58 *Md. L. Rev.* 346, 363–64 (1999) (“[T]he repercussions of being tested, highlight the importance of the pre-test counseling process and a genuine expression of informed consent.”).

165. See Garner & Kim, *supra* note 25, at 1245 (citing Tobias Haeusermann et al., *Genes Wide Open: Data Sharing and the Social Gradient of Genomic Privacy*, 9 *AJOB EMPIRICAL BLOETHICS* 207 (2018)).

166. See generally 410 *ILL. COMP. STAT.* 513/20 (2020) (providing just one example of a state that now prevents such acts).