UC Irvine Law Review

Volume 12 | Issue 1 Article 10

11-2021

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The Right to Delete: Protecting Consumer Autonomy in Direct-to-Consumer Genetic Testing

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We often think of DNA as a unique personal identifier. Yet, as of 2019, direct-to-consumer (DTC) genetic testing companies have amassed the genetic data of more than twenty-six million consumers. This raises the concern that companies do not uniformly protect consumers' genetic privacy. Substantiating such concerns are complaints that companies permit law enforcement access to their databases, sell consumer genetic information to third parties, pursue drug development, and suffer data breaches.

Regulators have been slow to respond to this emerging privacy issue. The current legal framework is largely inadequate: there is no federal data-privacy law; courts and agencies are ill-equipped or lack directive to tackle a privacy issue of this magnitude; and current genetic-related laws focus on notice, informed consent, and antidiscrimination. However, recently enacted state data-privacy laws like the California Consumer Privacy Act (CCPA) and California Privacy Rights Act (CPRA) may serve as a legal framework to address privacy in the DTC genetic testing context.

Under the CCPA and CPRA, the right to delete promises to give control back to consumers over their genetic information. However, further genetic-specific regulations under the CCPA and CPRA, or a separate genetic-privacy statute, are needed to protect privacy in the DTC genetic testing context while balancing against legitimate business and governmental interests. This Note attempts to delineate how such a balance can be achieved.

* J.D., University of California, Irvine School of Law, 2021. I thank Professor Michele B. Goodwin for her thoughtful guidance throughout the writing process and my colleagues in the Fall 2019 Biotechnology and The Law course for their commentary on the contours of this Note. I am also grateful for the work of Emma O'Hanlon, Alicia Hernandez, and the editorial team at the *UC Irvine Law Review*.

INTRODUCTION

For costs ranging from $99 to $199,[1] DTC genetic testing companies promise to provide personalized information to consumers about their ancestry, traits, and

1. 23ANDME, https://www.23andme.com [https://perma.cc/J8K4-B3PW] (last visited Oct. 23, 2021); *DNA*, ANCESTRY, https://www.ancestry.com/dna [https://perma.cc/MVW5-YBK2] (last visited Oct. 23, 2021).

health.[2] Ancestry, a leading DTC genetic testing company,[3] provides information on a person's ethnicity, ancestors' migration paths, and DNA matches to other users.[4] 23andMe, another leading DTC genetic testing company,[5] offers over 150 reports covering topics like health predisposition, genetic-carrier status, ancestry, and traits.[6] Arguably, DTC genetic tests may improve access to and engagement with health information, in contrast to the traditional form of health information delivery through medical professionals.[7] For example, 23andMe's "Health + Ancestry Service" includes health predisposition reports, wellness reports, and carrier-status reports that purport to assess a person's chances of developing health conditions like type 2 diabetes and the possibility of transmitting genetic variants

2. DTC genetic tests are marketed directly to consumers through television, print advertisements, or the internet; can be bought online or in stores; and require that consumers collect and send their biological samples, such as saliva, to companies for testing and analysis. *See Direct-to-Consumer Tests*, FDA, https://www.fda.gov/medical-devices/vitro-diagnostics/direct-consumer-tests [https://perma.cc/5K86-B6UV] (Dec. 20, 2019); *What Is Direct-to-Consumer Genetic Testing?*, MEDLINEPLUS, https://medlineplus.gov/genetics/understanding/dtcgenetictesting/direct toconsumer [https://perma.cc/HWN9-HT57] (Sept. 21, 2020).

3. Ancestry and 23andMe are the two "superpowers" dominating market share and decreasing competition due to the "network effect," a phenomenon where increased participants in a network improve the value of a good or service. *See* Antonio Regalado, *More than 26 Million People Have Taken an At-Home Ancestry Test*, MIT TECH. REV. (Feb. 11, 2019), https://www.technologyreview.com/s/612880/more-than-26-million-people-have-taken-an-at-home-ancestry-test [https://perma.cc/W7LW-XJXT]; *see also* Caroline Banton, *Network Effect*, INVESTOPEDIA, https://www.investopedia.com/terms/n/network-effect.asp [https://perma.cc/F2MV-WHZJ] (Apr. 3, 2021) (describing "network effect" phenomenon).

4. *What to Expect from Your AncestryDNA® Test Results.*, ANCESTRY, https://www.ancestry.com/dna/lp/what-to-expect-ancestrydna-test [https://perma.cc/D6TR-SDUA] (last visited Oct. 23, 2020).

5. *See* Regalado, *supra* note 3.

6. 23ANDME, *supra* note 1.

7. *See* Megan A. Allyse, David H. Robinson, Matthew J. Ferber & Richard R. Sharp, *Direct-to-Consumer Testing 2.0: Emerging Models of Direct-to-Consumer Genetic Testing*, 93 MAYO CLINIC PROC. 113, 114–15 (2018) (describing how some view the convenience of DTC genetic testing, the promotion of personalized medicine, and the reduced costs to consumers and the health-care system as reasons DTC genetic testing is superior to traditional genetic testing, which is characterized by a dependence on expert knowledge and has been criticized for dampening innovation and restricting information); *see also* Monica A. Giovanni, Matthew R. Fickie, Lisa S. Lehmann, Robert C. Green, Lisa M. Meckley, David Veenstra & Michael F. Murray, *Health-Care Referrals from Direct-to-Consumer Genetic Testing*, 14 GENETIC TESTING & MOLECULAR BIOMARKERS 817, 818 (2010) (describing a survey of genetics professionals wherein 59.1% of the patients seen had self-referred to a genetic counselor or medical geneticist after taking a DTC genetic test, and 52.4% of genetics professionals found the initial DTC genetic testing to be clinically useful). *But see* Kathy Hudson, Gail Javitt, Wylie Burke, Peter Byers & Am. Soc'y Hum. Genetics, Society News, *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, 81 AM. J. HUM. GENETICS 635, 636 (2007) ("Consumers are at a significant risk of selecting tests with unproven benefit, of obtaining testing services from laboratories of dubious quality, and of making decisions without timely and accurate genetic counseling.").

linked to inheritable diseases like cystic fibrosis.[8] Whether DTC genetic tests can integrate cohesively with health-care systems remains to be seen.[9]

Despite all that these tests may reveal, a disparity exists between what consumers and companies gain from DTC genetic testing. One issue is test reliability: one study found forty percent of harmful variants reported in the raw genetic data produced by DTC genetic tests were false positives when compared to confirmatory test results, almost all related to cancer susceptibility.[10] Concerns regarding test result accuracy have even led the Pentagon to urge military personnel not to take "mail-in DNA tests," as they could "create security risks, are unreliable and could negatively affect" careers.[11] DTC genetic tests may also be wildly misused. A person's used items, such as bedsheets or clothing, can be surreptitiously tested without his or her consent when another person sends the items to a DTC genetic testing company, often to ascertain paternity or infidelity.[12] Furthermore, companies have been accused of reeling in consumers through deeply discounted prices and aggressive marketing,[13] sometimes even towards parents and their children.[14] More people buying tests increases the potential for discrimination based

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8. *Health + Ancestry Service*, 23ANDME, https://www.23andme.com/dna-health-ancestry [https://perma.cc/9ACU-SLAS] (last visited Oct. 23, 2021).

9. Even though skepticism about the clinical utility of genomic information remains, forty-three percent of American primary care providers surveyed in a study indicated they would be likely or very likely to change the management of a hypothetical patient based on a complex disease report from a DTC genetic testing company. Barbara A. Bernhardt, Cara Zayac, Erynn S. Gordon, Lisa Wawak, Reed E. Pyeritz & Sarah E. Gollust, *Incorporating Direct-to-Consumer Genomic Information into Patient Care: Attitudes and Experiences of Primary Care Physicians*, 9 PERSONALIZED MED. 683, 687–88 (2012).

10. Stephany Tandy-Connor, Jenna Guiltinan, Kate Krempely, Holly LaDuca, Patrick Reineke, Stephanie Gutierrez, Phillip Gray & Brigette Tippin Davis, *False-Positive Results Released by Direct-to-Consumer Genetic Tests Highlight the Importance of Clinical Confirmation Testing for Appropriate Patient Care*, 20 GENETICS MED. 1515, 1518 (2018).

11. Heather Murphy & Mihir Zaveri, *Pentagon Warns Military Personnel Against At-Home DNA Tests*, N.Y. TIMES (Dec. 24, 2019), https://www.nytimes.com/2019/12/24/us/military-dna-tests.html [https://perma.cc/CG89-B9DQ].

12. *See* Andelka M. Phillips, *'Only a Click Away—DTC Genetics for Ancestry, Health, Love . . . and More: A View of the Business and Regulatory Landscape,'* 8 APPLIED & TRANSLATIONAL GENOMICS 16, 19 (2016). One recent survey of ninety DTC genetic testing companies found that almost one-third offered some form of surreptitious testing. 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, 47–48 (2018); *see also* Phillips, *supra*, at 17 (finding 34 of 246 DTC genetic companies profiled, or fourteen percent of companies, conducted surreptitious testing). Another study found that thirty-five percent of consumers who had purchased tests reported they had submitted the sample of another person for testing, and thirty-eight percent of those who had ordered a test on someone else had done so without consent. Emily Christofides & Kieran O'Doherty, *Company Disclosure and Consumer Perceptions of the Privacy Implications of Direct-to-Consumer Genetic Testing*, 35 NEW GENETICS & SOC'Y 101, 112–13 (2016).

13. Ruth Padawer, *Sigrid Johnson Was Black. A DNA Test Said She Wasn't.*, N.Y. TIMES MAG. (Nov. 19, 2018), https://www.nytimes.com/2018/11/19/magazine/dna-test-black-family.html [https://perma.cc/LQJ9-4LH9].

14. DTC genetic testing companies have also used clever marketing and holiday deals to target parents and children, such as when 23andMe ran a commercial about Dr. Seuss's the Grinch receiving a DNA kit as a gift. Emily Mullin, *Should You Send Your Kid's DNA to 23andMe?*, WASH. POST

on genetic composition, which can occur in schools, the workplace, and with insurance companies.[15]

DTC genetic testing companies stand to gain much from consumers' biological samples and genetic information.[16] First, companies have amassed enormous databases that are still growing,[17] which help improve database reference populations that are too small or insular to be accurately applied to consumers.[18] As the databases continue to grow and the accuracy of results improve, the value of genetic tests increases, enticing more consumers to buy them.[19] After the initial testing and analysis of biological samples, companies have further capitalized on the genetic information obtained by allowing law enforcement access into databases,[20] selling consumer genetic information to third parties,[21] and pursuing drug development.[22] For example, 23andMe has disclosed that it works with a variety of academic, industry, and nonprofit collaborators to study ancestry, traits, and

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(Dec. 19, 2018), https://www.washingtonpost.com/lifestyle/2018/12/19/should-you-send-your-kids-dna-andme [https://perma.cc/V568-9TDT].

15. *See, e.g.*, Lowe v. Atlas Logistics Grp. Retail Servs. (Atlanta), LLC, 102 F. Supp. 3d 1360, 1362–64 (N.D. Ga. 2015) (finding federal genetic nondiscrimination law was violated where two warehouse employees were asked by their employer to take DNA tests to compare their DNA with fecal matter left on grocery products in the warehouse); Sarah Zhang, *DNA Got a Kid Kicked Out of School—and It'll Happen Again*, WIRED (Feb. 1, 2016, 7:00 AM), https://www.wired.com/2016/02/schools-kicked-boy-based-dna [https://perma.cc/BAD9-MEVR] (reporting the case of Colman Chadam, a sixth grader whom a local school district decided to transfer out of a particular school after teachers divulged to other parents that he carried genetic markers associated with cystic fibrosis, despite not having the disease).

16. In this Note, the term "genetic information" is used to refer to raw genetic code and the corresponding test results provided by DTC genetic testing companies.

17. *Ancestry Surpasses 15 Million DNA Customers*, ANCESTRY CORP. (May 31, 2019), https://www.ancestry.com/corporate/blog/ancestry-surpasses-15-million-dna-customers [https://perma.cc/X8JP-N4QH] ("[M]ore than 15 million customers have received DNA results! . . . But this is just the beginning. As the network continues to grow, we can deliver even more value to our members, including more granular insights about heritage and compelling new paths to learn about ourselves using genetics.").

18. *See* Troy Duster, *A Post-Genomic Surprise. The Molecular Reinscription of Race in Science, Law and Medicine*, 66 BRIT. J. SOCIO. 1, 11 (2015).

19. *See* Zhang, *supra* note 15.

20. Matthew Haag, *FamilyTreeDNA Admits to Sharing Genetic Data with F.B.I.*, N.Y. TIMES (Feb. 4, 2019), https://www.nytimes.com/2019/02/04/business/family-tree-dna-fbi.html [https://perma.cc/GFN9-MBRR] (reporting FamilyTreeDNA's press release apologizing for failing to disclose that it was allowing the FBI to access its database of over two million records to solve violent crimes).

21. Erin Brodwin, *DNA-Testing Companies Like 23andMe Sell Your Genetic Data to Drugmakers and Other Silicon Valley Startups*, BUS. INSIDER (Aug. 3, 2018, 8:45 AM), https://www.businessinsider.com/dna-testing-ancestry-23andme-share-data-companies-2018-8 [https://perma.cc/9CAE-CUJC] (highlighting particular DTC genetic testing companies' third-party partnerships with pharmaceutical companies, personal-care companies, public academic institutions, nonprofit research groups, startups, and health-care providers).

22. Denise Roland, *How Drug Companies Are Using Your DNA to Make New Medicine*, WALL ST. J. (July 22, 2019), https://www.wsj.com/articles/23andme-glaxo-mine-dna-data-in-hunt-for-new-drugs-11563879881 [https://perma.cc/8DBT-LH2C] (describing 23andMe's partnership with GlaxoSmithKline that produced six potential drug targets).

diseases; conduct clinical trials evaluating treatments for diseases; and identify new genetic associations.[23]

These privacy concerns lead to important questions, including to what extent consumers may control their genetic information once given to DTC genetic testing companies. It is extremely easy to share one's DNA with DTC genetic testing companies—sending them a simple saliva sample will suffice.[24] Unfortunately, as journalist Kristen V. Brown found, genetic information, once shared, is "brutally difficult" to delete.[25] Brown had shared her genetic information with "nearly a dozen companies" and wanted to delete her information from these companies' databases.[26] Through an arduous, weeks-long process of calling and emailing various companies' customer-service personnel, she discovered deletion was impossible due to federal and state regulations regarding laboratory quality control and her initial agreement to contribute her information towards research.[27] Ultimately, she concluded, "When you delete your DNA information, you are mainly hiding your information from yourself."[28] In other words, the companies she used for testing still retained her genetic information.

Consumers are concerned about their genetic privacy.[29] Yet, as of the beginning of 2019, more than twenty-six million consumers have added their genetic information to the top four DTC genetic testing companies at the time: Ancestry, Gene By Gene, MyHeritage, and 23andMe.[30] The fact that so many consumers have used DTC genetic tests can be attributed to "[s]urging public interest in ancestry and health—propelled by heavy TV and online marketing."[31] Indeed, Ancestry's family-tree-building feature has allowed people to discover

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23. *Research*, 23ANDME, https://www.23andme.com/research/?vip=true [https://perma.cc/ZB9K-5HMR] (last visited Oct. 23, 2021).

24. *See Direct-to-Consumer Tests*, *supra* note 2.

25. Kristen V. Brown, *Deleting Your Online DNA Data Is Brutally Difficult*, BLOOMBERG (June 15, 2018, 2:00 AM), https://www.bloomberg.com/news/articles/2018-06-15/deleting-your-online-dna-data-is-brutally-difficult [http://web.archive.org/web/20180615132259/https://www.bloomberg.com/news/articles/2018-06-15/deleting-your-online-dna-data-is-brutally-difficult].

26. *Id.*

27. *Id.* ("'The federal Clinical Laboratory Improvement Amendments (CLIA) of 1988 and California laboratory regulations require the lab store your de-identified genotyping test results and to keep a minimal amount of test result or analysis information,' an email from 23andMe said.").

28. *Id.*

29. Sarah E. Gollust, Stacy W. Gray, Deanna Alexis Carere, Barbara A. Koenig, Lisa Soleymani Lehmann, Amy L. McGuire, Richard R. Sharp, Kayte Spector-Bagdady, Na Wang, Robert C. Green & J. Scott Roberts, *Consumer Perspectives on Access to Direct-to-Consumer Genetic Testing: Role of Demographic Factors and the Testing Experience*, 95 MILBANK Q. 291, 300 (2017) ("83.2% [of 941 study participants] agree[d] overall . . . that it is important that genetic information is kept private.").

30. Regalado, *supra* note 3. According to Ancestry's president and CEO Margo Georgiadi, thirty million people globally have taken a DNA test. Rani Molla, *Why DNA Tests Are Suddenly Unpopular*, VOX (Feb. 13, 2020, 8:00 AM), https://www.vox.com/recode/2020/2/13/21129177/consumer-dna-tests-23andme-ancestry-sales-decline [https://web.archive.org/web/20200518173157/https://www.vox.com/recode/2020/2/13/21129177/consumer-dna-tests-23andme-ancestry-sales-decline].

31. Regalado, *supra* note 3.

relatives they never knew about.[32] As of November 2020, 23andMe has published 172 scientific papers in various journals based on internal and collaborative research using its consumer database.[33] These companies are here to stay, and consumers will likely continue to engage with them as companies expand their offerings in the health-care space.[34] The central inquiry thus becomes how the legal framework in the United States can be improved upon to adequately secure genetic privacy by protecting consumer autonomy over genetic information, while simultaneously ensuring that business and governmental interests such as research and law enforcement are not unduly burdened by strict privacy laws.

This Note makes three conceptual arguments. First, genetic-privacy concerns necessitate context-specific policies that maximize consumer autonomy. Second, the current legal framework in the United States applicable to DTC genetic testing is largely inadequate, but recent state data-privacy laws like the California Consumer Privacy Act (CCPA) and California Privacy Rights Act (CPRA) may serve as model legislation for genetic-privacy protection. Third, a balanced approach to the right to delete under the CCPA and CPRA will help secure genetic privacy by protecting consumer autonomy over genetic information.

Part I describes the DTC genetic testing industry's development in the age of big data and personalized medicine and the federal government's response to the emerging industry. Part II argues consumers need context-specific genetic-privacy policies that maximize their autonomy. Currently, companies and affiliated third parties erode autonomy by collecting and using genetic information in ways that are not transparent and bypass consent. Part III highlights how the current legal framework largely fails to adequately prevent the loss of autonomy, apart from the CCPA and CPRA. Part IV explores how the right to delete under the CCPA and CPRA could be applied to ensure consumer autonomy in the DTC genetic testing context while balancing against legitimate business and governmental interests.

I. THE COMMERCIALIZATION OF HUMAN GENETIC CODE

An understanding of the discovery of DNA, the development of related technology, and the subsequent commercialization of that technology leads to a deeper appreciation of the promise and danger of DTC genetic testing. Part I

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32. *It's All in the Genes: One Man Discovers Seven Famous Relatives*, ANCESTRY (Aug. 25, 2016), https://blogs.ancestry.com/cm/its-all-in-the-genes-one-man-discovers-seven-famous-relatives [https://perma.cc/T7AG-4XUA] (describing man who discovered seven famous relatives using DTC genetic test results); Amy Dockser Marcus, *Two Sisters Bought DNA Kits. The Results Blew Apart Their Family.*, WALL ST. J. (Feb. 1, 2019, 11:18 AM), https://www.wsj.com/articles/two-sisters-bought-dna-kits-the-results-blew-apart-their-family-11549037904 [https://perma.cc/J7TP-G8JP] (detailing how two sisters took DTC genetic tests and found out both their parents had extramarital affairs).

33. *Since 2010, 23andMe Has Published 172 Papers*, 23ANDME, https://www.23andme.com/publications [https://perma.cc/8FF8-4E6K] (last visited Oct. 23, 2021).

34. *See* Zoë LaRock, *23andMe's Latest FDA Approval Should Boost Its Personalized Medicine Play*, BUS. INSIDER (Aug. 21, 2020, 6:19 AM), https://www.businessinsider.com/23andme-takes-bigger-step-into-personalized-medicine-2020-8 [https://perma.cc/3MVC-R953].

explores the discovery of DNA and the development of sequencing technology and identifies two recent shifts in technology and medicine that hastened the commercial growth of the DTC genetic testing industry. Part I also details the federal government's regulatory response and later cautious approval of DTC genetic testing, which opened the door for companies to enter the health-care space.

A. The Discovery of DNA and Development of Sequencing Technology

The pathway to discovering what is known today as DNA[35] had humble beginnings. In 1865, Gregor Mendel, also known as the "father of genetics," discovered certain principles of heredity based on his experiments with pea plants.[36] In 1869, Swiss scientist Friedrich Miescher first isolated DNA—which he called "nuclein"—from white blood cells.[37] This term was eventually changed to deoxyribonucleic acid, or DNA.[38]

Continuing up to the middle of the twentieth century, numerous scientists continued to build upon prior research in the pursuit of learning more about DNA, leading to stepwise discoveries regarding the phosphate-sugar-base structure of nucleotides and the base pairing of purines and pyrimidines.[39] In the early 1950s, researchers Rosalind Franklin and Maurice Wilkins at King's College London conducted experiments to determine the structure of DNA through imaging using X-ray crystallography.[40] This research, particularly Wilkins's unpermitted showing of Franklin's Photo 51, led directly to James Watson and Francis Crick's famous discovery of DNA's double-helix structure.[41]

By the 1970s, researchers had begun piecing together the conceptual framework for DNA replication and the encoding of proteins, but they still could not "read" DNA sequences.[42] Then, in 1977, a major breakthrough that "forever altered the progress of DNA sequencing technology" occurred: Frederick Sanger developed the chain-termination method for rapidly sequencing DNA, now known

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35. DNA makes up the hereditary material in humans and is formed by the sequential pairing of four chemical bases—adenine, thymine, guanine, and cytosine. *What Is DNA?*, MEDLINEPLUS, https://medlineplus.gov/genetics/understanding/basics/dna [https://perma.cc/UMV9-T3GR] (Jan. 19, 2021).

36. Robert Olby, *Gregor Mendel*, ENCYC. BRITANNICA, https://www.britannica.com/biography/Gregor-Mendel [https://perma.cc/FZ5F-4D6P] (last visited Oct. 23, 2021).

37. Ralf Dahm, Review, *Friedrich Miescher and the Discovery of DNA*, 278 DEVELOPMENTAL BIOLOGY 274, 275–77 (2005).

38. Leslie A. Pray, *Discovery of DNA Structure and Function: Watson and Crick*, 1 NATURE EDUC. 100 (2008).

39. *Id.*

40. *James Watson, Francis Crick, Maurice Wilkins, and Rosalind Franklin*, SCI. HIST. INST., https://www.sciencehistory.org/historical-profile/james-watson-francis-crick-maurice-wilkins-and-rosalind-franklin [https://perma.cc/7TMR-RLSU] (Dec. 4, 2017).

41. Jane J. Lee, *6 Women Scientists Who Were Snubbed Due to Sexism*, NAT'L GEOGRAPHIC (May 19, 2013), https://www.nationalgeographic.com/news/2013/5/130519-women-scientists-over looked-dna-history-science [https://perma.cc/GF5J-NKCF].

42. James M. Heather & Benjamin Chain, Review, *The Sequence of Sequencers: The History of Sequencing DNA*, 107 GENOMICS 1, 1 (2016).

as the predominant first-generation DNA sequencing technique.[43] Rapid sequencing facilitated the completion of the Human Genome Project (1990–2003),[44] during which researchers determined the complete sequence of human DNA, mapped gene locations for major sections of all chromosomes, and produced linkage maps for tracking inherited traits.[45] In the span of just fifty years, scientists learned the sequence and intricacies of what Francis Collins, then Director of the National Human Genome Research Institute, termed "an incredibly detailed blueprint for building every human cell" that would "give health care providers immense new powers to treat, prevent and cure disease."[46]

B. Harnessing DNA Testing Technology

Soon after the success of first-generation sequencing, the DTC genetic testing industry started to probe how sequencing could be harnessed to create commercial products.[47] Companies started to develop various alternative second-generation sequencing techniques that more quickly produced larger quantities of data at a higher quality and a reduced cost.[48] This period marked the broadening of the use of DNA technology beyond its original use as a tool purely for research purposes. For example, it was in this time of commercialization that future industry giants Ancestry, founded in 1996,[49] and 23andMe, founded in 2006,[50] established themselves.

Today, DNA can be tested commercially through genotyping or sequencing.[51] The fastest and cheapest way to conduct DTC genetic testing is through genotyping,[52] which looks at selected genetic markers called single nucleotide

43. *See id.* at 2–3.

44. *The Human Genome Project,* NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/human-genome-project [https://perma.cc/LZ6W-KDM4] (Dec. 22, 2020).

45. *What Is the Human Genome Project?,* NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/human-genome-project/What [https://perma.cc/74NL-G53J] (Oct. 28, 2018).

46. *Id.*

47. *See* Heather & Chain, *supra* note 42, at 3–5.

48. Jay Shendure & Hanlee Ji, Review, *Next-Generation DNA Sequencing*, 26 NATURE BIOTECHNOLOGY 1135, 1143 (2008).

49. *Our Story*, ANCESTRY CORP., https://www.ancestry.com/corporate/about-ancestry/our-story [https://perma.cc/U5UC-CPVZ] (last visited Nov. 19, 2020) (listing 1996 as the year Ancestry Publishing launched Ancestry.com).

50. *About Us*, 23ANDME, https://mediacenter.23andme.com/company/about-us [http://web.archive.org/web/20210313230453/https://mediacenter.23andme.com/company-2/about-us/] (last visited Mar. 13, 2021) (listing 2006 as the founding year).

51. *See* Behind the Bench Staff, *Direct-to-Consumer (DTC) Genetic Ancestry Reports: Why Genotyping Is Essential*, THERMO FISHER SCI. (June 13, 2019), https://www.thermofisher.com/blog/behindthebench/direct-to-consumer-dtc-genetic-ancestry-reports-why-genotyping-is-essential [https://perma.cc/8HVX-8F44].

52. *Id.*

polymorphisms (SNPs)[53] in the genome using DNA microarray technology.[54] Developed in the 1990s and 2000s, DNA microarray technology is a second-generation sequencing technique that has become "highly successful and widely used."[55] Ancestry and 23andMe both use genotyping and DNA microarray technology to analyze DNA samples collected from their consumers.[56]

Even though microarray-based tests are still the gold standard for DTC genetic testing, there is some interest in whole genome sequencing or whole exome sequencing,[57] which involve either sequencing the entire genome or only the protein-coding regions of genes, respectively.[58] Some DTC genetic companies are taking advantage of the advances in software, hardware, and artificial intelligence[59]: Veritas, for example, now offers a whole genome sequencing product for $599 and predicted the cost will fall to $100–$200 by 2021.[60] Similarly, California-based start-up Nebula Genomics has recently launched a whole genome sequencing consumer product for $299.[61] These costs are a stark contrast to the one billion dollars it took for the Human Genome Project's researchers to produce a complete reference sequence of the human genome.[62] With costs continuing to fall,

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53. An individual has approximately four to five million SNPs, or locations within DNA that differ in the chemical based used. *What Are Single Nucleotide Polymorphisms (SNPs)?*, MEDLINEPLUS, https://medlineplus.gov/genetics/understanding/genomicresearch/snp [https://perma.cc/72EK-3L82] (Sept. 18, 2020).

54. DNA microarray technology uses a "chip" with thousands of short, synthetic, single-stranded DNA, to which an individual's single-stranded DNA that is tagged with a dye and control DNA are added. *DNA Microarray Technology Fact Sheet*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/about-genomics/fact-sheets/DNA-Microarray-Technology [https://perma.cc/V9GF-RR8W] (Aug. 15, 2020). Based on how the individual's DNA and the control DNA bind to the chip's DNA, a researcher will be able to tell if the individual has a mutation for a specific genetic marker. *Id.*

55. Roger Bumgarner, *Overview of DNA Microarrays: Types, Applications, and Their Future*, 101 CURRENT PROTOCOLS MOLECULAR BIOLOGY 22.1.1, 22.1.2, 22.1.6 (2013); *see also* Shendure & Ji, *supra* note 48 (describing microarray technology as "widespread, commoditized and routine").

56. *Genotyping Services for Research*, 23ANDME, https://research.23andme.com/genotyping-services-research/ [https://perma.cc/AB67-Y3XN] (last visited Oct. 24, 2021); *Frequently Asked Questions*, ANCESTRY, https://www.ancestry.com/dna/en/legal/us/faq#about-3 [https://perma.cc/F53Y-6GVQ] (last visited Oct. 24, 2021).

57. *See* Allison Gatlin, *Genetic Testing Companies Take DNA Tests to a Whole New Level*, INV.'S BUS. DAILY (Dec. 6, 2019, 9:04 AM), https://www.investors.com/news/technology/genetic-testing-companies-take-dna-tests-new-level-genome-sequencing [https://perma.cc/X764-CSFU].

58. *What Are Whole Exome Sequencing and Whole Genome Sequencing?*, MEDLINEPLUS, https://medlineplus.gov/genetics/understanding/testing/sequencing [https://perma.cc/B9DA-PJ3T] (July 28, 2021).

59. Gatlin, *supra* note 57.

60. Joe Andrews, *23andMe Competitor Veritas Genetics Slashes Price of Whole Genome Sequencing 40% to $600*, CNBC (July 1, 2019, 9:30 AM), https://www.cnbc.com/2019/07/01/for-600-veritas-genetics-sequences-6point4-billion-letters-of-your-dna.html [https://perma.cc/NT8U-EWU9].

61. Dane Finley, *Nebula Genomics Rolled Out a Low-Cost Genome Sequencing Test to Consumers*, BUS. INSIDER (Feb. 20, 2020, 7:05 AM), https://www.businessinsider.com/nebula-launches-direct-to-consumer-whole-genome-sequencing-test-2020-2 [https://perma.cc/W354-K6RQ].

62. *The 10-Year Anniversary of the Human Genome Project: Commemorating and Reflecting*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/27555238/april-2013-the-10year-

whole genome or exome sequencing will continue to become more accessible, creating a potential area of growth for DTC genetic testing companies.

C. The Rapid Commercialization of DNA Testing

The growth of the DTC genetic testing industry did not occur in a vacuum. While testing technology developed and commercial interests intensified, two shifts in technology and medicine simultaneously helped hasten the growth of the industry: the rise of big data and personalized medicine.

1. Big Data

Big data in the biomedical context refers to a "new generation of technologies and architectures, designed to extract value from large volumes of a wide variety of data by enabling high-velocity capture, discovery and analysis."[63] Big data has led to the creation of the "Internet of Things" (IoT), the rise of social media and e-commerce, and the formation of large companies like Google and Amazon that collect and store data.[64] The massive amount of data collected from IoT devices and the increased capacity to store that data led to the development of artificial intelligence (AI) algorithms, which in turn improve based on the collection and input of even more data.[65]

In 2001, Doug Laney defined the "3Vs," or characteristics, of big data as high volume, velocity, and variety.[66] DTC genetic testing companies clearly share common traits with well-known big-data companies like Google, and some explicitly aim to become just as ubiquitous within the health-care space.[67] DNA data

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anniversary-of-the-human-genome-project-commemorating-and-reflecting [https://perma.cc/KS63-5VF2] (Oct. 21, 2013).

63. Fabricio F. Costa, Review, *Big Data in Biomedicine*, 19 DRUG DISCOVERY TODAY 433, 434 (2014).

64. In 2007, the launch of the first iPhone marked big data's move to the consumer space, which was quickly followed by a proliferation of smartphones, wearable technology, tablets, and other devices that collectively made up the IoT. Charles Towers-Clark, *Big Data, IoT, and AI, Part One: Three Sides of the Same Coin*, FORBES (Feb. 15, 2019, 11:36 AM), https://www.forbes.com/sites/charlestowersclark/2019/02/15/big-data-iot-and-ai-part-one-three-sides-of-the-same-coin/#4097becc69da [https://perma.cc/MT9V-R8GH].

65. *Id.*

66. Svetlana Sicular, *Gartner's Big Data Definition Consists of Three Parts, Not to Be Confused with Three "V"s*, FORBES (Mar. 27, 2013, 8:00 AM), https://www.forbes.com/sites/gartnergroup/2013/03/27/gartners-big-data-definition-consists-of-three-parts-not-to-be-confused-with-three-vs/?sh=175874d7 42f6 [https://perma.cc/86SC-M3LK] (stating that volume refers to the amount of data, velocity refers to the growth of data, and variety refers to the formats of data).

67. For example, Patrick Chung, a 23andMe board member, stated in 2013 that 23andMe aimed to become the "Google of personalized health care." Elizabeth Murphy, *Inside 23andMe Founder Anne Wojcicki's $99 DNA Revolution*, FAST CO. (Oct. 14, 2013), https://www.fastcompany.com/3018598/for-99-this-ceo-can-tell-you-what-might-kill-you-inside-23andme-founder-anne-wojcickis-dna-r [https://perma.cc/UL56-5JNE].

is high volume by nature.[68] With millions of consumers contributing DNA,[69] DTC genetic testing companies have cultivated a high variety of data at a high velocity. Thus, these companies can be appropriately categorized as big-data companies with incentives to refine their technologies and grow large collections of genetic information[70] despite privacy concerns.

2. Personalized Medicine

The DTC genetic testing industry's rise in the mid-2000s was in some ways a reaction to the traditional medical model of providing genetic testing that restricted genetics to medical settings and expert interpretation.[71] The medical model involves a medical professional ordering a clinically indicated genetic test for a patient and a licensed, board-certified medical provider interpreting and delivering the results.[72] A number of drawbacks to the medical model include slower innovation, scarcity of medical geneticists and genetic counselors, and restriction of genetic information to the health-care context.[73]

In opposition to the traditional medical model, DTC genetic testing companies offer an alternative consumer-initiated model of learning about one's health.[74] The consumer-initiated model is a big-data model that has the potential to "trigger[] a convergence between the healthcare industry and the life sciences industry," leading a shift away from population-based health care to personalized medicine.[75] Personalized medicine is defined as "an emerging practice of medicine that uses an individual's genetic profile to guide decisions made in regard to the prevention, diagnosis, and treatment of disease."[76] With the help of big data, researchers hope to create targeted treatments for specific diseases, with companies providing solutions to generate, store, and interpret data.[77]

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68. *See What Is DNA?*, *supra* note 35 ("Human DNA consists of about 3 billion [base pairs] . . . .").

69. Regalado, *supra* note 3.

70. Companies continue to improve DNA test results by refining their AI algorithms that are developed from reference data sets, which usually combine data from publicly available databases and the company's own and ever-growing consumer data. *See* Behind the Bench Staff, *supra* note 51; *see also* ERIC Y. DURAND, CHUONG B. DO, JOANNA L. MOUNTAIN & J. MICHAEL MACPHERSON, 23ANDME, ANCESTRY COMPOSITION: A NOVEL, EFFICIENT PIPELINE FOR ANCESTRY DECONVOLUTION (2014) (example of ancestry algorithm).

71. *See* Allyse et al., *supra* note 7, at 114.

72. *Id.*

73. *Id.* at 114–15.

74. *See* Nur Lalji, *Featurization and the Myth of Data Empowerment*, 15 WASH. J.L. TECH. & ARTS 1, 13 (2019) (describing products such as genetic testing kits as "marketed in a way that capitalizes on the mentality of the 'quantified self' movement—that more information and more revelations make life better").

75. *See* Costa, *supra* note 63, at 433, 436.

76. *Personalized Medicine*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/genetics-glossary/Personalized-Medicine [https://perma.cc/7ZGS-FC3Y] (last visited Oct. 24, 2021).

77. Costa, *supra* note 63, at 434 fig.1.

In 2008, leaders of prominent DTC genetic testing companies were invited to a workshop convened by the National Institutes of Health and the Centers for Disease Control and Prevention; they denied that their products were medical tests and that "medicalization," or entering the health-care space, was part of their business model.[78] Yet in 2011, DTC genetic testing companies began working with federally approved laboratories and sought to be providers of presymptomatic or diagnostic medical tests.[79] Perhaps to combat the recent decline in sales of DNA testing kits,[80] companies like 23andMe are seeking to maximize the interpretive value of their consumer data by developing new health-related tests[81] or upgrading their DNA microarray chips.[82] As companies continue to expand into the health-care space, it is clear they are actively seeking ways to get more value out of consumer data, which should be subject to more stringent regulatory and ethical scrutiny.

D. The Federal Government's Response

Despite the growth of the nascent industry in the early 2000s, the DTC genetic testing industry soon encountered a number of regulatory roadblocks that temporarily dampened growth.[83] Critics took issue with the methodology of finding potential associations between SNPs and disease outcomes, the risk of consumers misinterpreting results, the underinclusiveness of reference data sets of certain ethnic and racial populations, the framing of DTC genetic tests as commercial transactions, and the user agreements that did not require informed consent to sell

78. Kenneth Offit, Review, *Personalized Medicine: New Genomics, Old Lessons*, 130 HUM. GENETICS 3, 4 (2011); *see also* Muin J. Khoury, Colleen M. McBride, Sheri D. Schully, John P. A. Ioannidis, W. Gregory Feero, A. Cecile J. W. Janssens, Marta Gwinn, Denise G. Simons-Morton, Jay M. Bernhardt, Michele Cargill, Stephen J. Chanock, George M. Church, Ralph J. Coates, Francis S. Collins, Robert T. Croyle, Barry R. Davis, Gregory J. Downing, Amy DuRoss, Susan Friedman, Mitchell H. Gail, Geoffrey S. Ginsburg, Robert C. Green, Mark H. Greene, Philip Greenland, Jeffrey R. Gulcher, Andro Hsu, Kathy L. Hudson, Sharon L. R. Kardia, Paul L. Kimmel, Michael S. Lauer, Amy M. Miller, Kenneth Offit, David F. Ransohoff, J. Scott Roberts, Rebekah S. Rasooly, Kari Stefansson, Sharon F. Terry, Steven M. Teutsch, Angela Trepanier, Kay L. Wanke, John S. Witte & Jianfeng Xu, Review, *The Scientific Foundation for Personal Genomics: Recommendations from a National Institutes of Health–Centers for Disease Control and Prevention Multidisciplinary Workshop*, 11 GENETICS MED. 559, 559 (2009) (industry attendees included leaders from Navigenics, deCODE Genetics, and 23andMe).

79. Offit, *supra* note 78.

80. *See* Rachel Sandler, *23andMe Lays Off 14% of Workforce Amid Declining DNA Test Sales*, FORBES (Jan. 23, 2020, 3:22 PM), https://www.forbes.com/sites/rachelsandler/2020/01/23/23andme-lays-off-14-of-workforce-amid-declining-dna-test-sales/?sh=500ef1777f3a [https://perma.cc/X54M-5GFU].

81. *See infra* notes 89–92.

82. *Upgrading to 23andMe's Newest Chip Version*, 23ANDME, https://customercare.23andme.com/hc/en-us/articles/218392668-Upgrading-to-23andMe-s-Newest-Version [http://web.archive.org/web/20210301102745/https://customercare.23andme.com/hc/en-us/articles/218392668-Upgrading-to-23andMe-s-Newest-Version] (last visited Mar. 1, 2021).

83. *See* Allyse et al., *supra* note 7, at 116–17.

consumer data to third parties.[84] Spurred on by such concerns, the U.S. Government Accountability Office (GAO) launched an investigation into the practices of DTC genetic testing companies in 2006 and subsequently published a 2010 report concluding that DTC genetic test results were misleading and ten out of the fifteen companies investigated had engaged in "fraudulent, deceptive, or otherwise questionable marketing practices."[85]

Alerted by the GAO report, the U.S. Food and Drug Administration (FDA) sent letters to the five largest DTC genetic testing companies on June 10, 2010, informing them that their products were medical devices that had not been subject to premarket review and approval.[86] On July 22, 2010, the U.S. House Committee on Energy and Commerce convened a hearing to discuss DTC genetic testing and its consequences to public health.[87] Finally, on November 22, 2013, the FDA issued a cease-and-desist letter to 23andMe to stop the marketing of its DTC genetic test,[88] leading to one reporter proclaiming that "23andMe's Most Useful Service Is Basically Dead."[89]

However, the industry soon bounced back despite the initial regulatory roadblocks. Starting in 2015, the FDA authorized for marketing 23andMe's Bloom Syndrome carrier test and further stated that it intended to exempt carrier screening tests from premarket review.[90] In 2017, the FDA allowed 23andMe to market its

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84. *Id.* at 115–16.

85. U.S. GOV'T ACCOUNTABILITY OFF., GAO-10-847T, DIRECT-TO-CONSUMER GENETIC TESTS: MISLEADING TEST RESULTS ARE FURTHER COMPLICATED BY DECEPTIVE MARKETING AND OTHER QUESTIONABLE PRACTICES 1–4, 15 (2010).

86. *See* Letter from Alberto Gutierrez, Dir., OHT7, FDA, to Anne Wojcicki, President & Co-Founder, 23andMe, Inc. (June 10, 2010), https://www.fda.gov/media/79205/download [https://perma.cc/94L7-KQYD]; Letter from Alberto Gutierrez, Dir, OHT7, FDA to Earl M. Collier, Jr., CEO, deCODE Genetics (June 10, 2010), https://www.fda.gov/media/79216/download [https://perma.cc/D82T-GYJQ]; Letter from Alberto Gutierrez, Dir., OHT7, FDA to Jay T. Flatley, President & CEO, Illumina, Inc. (June 10, 2010), https://www.fda.gov/media/79226/download [https://perma.cc/APN2-GHZ6]; Letter from Alberto Gutierrez, Dir., OHT7, FDA to Jorge Conde, Co-Founder & CEO, Knome, Inc. (June 10, 2010), https://www.fda.gov/media/79198/download [https://perma.cc/8Z6T-CEUB]; Letter from Alberto Gutierrez, Dir., OHT7, FDA to Vance Vanier, President & CEO, Navigenics (June 10, 2010), https://www.fda.gov/media/79235/download [https://perma.cc/5K2A-6LSX].

87. *See generally Direct-to-Consumer Genetic Testing and the Consequences to the Public Health: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Com.*, 111th Cong. (2010).

88. Letter from Alberto Gutierrez, Dir., OHT7, FDA to Anne Wojcicki, CEO, 23andMe, Inc. (Nov. 22, 2013), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/23andme-inc-11222013 [https://web.archive.org/web/20190513203251/https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/23andme-inc-11222013].

89. Megan Rose Dickey, *23andMe's Most Useful Service Is Basically Dead*, BUS. INSIDER (Dec. 6, 2013, 1:57 AM), https://www.businessinsider.com/23andmes-most-useful-service-is-dead-2013-12 [https://perma.cc/3SJG-ZHX5].

90. Press Release, FDA, FDA Permits Marketing of First Direct-to-Consumer Genetic Carrier Test for Bloom Syndrome (Feb. 19, 2015), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm435003.htm [https://wayback.archive-it.org/7993/20171114165526/https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm435003.htm] (classifying carrier

genetic health risk tests for ten diseases or conditions, including Parkinson's disease, late-onset Alzheimer's disease, and celiac disease.[91] In 2018, the FDA granted marketing authorization to 23andMe for two DTC genetic tests that report three mutations in the BRCA breast cancer genes[92] and detect genetic variants potentially associated with medication metabolism.[93] Most recently, 23andMe received FDA clearance for a genetic health risk report on a hereditary colorectal cancer syndrome[94] and a pharmacogenetics report that provides interpretive drug information for certain heart and depression medications.[95] These rapid authorizations, coupled with the FDA's own statement implementing a streamlined review process for DTC genetic tests, indicate that the FDA's concerned attention to DTC genetic testing companies in 2010–2013 did not herald a strong regulatory response after all.[96]

There are other indicators that the DTC genetic testing industry is growing. Despite the COVID-19 pandemic, Blackstone—the nation's largest private equity firm—is set to acquire Ancestry.com for $4.7 billion.[97] As Ancestry President and CEO Margo Georgiadis noted, "Looking ahead, in collaboration with Blackstone, we will continue to leverage our unique content, powerhouse consumer brand and

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screening tests as Class II devices and exempting these devices from FDA premarket review based on the goal of promoting consumers' direct access to personal genetic information and the requirement that DTC genetic testing companies explain the meaning of results to consumers in the product labeling).

91. Press Release, FDA, FDA Allows Marketing of First Direct-to-Consumer Tests that Provide Genetic Risk Information for Certain Conditions (Apr. 6, 2017), https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-direct-consumer-tests-provide-genetic-risk-information-certain-conditions [https://perma.cc/Q9TX-QQRM].

92. Press Release, FDA, FDA Authorizes, With Special Controls, Direct-to-Consumer Test that Reports Three Mutations in the BRCA Breast Cancer Genes (Mar. 6, 2018), https://www.fda.gov/news-events/press-announcements/fda-authorizes-special-controls-direct-consumer-test-reports-three-mutations-brca-breast-cancer [https://perma.cc/6UDS-D4SN].

93. Press Release, FDA, FDA Authorizes First Direct-to-Consumer Test for Detecting Genetic Variants that May Be Associated with Medication Metabolism (Oct. 31, 2018), https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-direct-consumer-test-detecting-genetic-variants-may-be-associated-medication [https://perma.cc/ULG6-CK3K].

94. Press Release, 23andMe, 23andMe Receives FDA Clearance for Direct-to-Consumer Genetic Test on a Hereditary Colorectal Cancer Syndrome (Jan. 22, 2019), https://mediacenter.23andme.com/press-releases/23andme-receives-fda-clearance-for-direct-to-consumer-genetic-test-on-a-hereditary-colorectal-cancer-syndrome [https://perma.cc/749X-ATUB].

95. Press Release, 23andMe, 23andMe Granted New FDA Clearance to Provide Interpretive Drug Information for Two Commonly Prescribed Medications (Aug. 18, 2020), https://mediacenter.23andme.com/press-releases/23andme-granted-clearance [https://perma.cc/5F9Y-WBVQ].

96. Press Release, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on Implementation of Agency's Streamlined Development and Review Pathway for Consumer Tests that Evaluate Genetic Health Risks (Nov. 6, 2017), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-implementation-agencys-streamlined-development-and [https://perma.cc/CFR7-8GEV]. For further background on the history of the FDA's regulation of DTC genetic tests, see *infra* Section III.C.

97. Stephen Gandel, *Private Equity Wants to Own Your DNA*, CBS NEWS (Aug. 7, 2020, 4:52 PM), https://www.cbsnews.com/news/blackstone-private-equity-ancestry-com-dna [https://perma.cc/NS9H-3F4B].

technology platform to expand our global Family History business while bringing to life our long-term vision of personalized preventive health."[98] 23andMe continues to have an eye towards research and has recently published a study indicating genetic and non-genetic associations related to COVID-19.[99] In sum, the FDA's actions in 2010–2013 did not deter the growth of the DTC genetic testing industry. On the contrary, the industry learned to adapt, increased its repertoire of genetic tests, and actively used its trove of consumer genetic information to conduct internal and collaborative research.

II. PRESERVING AUTONOMY OVER GENETIC INFORMATION

Part I describes the scientific and societal context that led to the rise of the DTC genetic testing industry. Part II first examines the concept of genetic exceptionalism as an underlying rationale for protecting genetic information and surveys consumer perspectives on genetic privacy, which suggest that context-specific genetic-privacy policies that maximize consumer autonomy are needed. Part II subsequently analyzes how companies and third parties erode consumer autonomy over genetic information.

A. Moving from Genetic Exceptionalism Towards Genetic Contextualism

Arguments for genetic exceptionalism—an underlying rationale for strong genetic-privacy protection—first surfaced in the 1990s after the development of the first wave of predictive genetic tests.[100] Genetic exceptionalism is the idea that genetic information should be treated differently than other types of medical data or personally identifiable information because it has certain special characteristics, including the uniqueness of each individual's genetic code, the ability to predict the development of disease or the response to a drug, the immutable quality of DNA throughout an individual's lifetime, the historical misuse of genetic information to promote eugenics and discrimination, the ability to reveal information about blood relatives, and the ease of procuring biological samples.[101] Genetic information is even arguably more sacred than personal and health data retrieved from wearable

98. *Blackstone to Acquire Ancestry®, Leading Online Family History Business, for $4.7 Billion*, BLACKSTONE (Aug. 5, 2020), https://www.blackstone.com/press-releases/article/blackstone-to-acquire-ancestry-leading-online-family-history-business-for-4-7-billion [https://perma.cc/W5LK-6SQH].

99. JANIE F. SHELTON, ANJALI J. SHASTRI, CHELSEA YE, CATHERINE H. WELDON, TERESA FILSHTEIN-SOMNEZ, DANIELLA COKER, ANTONY SYMONS, JORGE ESPARZA-GORDILLO, 23ANDME COVID-19 TEAM, STELLA ASLIBEKYAN & ADAM AUTON, MEDRXIV, TRANS-ETHNIC ANALYSIS REVEALS GENETIC AND NON-GENETIC ASSOCIATIONS WITH COVID-19 SUSCEPTIBILITY AND SEVERITY (2020), https://www.medrxiv.org/content/10.1101/2020.09.04.20188318v1.full.pdf [https://perma.cc/Y3A2-KV3B].

100. Nanibaa' A. Garrison, Kyle B. Brothers, Aaron J. Goldenberg & John A. Lynch, *Genomic Contextualism: Shifting the Rhetoric of Genetic Exceptionalism*, AM. J. BIOETHICS, Jan. 2019, at 51, 52.

101. *See* Amy L. McGuire, Rebecca Fisher, Paul Cusenza, Kathy Hudson, Mark A. Rothstein, Deven McGraw, Stephen Matteson, John Glaser & Douglas E. Henley, Commentary, *Confidentiality, Privacy, and Security of Genetic and Genomic Test Information in Electronic Health Records: Points to Consider*, 10 GENETICS MED. 495, 496–97 (2008).

devices that routinely capture metrics such as heart rate, body temperature, movement, brain activity, moods, and emotions.[102] This is because such biometric data is not unique to each individual, can change daily, and confers little knowledge about one's blood relatives.

However, some scholars are critical of genetic exceptionalism as a concept and as public policy.[103] For example, Professors Lawrence O. Gostin and James G. Hodge, Jr., argue genetic information is not exceptional because it is not always determinative of disease like in the case of a single-gene disorder, and it is not feasible to separate genetic information from nongenetic information in a medical record.[104] The professors claim the "principal problem" of genetic-specific statutes that afford special protection to genetic information is that they provide different privacy protections to two people with the same disease, the sole difference being one person's disease is of genetic origin, while the other person's disease is due to environmental or behavioral factors.[105] Furthermore, strong protection of individual privacy may impede the collective social benefits that could be gained through enhanced patient choice, clinical benefits, improved research, and protection of public health.[106] Professor Mark A. Rothstein also argues genetic-specific laws "have limited value in preventing or redressing harms caused by the uses and disclosures of genetic information" and supports general legal standards that more effectively deal with genetic-privacy and discrimination issues.[107]

The genetic-exceptionalism debate obfuscates the goal of protecting genetic privacy. The binary portrayal of genetic information as exceptional or not "reinforces the assumption that tailored policies are only justified if genetic tests and information are globally exceptional."[108] Second, any perspective arguing for tailored policies can be discounted by arguing that genetic tests and information should not be treated differently than other personal and health information.[109] However, tailored laws, regulations, and policies are needed regarding DTC genetic testing due to its rapid and largely unregulated commercialization in the era of big

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102. KATHRYN C. MONTGOMERY, JEFF CHESTER & KATHARINA KOPP, CTR. FOR DIGIT. DEMOCRACY, HEALTH WEARABLE DEVICES IN THE BIG DATA ERA: ENSURING PRIVACY, SECURITY, AND CONSUMER PROTECTION 14 (2017), https://www.democraticmedia.org/sites/default/files/field/public/2016/aucdd_wearablesreport_final121516.pdf [https://perma.cc/HC3N-9SYQ].

103. *See* Lawrence O. Gostin & James G. Hodge, Jr., *Genetic Privacy and the Law: An End to Genetic Exceptionalism*, 40 JURIMETRICS 21 (1999); Mark A. Rothstein, *Genetic Exceptionalism and Legal Pragmatism*, 35 J.L. MED. & ETHICS (SPECIAL SUPP.) 59 (2007).

104. Gostin & Hodge, *supra* note 103, at 32–33.

105. *Id.* at 33. Respondents argue that these critics of genetic exceptionalism "conflate certain practical challenges with the conceptual argument for genetic exceptionalism." Samual 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, 1245 (2019).

106. Gostin & Hodge, *supra* note 103, at 36–39.

107. Rothstein, *supra* note 103, at 62.

108. Garrison et al., *supra* note 100, at 53.

109. *Id.*

data and personalized medicine. Some scholars have therefore argued for a new rhetorical term, "genomic contextualism," to reframe the genetic exceptionalism debate.[110] This term encapsulates the concept that the contexts where genetic information is used should guide policymaking.[111] Accordingly, public perspectives on how genetic information is used and understood in social and physical environments should be considered in any effort to protect genetic privacy.[112]

B. Consumer Perspectives

In looking at consumer perspectives on general data privacy and privacy related to DTC genetic testing, certain attitudes and trends are clear. According to a 2019 Pew Research Center survey, 81% of Americans feel they have very little or no control over the data collected by companies.[113] Similarly, 84% of Americans also feel they lack control over data collected by the government.[114] Only 4–6% of Americans feel they understood what companies or the government are doing with their data.[115] Notably, 70% of Americans feel their data is less secure today than it was five years ago.[116] Roughly 80% of Americans think the risks of companies collecting data outweigh the benefits.[117] Based on this research, it is clear consumers in the United States care about protecting their data privacy.

Nevertheless, consumer perspectives on genetic privacy are less definitive. For example, among the 52% of consumers who stated they recently decided not to use a product or service because of concerns regarding personal-data collection, 21% of that group decided not to use websites, whereas 10% decided not to use DNA, financial, or health-care services.[118] Furthermore, 48% of U.S. adults find it

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110. *See id.* at 57. The shift away from the binary genetic exceptionalism debate and the need for a nuanced approach based on context has subsequently been echoed by other scholars in the ethical, legal, and social implications field. *See, e.g.*, Thomas H. Murray, Guest Editorial, *Is Genetic Exceptionalism Past Its Sell-By Date? On Genomic Diaries, Context, and Content*, AM. J. BIOETHICS, Jan. 2019, at 13, 15 ("[Genetic exceptionalism] served a purpose in its time as a counter against genetic determinism and the exaggerated fears it engendered. But it's been pulled in so many, even contradictory, directions in recent years that its meaning and usefulness have dissipated."); *see also* Müge Fazlioglu, *Beyond the "Nature" of Data: Obstacles to Protecting Sensitive Information in the European Union and the United States*, 46 FORDHAM URB. L.J. 271, 300 (2019) ("Simply prioritizing certain 'categories' of information without taking into account the context of use might be too blunt an approach to protect data subjects' privacy.").

111. *See* Garrison et al., *supra* note 100, at 57.

112. *See id.*

113. BROOKE AUXIER, LEE RAINIE, MONICA ANDERSON, ANDREW PERRIN, MADHU KUMAR & ERICA TURNER, PEW RSCH. CTR., AMERICANS AND PRIVACY: CONCERNED, CONFUSED AND FEELING LACK OF CONTROL OVER THEIR PERSONAL INFORMATION 4 (2019), https://www.pewresearch.org/internet/2019/11/15/americans-and-privacy-concerned-confused-and-feeling-lack-of-control-over-their-personal-information [https://perma.cc/EU82-LYPP].

114. *Id.*

115. *Id.* at 10.

116. *Id.* at 15.

117. *Id.* at 28.

118. Andrew Perrin, *Half of Americans Have Decided Not to Use a Product or Service Because of Privacy Concerns*, PEW RSCH. CTR. (Apr. 14, 2020), https://www.pewresearch.org/fact-tank/2020/

acceptable for DTC genetic testing companies to share users' genetic data with law enforcement.[119] A national survey of U.S. adults found 57% of respondents believed the federal government should spend more on research into genetic causes of disease, which shows Americans are generally receptive towards the goal of advancing scientific and medical knowledge.[120] These findings seem to indicate that while consumers care about genetic privacy, they are willing to sacrifice some aspects of privacy in order to contribute to societal benefits such as improved law enforcement and scientific research.

Not surprisingly, acceptance of certain trade-offs is more pronounced among consumers of DTC genetic testing. A Stanford University study based on qualitative interviews of 23andMe customers found they viewed their relationships with 23andMe as transactionally focused but the possibility of contributing to 23andMe's research programs "deepened their commitment and motivation towards their decision to participate."[121] These consumers had few immediate privacy concerns about the use of their DNA, but some believed there may be general or future concerns.[122] Consumers have also consistently felt that people should have access to DTC genetic testing: a 2013 survey of Navigenics, 23andMe, and deCODEme consumers found 66% of respondents believed it was at least somewhat important that DTC genetic services be available without government oversight.[123] A 2017 study of 23andMe and Pathway Genomics consumers found 89.9% of participants believed people should have access to DTC genetic testing, with 68.3% believing test kits should be available more widely through outlets like drugstores.[124]

The research findings discussed above demonstrate that while consumers are concerned about general data privacy, their perspectives are more varied when it comes to genetic privacy. While the nation at large is more cautious about DTC genetics than consumers who have already taken tests, both groups acknowledge certain societal benefits that may warrant fewer strict privacy protections. Such benefits include better law enforcement and the advancement of research. Consequently, protecting privacy in the DTC genetic testing context necessitates a

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04/14/half-of-americans-have-decided-not-to-use-a-product-or-service-because-of-privacy-concerns [https://perma.cc/8BBF-XN6M].

119. Andrew Perrin, *About Half of Americans Are OK with DNA Testing Companies Sharing User Data with Law Enforcement*, PEW RSCH. CTR. (Feb. 4, 2020), https://www.pewresearch.org/fact-tank/2020/02/04/about-half-of-americans-are-ok-with-dna-testing-companies-sharing-user-data-with-law-enforcement [https://perma.cc/TR26-X4D8].

120. *See* Rene Almeling & Shana Kushner Gadarian, Brief Report, *Public Opinion on Policy Issues in Genetics and Genomics*, 16 GENETICS MED. 491, 492 (2014).

121. Jennifer King, *"Becoming Part of Something Bigger": Direct to Consumer Genetic Testing, Privacy, and Personal Disclosure*, PROC. ACM HUM.-COMPUT. INTERACTION, Nov. 2019, at 158:1, 158:10 (2019).

122. *Id.*

123. Juli Murphy Bollinger, Robert C. Green & David Kaufman, *Attitudes About Regulation Among Direct-to-Consumer Genetic Testing Customers*, 17 GENETIC TESTING & MOLECULAR BIOMARKERS 424, 425 (2013).

124. Gollust et al., *supra* note 29, at 292, 305, 307.

balanced approach that gives consumers the ability to choose to protect data they deem sensitive.

C. Electronic Agreements, Collection, and Use

Currently, consumer autonomy over genetic information is eroded at three key stages of the DTC genetic testing process: when consumers sign electronic agreements with the companies, when DNA is collected, and when companies and third parties use consumer genetic information for their own purposes. Beyond the initial transaction of obtaining test results, numerous entities seek to access company databases, including data brokers, marketing and advertising corporations, pharmaceutical companies, employers, insurers, and law enforcement.[125] Therefore, DTC genetic testing companies have an enormous incentive to aggregate data to the detriment of consumers.

First, consumer autonomy is lost when individuals "sign" DTC genetic testing companies' electronic agreements prior to testing. These agreements are typically "clickwrap" agreements, where a consumer is forced to scroll through before clicking "I agree," or "browsewrap" agreements, where a consumer can access the terms through a hyperlink but clicking on the link is not required to enter into the contract.[126] Due to the fast-paced nature of the online world and how often consumers encounter clickwrap and browsewrap agreements,[127] many scholars have raised concerns that these agreements may not provide consumers with sufficient notice of companies' data practices or afford them the opportunity for real choice or consent to those practices.[128]

In one study that surveyed ninety DTC genetic testing companies operating in the United States, researchers found 10% of the companies had no readily accessible privacy documents such as privacy policies or terms of service.[129] Additionally, 29% only had documents covering website use such as "cookie" and web-tracking policies.[130] These two groups combined created an alarming percentage: 39% of

125. Katherine Drabiak, *Caveat Emptor: How the Intersection of Big Data and Consumer Genomics Exponentially Increases Information Privacy Risks*, 27 HEALTH MATRIX 143, 171 (2017).

126. Andelka M. Phillips, *Reading the Fine Print When Buying Your Genetic Self Online: Direct-to-Consumer Genetic Testing Terms and Conditions*, 36 NEW GENETICS & SOC'Y 273, 278 (2017).

127. *See* AUXIER ET AL., *supra* note 113, at 5 ("About eight-in-ten Americans say they are asked to agree to a privacy policy at least monthly, including one-quarter who say this happens almost every day.").

128. *See, e.g.*, Charles E. MacLean, *It Depends: Recasting Internet Clickwrap, Browsewrap, "I Agree," and Click-Through Privacy Clauses as Waivers of Adhesion*, 65 CLEV. STATE L. REV. 45, 48–50 (2016) (arguing that clickwrap agreements are adhesion contracts); Jonathan A. Obar & Anne Oeldorf-Hirsch, *The Clickwrap: A Political Economic Mechanism for Manufacturing Consent on Social Media*, SOC. MEDIA + SOC'Y, July–Sept. 2018, at 1, 9–10 (arguing that clickwrap agreements fail to notify users about the consent process, suggest that the consent process is unimportant, and discourage engagement with the consent process).

129. Hazel & Slobogin, *supra* note 12, at 48.

130. *Id.*

companies had no readily accessible documents applicable to genetic data.[131] Thus, even if one argues that clickwrap and browsewrap agreements sufficiently establish consumer notice, choice, and consent, the fact that companies differ so widely in their privacy documents and transparency means different consumers will have different protections regarding their genetic information.

Second, consumer autonomy is lost when companies collect consumer DNA in ways that are not fully transparent. Data collection issues concern what information is shared with the testing laboratory, how a consumer's biological sample is treated after testing, for how long consumer genetic data is retained, and whether retained genetic data can be deleted.[132] If genetic information is stored online in the cloud, such data is also vulnerable to security breaches. For example, a MyHeritage security researcher discovered over ninety-two million email addresses and hashed passwords had been transferred to a private server unaffiliated with the company over seven months after the initial data breach.[133] Even though genetic information was not leaked, this incident heightens the concern that consumer genetic information is of interest and vulnerable to hackers with inscrutable motives and affiliations.

Third, consumer autonomy is lost when companies and third parties use consumer data. Data-use issues revolve around companies' ability to own and commercialize consumer genetic information; internal research and development; sharing of data with third parties for external research; transferring of data in the event of a sale, merger, or bankruptcy; and sharing of data with law enforcement.[134] Examples of possible data misuse include GlaxoSmithKline's purchase of a $300 million stake in 23andMe that allowed it to use 23andMe's genetic database to develop new drugs[135] and the arrest of the Golden State Killer based off of genetic data from his family members found in a genealogy database.[136] These examples show how companies and affiliated third parties may use genetic information in ways beyond what consumers likely believed they signed up for when they initially decided to test their DNA.

Thus, the loss of consumer autonomy over genetic information occurs at three main stages: (1) when consumers encounter electronic agreements prior to testing, (2) when companies collect DNA and associated information, and (3) when

131. *Id.*

132. *Id.* at 49–51.

133. Press Release, MyHeritage, MyHeritage Statement About a Cybersecurity Incident (June 4, 2018), https://blog.myheritage.com/2018/06/myheritage-statement-about-a-cybersecurity-incident [https://perma.cc/7DCR-E828].

134. *See* Hazel & Slobogin, *supra* note 12, at 52–53, 55–57.

135. Jamie Ducharme, *A Major Drug Company Now Has Access to 23andMe's Genetic Data. Should You Be Concerned?*, TIME (July 26, 2018, 3:47 PM), https://time.com/5349896/23andme-glaxo-smith-kline [https://perma.cc/UB43-HZVW].

136. Michael Levenson & Heather Murphy, *Golden State Killer Suspect Offers to Plead Guilty*, N.Y. TIMES (June 29, 2020), https://www.nytimes.com/2020/03/04/us/golden-state-killer-trial.html [https://perma.cc/QF7G-HSJX].

companies and third parties use that genetic information for various purposes beyond the original transaction. Companies vary drastically in their data practices, which unfortunately creates disparities in the levels of genetic-privacy protection consumers receive. The existence of these varying data practices demonstrates the need for an updated legal framework that allows individuals to regain control over their genetic information, particularly where consumers arguably did not consent to certain collection or use practices.

III. THE CURRENT LEGAL FRAMEWORK

Part II addressed privacy concerns and the corresponding loss of consumer autonomy within the DTC genetic testing industry. Part III reviews the current legal framework applicable to the industry and considers whether the current legal framework adequately protects consumer autonomy over genetic information. Part III argues the current legal framework is inadequate in preventing and remedying the loss of autonomy. However, recent general data-privacy laws from the states may provide a pathway to securing consumer autonomy regarding DTC genetic tests.

A. Industry Self-Regulation

This Section considers whether industry self-regulation is a viable method for the protection of consumer autonomy over genetic information. Self-regulation in the DTC genetic testing context takes two forms: contracts and best practices.[137] As previously discussed, the use of contracts in the form of clickwrap agreements, browsewrap agreements, privacy policies, or terms of service is highly skewed in favor of DTC genetic testing companies.[138] This Section assesses the value of privacy best practices created with industry cooperation.

The Future of Privacy Forum (FPF), a nonprofit organization that brings together industry, academia, law, and advocacy groups, put forth privacy best practices for DTC genetic testing companies in 2018.[139] FPF acknowledges that "Genetic Data is sensitive information that warrants a high standard of privacy protection" due to its possibly identifying genetic predispositions, disease risks, and future medical conditions; revealing information about one's family, including children; containing unexpected information; and being culturally significant for groups or individuals.[140] FPF recommends that companies obtain express consent for collection, analysis, sharing, or reporting of genetic data; obtain informed

137. *See* Phillips, *supra* note 126, at 273 (discussing the use of contracts by the DTC genetic testing industry as the "dominant means of industry self-regulation"); FUTURE OF PRIVACY FORUM, PRIVACY BEST PRACTICES FOR CONSUMER GENETIC TESTING SERVICES (2018), https://fpf.org/wp-content/uploads/2018/07/Privacy-Best-Practices-for-Consumer-Genetic-Testing-Services-FINAL.pdf [https://perma.cc/34L5-JXE3] (establishing DTC genetic testing industry best practices).

138. *See supra* Section II.C.

139. FUTURE OF PRIVACY FORUM, *supra* note 137, at 19.

140. *Id.* at 1.

consent for internal or external research; provide a method for consumers to access their genetic data through the services; and provide "clear and prominent methods" for consumers to delete their account, delete their genetic data, and destroy biological samples, with the exception of genetic data being used for active or completed research.[141]

While the FPF best practices highlight important privacy-protection goals, these best practices are not legally enforceable. Companies superficially striving for compliance are not held responsible for failing to protect genetic privacy. For example, 23andMe, Ancestry, Helix, MyHeritage, Habit, and FamilyTreeDNA all initially supported the FPF best practices, but FamilyTreeDNA was notably removed as a supporter after it revealed in January 2019 that it had an agreement with the FBI to search its databases.[142] Additionally, industry self-regulation is likely only achievable where ethical considerations align with every business's end goal—profit maximization.[143] Even though bigger companies such as 23andMe and Ancestry may be more inclined to follow these best practices due to heightened name recognition and the threat of consumer outrage,[144] smaller companies are not subject to that same pressure.[145]

Industry self-regulation has been found to be difficult to maintain in industries outside of DTC genetic testing. In a 2000 study, Professors Andrew A. King and Michael J. Lenox examined the performance of the Chemical Manufacturers Association's Responsible Care Program, which required all members of the trade association to adopt over 100 management practices addressing interaction with the community, facilities management, and interaction with suppliers and customers.[146] Professors King and Lenox's data suggests the program had "fallen victim to

141. *Id.* at 4–8.

142. Press Release, Future of Privacy Forum, Future of Privacy Forum and Leading Genetic Testing Companies Announce Best Practices to Protect Privacy of Consumer Genetic Data (July 31, 2018), https://fpf.org/blog/future-of-privacy-forum-and-leading-genetic-testing-companies-announce-best-practices-to-protect-privacy-of-consumer-genetic-data [https://perma.cc/YQQ4-9JNV].

143. *See* Garner & Kim, *supra* note 105, at 1261; Matthew Piehl, *Regulating Hype and Hope: A Business Ethics Model Approach to Potential Oversight of Direct-to-Consumer Genetic Tests*, 16 MICH. STATE U. J. MED. & L. 59, 82 (2011); *see also* J. Lyn Entrikin, *Family Secrets and Relational Privacy: Protecting Not-So-Personal, Sensitive Information from Public Disclosure*, 74 U. MIA. L. REV. 781, 867 (2020) ("While voluntary guidelines are a step in the right direction, they may not be enough to ensure that consumers are well informed about their rights to control access to their genetic data, including the rights they *expressly waive* . . . .").

144. *See* Eric Ravenscraft, *How to Protect Your DNA Data Before and After Taking an at-Home Test*, N.Y. TIMES (June 12, 2019), https://www.nytimes.com/2019/06/12/smarter-living/how-to-protect-your-dna-data.html [https://perma.cc/2HWX-FW64] (stating the "Big Three" companies, 23andMe, Ancestry, and MyHeritage, generally allow consumers to delete their accounts and genetic data but will retain genetic data to comply with the Clinical Laboratory Improvement Amendments).

145. *See* Hazel & Slobogin, *supra* note 12, at 51 (finding of fifty-five companies with readily accessible privacy policies regarding genetic data, 44% (24 of 55) addressed deletion, and of the 44%, 21% (5 of 24) explicitly allowed deletion of all genetic data, while one company did not allow for deletion at all).

146. Andrew A. King & Michael J. Lenox, *Industry Self-Regulation Without Sanctions: The Chemical Industry's Responsible Care Program*, 43 ACAD. MGMT. J. 698, 699 (2000).

enough opportunism that it include[d] a disproportionate number of poor performers, and its members [did] not improve faster than nonmembers."[147] In a subsequent study of four environmental self-regulatory programs in the chemical, textile, and pulp and paper industries, researchers found the inclusion of sanctioning mechanisms was critical for the functioning of industry self-regulation.[148]

Such studies cut against proponents of industry self-regulation who argue self-regulation can control behavior through informal means, while supporting critics of self-regulation who posit industries lacking sanctioning mechanisms allow bad actors to disguise their poor performances and shirk the real effort required to meet set goals.[149] Notably, the FPF is not a trade association that can monitor and expel members for failing to comply with best practices.[150] The DTC genetic testing industry lacks a well-established trade association like the chemical industry's Chemical Manufacturers Association.[151] While the FPF best practices may outline important privacy-protection goals, enforceable regulatory mechanisms are needed to ensure the application of uniform standards and practices across the industry.

B. The Courts

Given the unenforceability of self-regulatory industry rules, this Note next assesses the current legal framework applicable to DTC genetic testing, beginning with the courts and the idea of a constitutional right to informational privacy. In *Griswold v. Connecticut*, the U.S. Supreme Court found an independent right to privacy in the "penumbras" of the U.S. Constitution.[152] Subsequently in *Whalen v. Roe*, the Court described two different privacy interests, one involving "the individual interest in avoiding disclosure of personal matters, and another [in the] independence in making certain kinds of important decisions."[153] *Whalen* is the first Supreme Court case that articulated some form of a constitutional right to informational privacy,[154] which was later supported in *Nixon v. Administrator of General Services*.[155] However, in *National Aeronautics & Space Administration*

147. *Id.* at 713.

148. Michael J. Lenox & Jennifer Nash, *Industry Self-Regulation and Adverse Selection: A Comparison Across Four Trade Association Programs*, 12 BUS. STRATEGY & ENV'T 343, 344, 354 (2003).

149. King & Lenox, *supra* note 146, at 700–01.

150. FUTURE OF PRIVACY FORUM, *supra* note 137, at 19.

151. King & Lenox, *supra* note 146, at 699 (explaining that the Chemical Manufacturers Association, established in 1872, is the "oldest and most prominent trade association of the U.S. chemical industry").

152. Griswold v. Connecticut, 381 U.S. 479, 484 (1965).

153. Whalen v. Roe, 429 U.S. 589, 599–600 (1977). A constitutional right to information privacy is founded in the Fourteenth Amendment's concept of personal liberty. *Id.* at 598 n.23.

154. *See id.* at 599 & n.25 (citing Justice Brandeis's dissent in *Olmstead v. United States*, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting) in support of "the individual interest in avoiding disclosure of personal matters," where Justice Brandeis characterized "the right to be let alone" as "the right most valued by civilized men").

155. Nixon v. Adm'r of Gen. Servs., 433 U.S. 425, 455–57 (1977) (citing to "the individual interest in avoiding disclosure of personal matters" as articulated in *Whalen*, although ultimately holding

v. Nelson, the Court retreated from reaffirming the right, instead stating that it would "assume for [the purposes of the case] that the Government's challenged inquiries implicate a privacy interest of constitutional significance."[156] The federal circuit courts have since been split on broadly or narrowly interpreting the right.[157]

Despite the Supreme Court's tentative recognition of the need for informational privacy, it is unlikely that a genetic information privacy right applicable to DTC genetic testing can be obtained through the federal courts. Importantly, the right to privacy under the U.S. Constitution is limited to state action.[158] Since DTC genetic testing companies are not governmental actors,[159] they fall outside the purview of the constitutional right to information privacy. Furthermore, the public function exception[160] and the entanglement exception[161] to the state action doctrine likely cannot be applied to DTC genetic testing companies, as these companies are not taking on a governmental role and the government is not involved in encouraging industry conduct.

Consequently, plaintiffs seeking to enforce their privacy interests in the courts have sought to file class action lawsuits, which are now on the rise.[162] However, *Tompkins v. 23andMe, Inc.*—the class action case precipitated by the FDA's 2013 cease-and-desist notification to 23andMe—demonstrates the limitations of contract law in protecting consumers.[163] Even though the lawsuit involved serious class action claims regarding false advertising, unfair competition, and consumer protection,[164] the Ninth Circuit held that the case must proceed to arbitration because 23andMe's arbitration agreement in its Terms of Service was not unconscionable.[165] The case ultimately settled, and class members were given the

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the Presidential Recordings and Materials Preservation Act did not unconstitutionally violate former President Richard M. Nixon's right of privacy).

156. Nat'l Aeronautics & Space Admin. v. Nelson, 562 U.S. 134, 147 (2011).

157. *See* Larry J. Pittman, *The Elusive Constitutional Right to Informational Privacy*, 19 NEV. L.J. 135, 167 (2018).

158. *See, e.g.*, Shelley v. Kraemer, 334 U.S. 1, 13 (1948) ("[T]he action inhibited by the first section of the Fourteenth Amendment is only such action as may fairly be said to be that of the States. The Amendment erects no shield against merely private conduct, however discriminatory or wrongful.").

159. *See id.*

160. There is state action where a private entity exercises powers traditionally exclusively reserved to the state. *See* Jackson v. Metro. Edison Co., 419 U.S. 345, 352 (1974).

161. There is also state action where the government has authorized, encouraged, or facilitated private conduct. *See* Edmonson v. Leesville Concrete Co., 500 U.S. 614, 619–20 (1991).

162. *See* Nancy R. Thomas, Zachary Maldonado & Ani Oganesian, *Privacy Litigation 2020 Year in Review: Data Breach Litigation*, MORRISON FOERSTER (Jan. 4, 2021), https://www.mofo.com/resources/insights/210104-data-breach-litigation-2020.html [https://perma.cc/DP6G-8X4G].

163. *See* Tompkins v. 23andMe, Inc., 840 F.3d 1016, 1033 (9th Cir. 2016).

164. Tompkins v. 23andMe, Inc., No. 5:13-CV-05682-LHK, 2014 WL 2903752, at *3 (N.D. Cal. June 25, 2014), *aff'd*, 840 F.3d 1016 (9th Cir. 2016).

165. *Tompkins*, 840 F.3d at 1033.

choice of receiving $12.50 in cash for each personal genome service purchased or a certificate for forty dollars off a future purchase of a genetic testing kit.[166]

Some scholars have advocated for the use of the courts in addressing genetic-privacy violations by arguing for the use of tort liability for genetic-privacy violations[167] and property rights over genetic information.[168] While these theories may help individuals pursue privacy litigation, they are not likely to help larger groups of people in protecting their genetic privacy. At the outset, privacy litigation plaintiffs trying to sue in federal court may find it difficult to establish an injury-in-fact to support Article III standing.[169] Class certification according to the Federal Rules of Civil Procedure may be challenging to meet,[170] and related case law

166. Stipulation and Agreement of Settlement and Release, Ex. 2 at 1, Davis-Hudson v. 23andMe, Inc., AAA Case No. 74-20-1400-0032 (2017) [hereinafter Stipulation and Agreement]. *See generally* Settlement Approval Order and Final Award, Davis-Hudson v. 23andMe, Inc., AAA Case No. 74-20-1400-0032 (2017).

167. *See* Ifeoma Ajunwa, *Genetic Testing Meets Big Data: Tort and Contract Law Issues*, 75 OHIO ST. L.J. 1225, 1257–61 (2014) (advocating for a tort of genetic-information disclosure); *see also* Benjamin Sundholm, *Strict Liability for Genetic Privacy Violations in the Age of Big Data*, 49 U. MEM. L. REV. 759, 797–98 (2019) (supporting a strict-liability regime that will deter risky behavior while providing compensation to acknowledge wrongs to victims of genetic-privacy violations). *But see* Helen C. Dick, Comment, *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, 171–72 (arguing the tort system is incapable of regulating the DTC genetic testing industry because of procedural difficulties and the technical, yet unsettled, nature of the technology); Garner & Kim, *supra* note 105, at 1234 ("[T]he utility of privacy torts in this area is unclear because there is currently no legal precedent recognizing these torts for consumers' genetic information from DTC-GT companies.").

168. Tufik Y. Shayeb, *You Are What You Own: Reopening the Discussion on Universally Recognizing a Property Right in Genetic Information and Material*, 38 WHITTIER L. REV. 181, 205–07 (2017) (advocating for a property right in genetic materials and information to confer the rights to exclude, use, enjoy, and alienate one's own information); *see* G. Alex Sinha, *A Real-Property Model of Privacy*, 68 DEPAUL L. REV. 567, 588 (2019) ("[P]rivacy rights should be understood as rights of control over the private sphere that resemble rights of control over real property."). *But see* Lothar Determann, *Healthy Data Protection*, 26 MICH. TECH. L. REV. 229, 269 (2020) (rejecting property rights in data because they would not promote innovation or other public goods and would not benefit individuals but would limit free speech, information freedom, science, commerce, and technological progress); Anya E.R. Prince, *Comprehensive Protection of Genetic Information: One Size Privacy or Property Models May Not Fit All*, 79 BROOK. L. REV. 175, 186, 188, 191–92 (2013) (highlighting how courts have expressed distaste for treating human body parts as property, the difficulty that a property interest in genetic data may create dual ownership of information, and the potential for a property interest to hamper research by requiring researchers to follow a chain of title in each piece of genetic data obtained).

169. *See* Spokeo, Inc. v. Robins, 136 S. Ct. 1540, 1548 (2016) ("To establish injury in fact, a plaintiff must show that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" (quoting Lujan v. Defs. of Wildlife, 504 U.S. 555, 560 (1992)); *id.* at 1549 ("Congress' role in identifying and elevating intangible harms does not mean that a plaintiff automatically satisfies the injury-in-fact requirement whenever a statute grants a person a statutory right and purports to authorize that person to sue to vindicate that right.").

170. *See, e.g.*, Cole v. Gene by Gene, Ltd., 735 F. App'x 368, 369–70 (9th Cir. 2018) (affirming the district court's order denying class certification due to the wide variance of damages available under Alaska's Genetic Privacy Act, distinct and individualized issues of the class, limited resources saved through certification, and the absence of pending or duplicative lawsuits).

may impede the impact of class actions.[171] Even if class certification can be met, class action cases can proceed too slowly for plaintiffs.[172] As seen in *Tompkins*, settlements do not sufficiently compensate victims through class action lawsuits: the final settlement term of $12.50 in cash for each purchase of a personal genome service product is likely not adequate given the gravity of the harms alleged.[173] Finally, in the interest of maintaining privacy in the digital age, it would be more effective and efficient to prevent harm than to remedy it in the courts after damage has been done.

C. Agency Regulation

Several federal agencies have jurisdiction to regulate the DTC genetic testing industry.[174] The FDA has jurisdiction under the Food, Drug, and Cosmetic Act of 1976 (FDCA) to regulate genetic tests as medical devices.[175] The Centers for Medicare and Medicaid Services (CMS) has authority under the Clinical Laboratory Improvement Amendments (CLIA) to regulate laboratory testing that is performed on human materials in the United States.[176] Finally, the Federal Trade Commission (FTC) has jurisdiction through the Federal Trade Commission Act to regulate unfair or deceptive trade practices.[177]

In terms of being able to comprehensively regulate DTC genetic companies, each agency has its weaknesses. First, the CMS cannot be a strong regulator for genetic privacy because CLIA standards focus on clinical testing quality.[178] Laboratories that perform high-complexity tests, such as certain Ancestry and

171. *See, e.g.*, Mazza v. Am. Honda Motor Co., 666 F.3d 581, 590, 596 (9th Cir. 2012) (holding the district court abused its discretion in certifying a class under one state's consumer protection law because there were material differences with other state consumer protection laws).

172. Class actions take, on average, between two to three years to resolve, but they can last as long as twenty years, as was the case in the class action suits arising out of the Exxon Valdez oil spill. *How Long Does a Class Action Take?*, CLASSACTION.ORG, https://www.classaction.org/learn/how-long-it-takes [https://perma.cc/L83F-LQNN] (last visited Oct. 24, 2021).

173. *See* Stipulation and Agreement, *supra* note 166.

174. Stephanie Bair, Article, *Direct-to-Consumer Genetic Testing: Learning from the Past and Looking Toward the Future*, 67 FOOD & DRUG L.J. 413, 426–29 (2012).

175. *See* 21 U.S.C. § 321(h)(2) (defining "device" as an article "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals").

176. *See* 42 U.S.C. § 263a (listing requirements regarding the certification of laboratories).

177. 15 U.S.C. § 45(a) (empowering the FTC to prevent entities "from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce").

178. *See* Bair, *supra* note 174, at 431; *Regulation of Genetic Tests*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/about-genomics/policy-issues/Regulation-of-Genetic-Tests [https://perma.cc/LHF4-BBA5] (Sept. 25, 2020).

23andMe tests,[179] must secure certification to be compliant with CLIA.[180] The CMS arguably contributes to the difficulty in protecting genetic privacy because records of these tests must be retained for at least two years.[181] Even though well-known DTC genetic companies such as 23andMe, Ancestry, and MyHeritage are more likely to be protective of consumer data and honor any consumer deletion requests, certain data must still be kept for regulatory compliance since these companies used CLIA-certified laboratories.[182]

Second, the FTC is not a reliable regulatory channel for securing genetic privacy because its role is centered on preventing misleading advertising.[183] For example, the FTC announced enforcement actions in 2014 against GeneLink, Inc., and its former subsidiary for deceptive advertising, where the companies claimed their genetically personalized nutritional supplements could treat diabetes, heart disease, arthritis, insomnia, and other diseases.[184] The FTC also claimed the companies failed to secure the personal information of nearly 30,000 consumers, which included genetic information, Social Security numbers, bank account information, and credit card numbers.[185] As part of the settlements, the companies were required to establish and maintain comprehensive information security programs and submit to biennial security audits.[186] Even though these requirements demonstrate the FTC can regulate some privacy issues, the GeneLink case shows the FTC's regulation must be tied to companies' misrepresentation of their privacy and security practices.[187] Thus, privacy is secondary to the core issue of deceptive advertising.

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179. A search for "Illumina," the maker of 23andMe's DTC genetic tests, *see Genotyping Services for Research*, *supra* note 56, in the CLIA database showed that 23andMe's tests are all considered "high complexity." *CLIA - Clinical Laboratory Improvement Amendments*, FDA, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/results.cfm?start_search=1&Test_System_Name=Illumina&Qualifier=&Analyte_Name=&Document_Number=&Clia_Analyte_Specialty=&Clia_Complexity=&Effective_Date_FROM=&Effective_Date_TO=&Exempt_510k=&SortColumn=ded&pagenum=50 [https://perma.cc/6H84-6PZQ] (Oct. 18, 2021).

180. 42 C.F.R. § 493.25 (2019).

181. *See* 42 C.F.R. § 493.1105 (2019).

182. *See* Ravenscraft, *supra* note 144.

183. *See* Ellen Wright Clayton, Barbara J. Evans, James W. Hazel & Mark A. Rothstein, *The Law of Genetic Privacy: Applications, Implications, and Limitations*, 6 J.L. & BIOSCIENCES 1, 19 (2019) ("A relatively low baseline of protection is provided by the Federal Trade Commission (FTC), which has broad authority to police 'unfair' or 'deceptive' business practices under the century-old Federal Trade Commission Act. Despite this authority, the FTC has rarely taken action against DTC genetic testing companies.").

184. Press Release, Fed. Trade Comm'n, Companies Pitching Genetically Customized Nutritional Supplements Will Drop Misleading Disease Claims (Jan. 7, 2014), https://www.ftc.gov/news-events/press-releases/2014/01/companies-pitching-genetically-customized-nutritional-supplements [https://perma.cc/YB7B-YM46].

185. *Id.*

186. *Id.*

187. *See id.*

Third, the FDA is also not suitable for securing genetic privacy, even though it has had the most interaction with DTC genetic testing companies.[188] Under the FDCA, the FDA would classify a DTC genetic test that is not an ancestry test, low-risk general wellness test, or carrier screening test[189] as either a Class I (low-risk), II (medium-risk), or III (high-risk) medical device; this determines whether a company needs to obtain premarket approval from the FDA before placing a product on the market.[190] DTC genetic tests have historically avoided being classified as Class III devices through the laboratory-developed test exception that encompasses tests developed in-house by the company offering the service.[191] Even as the industry grew, the FDA continued to exercise its "enforcement discretion" regarding laboratory-developed tests, thereby exempting DTC genetic tests from the requirement of premarket approval since at least the early 1990s.[192] It was not until 2010 that the FDA sent out letters to various companies stating that their tests were medical devices that had not been subject to premarket review and approval.[193] Even then, the FDA seems to have relented to the industry by authorizing for marketing many of 23andMe's health-related DTC genetic tests.[194]

The three main agencies currently regulating the DTC genetic testing industry thus do not regulate on a comprehensive level and do not squarely address genetic-privacy concerns. Like the courts, agencies should play an important role in the legal framework governing genetic privacy through enforcement of the law. However, both the courts and regulatory agencies need new and specific directives through legislation to begin directly tackling genetic-privacy issues.

D. Legislation

Having surveyed the drawbacks of regulation through the DTC genetic testing industry, courts, and agencies, legislation remains the most promising pathway to securing better genetic-privacy protections for consumers. Current federal and traditional state laws do not adequately protect against the loss of autonomy over genetic information. To begin with, current federal data-protection laws are industry

188. *See supra* Section I.D.

189. The FDA recognizes six types of DTC genetic tests. *Direct-to-Consumer Tests*, *supra* note 2. Ancestry tests that explore family history and low-risk general wellness tests that predict traits like athletic ability are not regulated by the FDA, and carrier screening tests identifying genes that could be passed on to future children are exempt from FDA premarket review. *Id.* The other three types of tests are substantially health-related and regulated by the FDA: genetic health risk tests calculate an individual's risk for certain medical diseases or conditions, pharmacogenetic tests determine an individual's reaction to drugs, and cancer predisposition tests gauge an individual's risk for getting certain kinds of cancer. *Id.*

190. 21 U.S.C. § 360c(a)(1).

191. Bair, *supra* note 174, at 429.

192. *See* Jessica Elizabeth Palmer, *Genetic Gatekeepers: Regulating Direct-to-Consumer Genomic Services in an Era of Participatory Medicine*, 67 FOOD & DRUG L.J. 475, 500 (2012).

193. *See supra* Section I.D.

194. *Id.*

specific.[195] Among these laws, there are two federal laws that directly cover genetic information: the Health Insurance Portability and Accountability Act (HIPAA)[196] and the Genetic Information Nondiscrimination Act (GINA).[197] HIPAA's Privacy Rule regulates the use and disclosure of protected health information for treatment, payment, or health-care operations by certain covered entities and business associates.[198] Unfortunately, HIPAA does not cover DTC genetic testing companies because they are neither covered entities nor business associates as defined under the Act.[199]

On the other hand, GINA is an antidiscrimination statute that is split into two parts.[200] Title I prohibits genetic discrimination in health insurance.[201] Under Title I, group health plans and a health-insurance issuer in connection with a group health plan are prohibited from establishing rules for eligibility or adjusting premiums on the basis of genetic information, requiring genetic testing, and collecting genetic information.[202] Title II prohibits employment discrimination on the basis of genetic information.[203] Under Title II, employers are prohibited from discriminating against or segregating employees based on genetic information, and they also cannot require genetic information of their employees.[204] Scholars have pointed out GINA's main drawback is its limitations to the health insurance and employment contexts.[205]

Current federal laws relating to genetic privacy are thus limited by their definitions and scope. Furthermore, Congress has historically been slow to pass genetic-privacy legislation, as the first version of GINA was introduced in 1995,

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195. Michael L. Rustad & Thomas H. Koenig, *Towards A Global Data Privacy Standard*, 71 FLA. L. REV. 365, 381 (2019).

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

197. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (codified as amended in scattered sections of 29 and 42 U.S.C.).

198. *See* 45 C.F.R. § 164.506 (2019) (HIPAA Privacy Rule); *see also* 45 C.F.R. § 160.103 (2019) ("A covered entity may be a business associate of another covered entity.").

199. *See* 45 C.F.R. § 160.103 (2019) (defining "covered entity"); *id.* (defining "business associate").

200. *See* 122 Stat. at 883, 905.

201. 29 U.S.C. § 1182.

202. *Id.*

203. 42 U.S.C. § 2000ff-1.

204. 42 U.S.C. § 2000ff-1(a)–(b).

205. *See* Bradley A. Areheart & Jessica L. Roberts, *GINA, Big Data, and the Future of Employee Privacy*, 128 YALE L.J. 710, 725 (2019) ("From a practical perspective, GINA's limited coverage means that a significant portion of genetic-privacy invasions and discrimination goes unregulated. In most states, for example, it is perfectly legal for banks, landlords, schools and even life insurers to make decisions based on genetic information."); Leslie E. Wolf, Erin Fuse Brown, Ryan Kerr, Genevieve Razick, Gregory Tanner, Brett Duvall, Sakinah Jones, Jack Brackney & Tatiana Posada, *The Web of Legal Protections for Participants in Genomic Research*, 29 HEALTH MATRIX 1, 36 (2019) ("GINA's protections contain notable gaps. First, the employer provisions of GINA only apply to employers with 15 or more employees . . . . Second, GINA's insurance provisions only apply to health insurers and do not apply to other forms of insurance . . . .").

twelve years before it passed in the House of Representatives.[206] The most recent effort targeting DTC genetic testing is S. 24, titled the "Protecting Personal Health Data Act," which is a Senate bill introduced in January 2021 aimed at regulating "consumer devices, services, applications, and software" including DTC genetic testing services.[207] This bill has only been introduced in the 117th Congress (2021–2022); an identical Senate version and a separate House bill both failed to progress past their introductions during the 116th Congress (2019–2020).[208] These examples demonstrate the difficulty in passing federal genetic-privacy legislation.

While genetic-privacy bills have languished in Congress, states have enacted a variety of statutes that address the issue. There are three traditional approaches to creating state genetic-privacy laws.[209] First, genetic notice or informed-consent laws impose restrictions on initial collection activities such as collecting DNA samples, analyzing DNA samples, and retaining data from the initial analysis.[210] Second, genetic antidiscrimination laws restrict the ability of insurers and employers to require genetic testing or information or make decisions based on genetic information.[211] Third, genetic redisclosure laws require companies to obtain consent from individuals before their genetic information is shared with a third party or confer explicit ownership rights to individuals over their data.[212] Notably, one study found that state approaches giving users control over redisclosure encouraged genetic testing, while notice or informed-consent models deterred genetic testing.[213]

The traditional state approaches cannot adequately remedy situations where genetic information ends up in the hands of a third party without consumers' informed consent or where informed consent is illusory. In other words, comprehensive genetic-privacy protection requires additional rights that promote consumers' direct autonomy over their genetic information. Even though both federal and state genetic-privacy laws fall short on this front, there has been

206. *See Timeline of the Genetic Information Nondiscrimination Act (GINA)*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/about-genomics/policy-issues/timeline-genetic-information-nondiscrimination-act-GINA [https://perma.cc/US49-RFNS] (Sept. 16, 2020).

207. Protecting Personal Health Data Act, S. 24, 117th Cong. § 4 (2021).

208. *See S.24 - Protecting Personal Health Data Act*, CONGRESS.GOV, https://www.congress.gov/bill/117th-congress/senate-bill/24 [https://web.archive.org/web/20210430023123/https://www.congress.gov/bill/117th-congress/senate-bill/24] (last visited Oct. 24, 2021); *S.1842 - Protecting Personal Health Data Act*, CONGRESS.GOV, https://www.congress.gov/bill/116th-congress/senate-bill/1842 [https://web.archive.org/web/20210605173633/https://www.congress.gov/bill/116th-congress/senate-bill/1842] (last visited Oct. 24, 2021); *H.R.2155 - Genetic Information Privacy Act of 2019*, CONGRESS.GOV, https://www.congress.gov/bill/116th-congress/house-bill/2155 [https://web.archive.org/web/20201211184943/https://www.congress.gov/bill/116th-congress/house-bill/2155] (last visited Oct. 24, 2021).

209. *See* Amalia R. Miller & Catherine Tucker, *Privacy Protection, Personalized Medicine, and Genetic Testing*, 64 MGMT. SCI. 4648, 4653, 4653 tbl.2 (2018).

210. *Id.* at 4653 tbl.2.

211. *Id.*

212. *Id.*

213. *Id.* at 4665.

promising movement towards general data-privacy laws that give consumers control over their data, especially at the state level.[214] For example, general data-privacy legislation in California, the CCPA[215] and the recently passed CPRA,[216] may rise to the challenge of protecting genetic privacy and serve as model legislation for other states and the federal government.

1. The CCPA

The CCPA has been called the "most stringent state regulation addressing data privacy in the United States."[217] Passed in 2018 with overwhelming support in both California's State Assembly and Senate,[218] the CCPA returns control over personal information to consumers from businesses that collect personal information by providing new privacy rights, including (1) the right to know what personal information is collected, used, and shared; (2) the right to delete collected personal information, with exceptions;[219] (3) the right to opt out of the sale of personal information; and (4) the right to nondiscrimination for exercising privacy rights.[220] These rights only apply to California residents[221] and only regulate for-profit businesses that do business in California and (1) have annual gross revenues of over twenty-five million dollars; (2) buy, receive, sell, or share for commercial purposes the personal information of fifty thousand or more California residents, households, or devices; or (3) derive fifty percent or more of their annual revenue from selling California residents' personal information.[222]

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214. *See 2020 Consumer Data Privacy Legislation*, NAT'L CONF. STATE LEGISLATURES (Jan. 17, 2021), https://www.ncsl.org/research/telecommunications-and-information-technology/2020-consumer-data-privacy-legislation637290470.aspx [https://perma.cc/A7TU-D6CD]. As for federal general data-privacy legislation, some argue that the likelihood of a federal law passing is increasing due to bipartisan and industry support. *See, e.g.*, Mabel Crescioni & Tara Sklar, *The Research Exemption Carve Out: Understanding Research Participants Rights Under GDPR and U.S. Data Privacy Laws*, 60 JURIMETRICS J. 125, 136 (2020).

215. CAL. CIV. CODE §§ 1798.100–.199 (2018).

216. *See* Aaron Holmes, *California Just Passed a Major Privacy Law that Will Make It Harder for Facebook and Google to Track People and Gather Data*, BUS. INSIDER (Nov. 4, 2020, 10:34 AM), https://www.businessinsider.com/prop-24-privacy-california-data-tracking-facebook-google-2020-11 [https://perma.cc/B293-4QQ8].

217. Heather Whitehead, *The Pandemic, Proposed Federal Privacy Regulation and the CCPA*, JDSUPRA (Oct. 29, 2020), https://www.jdsupra.com/legalnews/the-pandemic-proposed-federal-privacy-52186 [https://perma.cc/D53U-PR7H].

218. *See AB-375 Privacy: Personal Information: Businesses.*, CAL. LEGIS. INFO., https://leginfo.legislature.ca.gov/faces/billVotesClient.xhtml?bill_id=201720180AB375 [https://perma.cc/6XUM-KYNE] (last visited Oct. 24, 2021). For a brief history of the CCPA and subsequent amendments, see *California Consumer Privacy Act Basics*, PRIV. RTS. CLEARINGHOUSE (Jan. 6, 2020), https://privacyrights.org/resources/california-consumer-privacy-act-basics#:~:text=The%20CCPA%20began%20as%20a,Bill%20375%20(AB%20375).

219. *See* discussion *infra* Sections IV.B.2.b, IV.B.2.c.

220. CAL. CIV. CODE § 1798.100, .105, .110, .115, .120, .125.

221. § 1798.140(g).

222. § 1798.140(c)(1).

Personal information is defined as "information that identifies, relates to, describes, is reasonably capable of being associated with, or could reasonably be linked, directly or indirectly, with a particular consumer or household."[223] Personal information includes biometric information[224] that is further defined as "an individual's physiological, biological, or behavioral characteristics, including an individual's deoxyribonucleic acid (DNA), that can be used, singly or in combination with each other or with other identifying data, to establish individual identity."[225] Criticisms of the CCPA include that it does not separately define or categorize "sensitive data" and does not provide special rules for collecting and sharing biometric data.[226] However, the passing of the CPRA cures many of the supposed faults of the CCPA.[227]

2. The CPRA

The CPRA, which will become operative on January 1, 2023,[228] overhauls much of the CCPA that is potentially applicable to genetic information. First, the CPRA establishes a new category of "sensitive personal information" that expressly includes a consumer's genetic data.[229] It also changes what businesses are to be regulated to those (1) with annual gross revenues of over twenty-five million dollars; (2) that buy, sell, or share the personal information of one hundred thousand or more consumers or households; or (3) that derive fifty percent or more of their annual revenue from selling or sharing consumers' personal information.[230] The CPRA builds upon the right to delete in the CCPA by requiring businesses to notify service providers, contractors, and third parties to whom the businesses have sold or shared personal information to delete consumers' personal information from their records upon receipt of a verifiable consumer request.[231] The CPRA also contains a new privacy right to limit the use and disclosure of sensitive personal information.[232]

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223. § 1798.140(o)(1).

224. § 1798.140(o)(1)(E).

225. § 1798.140(b).

226. *See, e.g.*, DATAGUIDANCE & FUTURE OF PRIV. F., COMPARING PRIVACY LAWS: GDPR V. CCPA 15 (2018), https://fpf.org/wp-content/uploads/2018/11/GDPR_CCPA_Comparison-Guide.pdf [https://perma.cc/VXY9-PJW3].

227. *See* Brian H. Lam, *California Privacy Rights Act Passes - Dramatically Altering the CCPA*, NAT'L L. REV. (Nov. 6, 2020), https://www.natlawreview.com/article/california-privacy-rights-act-passes-dramatically-altering-ccpa [https://perma.cc/BN9B-BE6P].

228. California Privacy Rights Act of 2020, sec. 31(a), 2020 Cal. Legis. Serv. Prop. 24 (amending portions of CAL. CIV. CODE § 1798.100–.199).

229. *See* sec. 14, § 1798.140(ae)(1)(F).

230. § 1798.140(d)(1). Subdivision A clarified the time period for determining annual gross revenue; subdivision B eliminated the requirement that the buying, selling, or sharing of personal information be for commercial purposes but increased the threshold number of consumers or households from 50,000 to 100,000; and subdivision C added the sharing of personal information where the original CCPA only specified the selling of personal information. *Id.*

231. Sec. 5, § 1798.105(c).

232. Sec. 10, § 1798.121(a).

Businesses that control the collection of personal information must inform consumers as to the length of time of retention of the personal information and are prohibited from retaining it for longer than is reasonably necessary for the original disclosed purpose of collection.[233] Originally in the CCPA,[234] there is also a private right of action in the CPRA that allows consumers whose nonencrypted or nonredacted personal information, email addresses and passwords, or security questions and answers were compromised to sue businesses for damages, injunctive relief, or declaratory relief.[235] Finally, the CPRA establishes the California Privacy Protection Agency, which will perform administrative enforcement for privacy violations.[236] The revenue from administrative fines will be deposited in the Consumer Privacy Fund to offset costs incurred by state courts, the Attorney General, and the California Privacy Protection Agency.[237]

The CPRA builds upon the data-privacy framework established in the CCPA and appears to be a promising and comprehensive legislation that is directly applicable to genetic privacy. It may very well become a framework that will inspire other states, or even Congress, in drafting future data-privacy legislation. However, closer analysis is required to identify areas appropriate for regulation in the DTC genetic testing context to ensure genetic privacy is adequately protected, while not stifling legitimate governmental and business interests.

IV. REGAINING AUTONOMY OVER GENETIC INFORMATION

Part III highlighted how the current legal framework inadequately remedies the loss of individual autonomy over genetic information, with the exception that the CCPA and the CPRA may bring much needed genetic-privacy protection. Part IV first cautions against a rushed federal solution given recent legislative developments in California. Part IV then recommends ways to reestablish consumer autonomy over genetic information under the CPRA, highlights the importance of a right to delete, and discusses limitations of such a right.

A. Caution Against Rushing to a Federal Solution

Scholars and reporters have advocated for a federal law governing genetic privacy or data privacy in general.[238] The primary downside of state legislation is the

233. Sec. 4, § 1798.100(a)(3).

234. *See* CAL. CIV. CODE § 1798.150 (2018).

235. California Privacy Rights Act of 2020, sec. 16, § 1798.150(a).

236. Sec. 24, § 1798.199.10.

237. Sec. 17, § 1798.155. There is a maximum fine of $2,500 for each violation and a maximum fine of $7,500 for each intentional violation or violation involving the personal information of a consumer whom the business actually knows is under 16 years of age.

238. *See, e.g.*, Clayton et al., *supra* note 183, at 32 ("Despite repeated calls from legal scholars and government advisory committees for increased oversight . . . no comprehensive federal laws currently prohibit [surreptitious testing]."); Crescioni & Sklar, *supra* note 214, at 133; Bastien Inzaurralde, *The Technology 202: Consumers Advocates Want Washington to Tackle 'Wild West' of DNA Test Kits*, WASH. POST (Mar. 1, 2019), https://www.washingtonpost.com/news/powerpost/paloma/the-

creation of a "patchwork" system of laws.[239] The variety of state laws means different citizens' genetic information will be more or less protected based on which state they live in, while also discouraging large, multi-state public genomic research.[240] This suggests a broader federal law applicable to all states would be the most ideal in order to protect genetic privacy and autonomy across U.S. jurisdictions.

However, with the passing of both the CCPA and CPRA in California, there may be reason for pause. First, states have often been called the "laboratories of democracy," providing different solutions to common problems without affecting the rest of the country.[241] The CCPA, widely considered to be the most stringent state privacy law in the United States, and the CPRA, which builds upon the CCPA,[242] represent such an opportunity. How the CCPA and CPRA play out in the next couple of years will allow legislators to assess the pros and cons of CCPA- or CPRA-like privacy laws, including how they interact with key players such as companies, regulators, and consumers, and whether consumer autonomy over privacy is adequately protected. Further observation will allow future state laws, and an eventual federal data-privacy law, to be better tailored to the contexts in which the laws will govern.

Second, there is a cautionary reason for not jumping directly to federal law as the solution. Any federal law may preempt state law where "Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose."[243] Currently, various federal data-privacy proposals have failed to agree in three key areas, one being whether to preempt state privacy laws, the others being which federal agency would have enforcement power and whether to provide a private right of action.[244] A weak federal law that inadequately protects data privacy, including genetic privacy, and preempts strong state laws would be more of a detriment to consumer data privacy and autonomy. Consequently, proponents of federal data-privacy protection should heavily scrutinize various federal proposals and either support a federal law as the "floor" for protection without preemption

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technology-202/2019/03/01/the-technology-202-consumers-advocates-want-washington-to-tackle-wild-west-of-dna-test-kits/5c7828dc1b326b2d177d5f98 [https://perma.cc/DT99-G3BT].

239. *See* Clayton et al., *supra* note 183, at 32; Gostin & Hodge, *supra* note 103, at 45.

240. *See* John M. Conley, Adam K. Doerr & Daniel B. Vorhaus, *Enabling Responsible Public Genomics*, 20 HEALTH MATRIX 325, 369 (2010).

241. *See* New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

242. *See* Anna Mercado Clark & Mario Fadi Ayoub, *California Law Expands the California Consumer Privacy Act*, LEXOLOGY (Nov. 9, 2020), https://www.lexology.com/library/detail.aspx?g=0e0e4762-efec-4942-a87b-483babf1d45e [https://perma.cc/EL2H-RXY7].

243. Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992).

244. JONATHAN M. GAFFNEY, CONG. RSCH. SERV., LSB10441, WATCHING THE WATCHERS: A COMPARISON OF PRIVACY BILLS IN THE 116TH CONGRESS 1 (2020), https://crsreports.congress.gov/product/pdf/LSB/LSB10441 [https://web.archive.org/web/20210615100116/https://crsreports.congress.gov/product/pdf/LSB/LSB10441].

of state law or a comprehensive federal solution where preemption would be less of an issue.[245]

Third, California holds substantial influence over the rest of the country, and the CCPA and CPRA may have far-reaching effects beyond the borders of the state.[246] California has a $3.1 trillion economy, which would be the fifth largest in the world if it were a country, ranking between Germany and the United Kingdom.[247] Many of the big-data companies subject to the CCPA and CPRA, including 23andMe, are located in Silicon Valley, California.[248] These companies may find it easier to comply with the CCPA and CPRA and extend compliance across their platforms no matter where they do business, as it is more challenging to comply with potentially fifty different state laws than one stringent state law.[249] California also has a notable track record of influencing lawmakers in other states on topics ranging from the environment[250] to the minimum wage.[251] Therefore, strong privacy legislation passed in California holds the promise of not only helping protect others in different states but also serving as model legislation for other states and the federal government to follow.

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245. California Attorney General Xavier Becerra has advocated for the former option. Letter from Xavier Becerra, Att'y Gen., State of California, to Roger Wicker, Chairman, U.S. Senate Comm. on Com., Sci., & Transp., Maria Cantwell, Ranking Member, U.S. Senate Comm. on Com., Sci., & Transp., Frank Pallone, Jr., Chairman, U.S. House of Representatives Comm. on Energy & Com. & Greg Walden, Ranking Member, U.S. House of Representatives Comm. on Energy & Com. (Feb. 25, 2020), https://oag.ca.gov/system/files/attachments/press-docs/Letter%20to%20Congress%20on%20CCPA%20preemption.pdf [https://perma.cc/ZH2W-8RKV].

246. Maryam Casbarro, Monder Khoury & Rachel Marmor, *"Copycat CCPA" Bills Introduced in States Across Country*, JDSUPRA (Feb. 8, 2019), https://www.jdsupra.com/legalnews/copycat-ccpa-bills-introduced-in-states-20533 [https://perma.cc/2Q4C-FBLE].

247. *California*, FORBES, https://www.forbes.com/places/ca/?sh=6d52b81f3fef [https://perma.cc/4NDF-B92G] (Dec. 2019).

248. *See, e.g.*, *23andMe Inc*, BLOOMBERG, https://www.bloomberg.com/profile/company/8142214Z:US [https://perma.cc/V9JF-CM59] (last visited Oct. 24, 2021) (stating headquarters are in Mountain View, California).

249. *See* Yu Lee, *Three Ways Consumer Data Privacy Will Evolve*, FORBES (Aug. 10, 2020, 7:40 AM), https://www.forbes.com/sites/forbestechcouncil/2020/08/10/three-ways-consumer-data-privacy-will-evolve/?sh=17ab724f7629 [http://web.archive.org/web/20211020053948/https://www.forbes.com/sites/forbestechcouncil/2020/08/10/three-ways-consumer-data-privacy-will-evolve/?sh=17ab724f7629].

250. Dan Jacobson, *California Calls for All New Cars to Be Zero Emission by 2035, the State's Latest Bold Action on Climate*, ENV'T AM. (Oct. 6, 2020), https://environmentamerica.org/blogs/environment-america-blog/ame/california-calls-all-new-cars-be-zero-emission-2035-state%E2%80%99s [https://perma.cc/S5RY-EAJD] ("Policies in place in other states make it more likely that they will follow California's lead. Twelve other states, plus Washington, D.C., have adopted Clean Car Standards based on California's.").

251. Natalie Sherman, *How California Is Changing the US*, BBC (Oct. 16, 2018), https://www.bbc.com/news/business-45767736 [https://perma.cc/6P6G-UPN6] ("In recent years, [California] has passed a slew of progressive laws concerning everything from marijuana to the minimum wage, inspiring lawmakers in other states.").

B. Addressing the Erosion of Autonomy

The CCPA and CPRA framework likely can be used to adequately protect genetic privacy, provided regulations are tailored to address the loss of consumer autonomy through electronic agreements, data collection, and use. The following recommendations regarding the use of the right to delete[252] seek to address these issues. If regulations do not incorporate rules tailored to the genetic context, a separate genetic-privacy statute for DTC genetic testing companies may be needed.

1. Electronic Agreements: The Fiction of Informed Consent

The majority of personal genetic testing companies' electronic agreements do not provide consumers with information regarding disclosure of their information to third parties or how their biospecimens or data may be used in the future.[253] There has also been a shift of the type of consent employed by DTC genetic testing companies from the traditional model of consent in genomic research (where a participant agrees to participate in one specified study) to broad consent (where a participant agrees to whatever future research the company may conduct).[254] Informed consent represents "the intersection between the right of personal autonomy (to make intimate decisions about one's body or interpersonal relationships) and the right of informational privacy (to regulate both the subject's access to relevant information and its disclosure to third parties)."[255]

The illusory nature of consumer informed consent is an issue throughout the digital realm.[256] In the DTC genetic testing context, the sole use of

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252. A similar concept, the right to be forgotten, originated from French law that allows a former convict who has served her sentence to block the publication of facts of her conviction and incarceration. Jeffrey Rosen, *The Right to Be Forgotten*, 64 STAN. L. REV. ONLINE 88, 88 (2012). In 2012, the European Commission recognized the right to be forgotten in its proposal of the Global Data Protection Regulation (GDPR). Michael L. Rustad & Sanna Kulevska, *Reconceptualizing the Right to Be Forgotten to Enable Transatlantic Data Flow*, 28 HARV. J.L. & TECH. 349, 366–67 (2015). The right to delete has been noted as a "subtly important but different concept from the right to be forgotten." Grace Park, Note, *The Changing Wind of Data Privacy Law: A Comparative Study of the European Union's General Data Protection Regulation and the 2018 California Consumer Privacy Act*, 10 U.C. IRVINE L. REV. 1455, 1481 (2020) (citing PAUL BERNAL, INTERNET PRIVACY RIGHTS: RIGHTS TO PROTECT AUTONOMY 38 (2014)). Properly applied, the right to delete focuses on the right to control data and does not infringe upon the freedom of expression. *Id.* As such, a right to delete is more likely to be palatable to U.S. lawmakers, as scholars have noted the vast differences between the European and U.S. socio-legal contexts, including a difference in the value placed on securing the freedom of expression. *See, e.g.*, Robert Kirk Walker, Note, *The Right to Be Forgotten*, 64 HASTINGS L.J. 257, 270–72 (2012).

253. Valerie Gutmann Koch & Kelly Todd, *Research Revolution or Status Quo?: The New Common Rule and Research Arising from Direct-to-Consumer Genetic Testing*, 56 HOUS. L. REV. 81, 114 (2018); *see also* Hazel & Slobogin, *supra* note 12, at 48.

254. Koch & Todd, *supra* note 253, at 115.

255. Entrikin, *supra* note 143, at 862.

256. *See, e.g.*, Allyson W. Haynes, *Online Privacy Policies: Contracting Away Control Over Personal Information?*, 111 PENN STATE L. REV. 587, 610 (2007) ("The end-result of ubiquitous privacy policies should be an increase in the actual privacy of consumers' personal information. However, scholars note that the result of the disclosure approach that has developed seems instead to be the exact

informed-consent models inadequately protects genetic privacy. As one scholar notes, "[t]he problem with notice and choice models is that they create incentives for companies to hide the risks in their data practices though manipulative design, vague abstractions, and complex words as the companies also shift risk onto data subjects."[257] Companies "decide the kind of boxes people get to check, buttons they press, switches they activate and deactivate, and other settings they get to fiddle with," which amounts to a false sense of control by presenting limited choices as "more options" for users.[258] Studies showing that very few Americans read online terms of service further indicate informed consent is a fiction in the digital and social-media era.[259]

Professor Anya E. R. Prince has argued electronic agreements need to include information about the risks and benefits of current and potential future research, since it is impractical to require new informed consent for every subsequent research endeavor.[260] Additionally, others have called for the implementation of "something more robust than click-through forms,"[261] such as a web-based, interactive computer program that educates consumers on a specific subject matter while preventing "information overload,"[262] or dynamic consent, a two-way, ongoing communication between researcher and research participant.[263] While innovative informed-consent models could improve how informed consumers are,[264] they still do not sufficiently address the loss of autonomy over genetic

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opposite: more 'the appearance of privacy' than the reality."); Nancy S. Kim, *Clicking and Cringing*, 86 OR. L. REV. 797, 810–14 (2007) (describing the difficulty of applying contract law in favor of consumers regarding non-negotiated software licenses); MacLean, *supra* note 128 (arguing that clickwrap agreements are adhesion contracts).

257. Woodrow Hartzog & Neil Richards, *Privacy's Constitutional Moment and the Limits of Data Protection*, 61 B.C. L. REV. 1687, 1734 (2020).

258. *Id.* at 1735.

259. *See* Jonathan A. Obar & Anne Oeldorf-Hirsch, *The Biggest Lie on the Internet: Ignoring the Privacy Policies and Terms of Service Policies of Social Networking Services*, 23 INFO. COMMC'N & SOC'Y 128, 134, 137 fig.2, 138 (2020) (showing 97% and 93% of research participants agreed to a fictitious company's privacy policies and terms of service, respectively, despite only spending less than one minute reading either, thus failing to catch the researchers' "gotcha" clauses such as users' having to assign their first-born children as the property of the fictitious company); *see also* AUXIER ET AL., *supra* note 113, at 10 ("[O]ne-in-five of adults overall say they always (9%) or often (13%) read [privacy] policies. Some 38% of U.S. adults maintain they sometimes read such policies, and 36% say they never read a company's privacy policy before agreeing to it.").

260. Prince, *supra* note 168, at 218–19.

261. Angela L. Morrison, Note, *A Research Revolution: Genetic Testing Consumers Become Research (and Privacy) Guinea Pigs*, 9 J. ON TELECOMM. & HIGH TECH. L. 573, 604 (2011).

262. Deepthy Kishore, Comment, *Test at Your Own Risk: Your Genetic Report Card and the Direct-to-Consumer Duty to Secure Informed Consent*, 59 EMORY L.J. 1553, 1595 (2010).

263. Tara Sklar & Mabel Crescioni, *Research Participants' Rights to Data Protection in the Era of Open Science*, 69 DEPAUL L. REV. 699, 717 (2020).

264. *See* Rainer Böhme & Stefan Köpsell, *Trained to Accept? A Field Experiment on Consent Dialogs*, *in* PROCEEDINGS OF THE 2010 CHI CONFERENCE ON HUMAN FACTORS IN COMPUTING SYSTEMS 2404 (2010), https://dl.acm.org/doi/pdf/10.1145/1753326.1753689 [https://perma.cc/E32G-BNDZ] (finding button text most influential, with labels resembling an end user license agreement such as "I accept" or "I decline" receiving higher participation rates than those

information after consent has been given. The CCPA and CPRA seek to address this issue through new privacy rights, of which the right to delete deserves closer analysis as a mechanism for consumers to directly manage their genetic data beyond the initial signature on an electronic agreement.

2. Data Collection and Use: The Right to Delete

The CPRA's amendment to California Civil Code section 1798.105 provides Californians with a right to delete that expands upon the original version from the CCPA.[265] Under the right to delete, consumers "shall have the right to request that a business delete any personal information about the consumer which the business has collected from the consumer."[266] A business that receives a "verifiable consumer request" must delete the consumer's personal information from its records and notify any service providers, contractors, and third parties to delete the consumer's personal information, unless deletion would be "impossible or involves disproportionate effort."[267]

The right to delete is not absolute: a business, service provider, or contractor is not required to comply with a consumer's deletion request where it is "reasonably necessary" for the entity to maintain the consumer's personal information to meet certain exceptions.[268] The exceptions most clearly addressing company and third party data collection and use are those involving compliance with the California Electronic Communications Privacy Act (CalECPA) and engagement in public or peer-reviewed research.[269] Below are recommended parameters for the right to delete and each of these exceptions.

a. The Right to Delete in Practice

There are three considerations for a deletion request to be successfully processed under the California framework.[270] The first consideration is what entities

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indicating real choice such as "I take part" or "I do not take part," indicating that design of a consent form may influence user agreement or disagreement).

265. California Privacy Rights Act of 2020, sec. 5, § 1798.105, 2020 Cal. Legis. Serv. Prop. 24.

266. § 1798.105(a).

267. § 1798.105(c).

268. § 1798.105(d).

269. *Id.*

270. The CCPA is the first of its kind in the U.S. David Kessler & Anna Rudawski, *CCPA Extends "Right to Deletion" to California Residents*, NORTON ROSE FULBRIGHT (Sept. 27, 2018), https://www.dataprotectionreport.com/2018/09/ccpa-extends-right-to-deletion-to-california-residents/#:~:text=The%20law%2C%20the%20first%20of,is%20not%20a%20new%20right [https://perma.cc/757D-MQXN]. Even though the European and U.S. socio-legal contexts are different, California's right to delete has the potential to become a heavily used tool. *See* James Doubek, *Google Has Received 650,000 'Right to Be Forgotten' Requests Since 2014*, NPR (Feb. 28, 2018, 5:44 AM), https://www.npr.org/sections/thetwo-way/2018/02/28/589411543/google-received-650-000-right-to-be-forgotten-requests-since-2014#:~:text=Live%20Sessions-,Google%20Has%20Received%20650%2C000%20%27Right%20To%20Be%20Forgotten%27%20Requests%20Since,million%20URLs%20from%20search%20results [https://perma.cc/Q4UP-6BTB].

need to comply with a consumer's deletion request.[271] The CPRA envisions a two-phase framework for deletion, wherein the consumer first requests deletion from a business, and the business in turn notifies and directs service providers, contractors, and third parties to delete the consumer's personal information.[272] This is a promising framework that addresses the call for data collectors to act as information fiduciaries who should be required to have the duties of loyalty, care, and confidentiality towards their consumers.[273] Companies should not induce trust in their users to obtain information and then profit from the use of that information.[274]

One issue with this framework lies in the scope of covered entities. Under both the CCPA and CPRA, businesses that need to be regulated are defined by their annual gross revenue, the number of consumers or households they acquire or transmit personal information from, and whether they derive fifty percent or more of their annual revenue from transmitting personal information.[275] The CCPA and CPRA thus try to exclude small businesses from coverage, with the CPRA incorporating more small businesses by increasing the "number of consumers or households" prong.[276] To uniformly protect genetic privacy, the covered businesses under the CCPA and CPRA must include all small businesses.

The second consideration for successfully processing a deletion request is who should be able to make the request. Peter Fleischer, Google's Global Privacy Counsel, has commented that there are three common deletion scenarios on the internet, in order of increasing controversy: (1) an individual posts something online and later wants to delete it; (2) an individual posts something online and another person copies it and reposts it elsewhere that the individual wants deleted; or (3) another person posts something about an individual, who wants the post deleted.[277] The first and third deletion scenarios can be analogized to the DTC genetic testing context. Like the first deletion scenario, a consumer may send her

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271. California Privacy Rights Act of 2020 § 1798.105(c).

272. § 1798.105(c)(1), (3).

273. *See* Lindsey Barrett, *Confiding in Con Men: U.S. Privacy Law, the GDPR, and Information Fiduciaries*, 42 SEATTLE U. L. REV. 1057, 1094–95 (2019); *see also* Hartzog & Richards, *supra* note 257, at 1746 ("[T]he trust rules we are calling for have a broader application beyond the formalized framework of information fiduciaries. . . . [T]rustworthy entities have four features that the law should promote—discretion, honesty, protection, and loyalty.").

274. Barrett, *supra* note 273 (citing Jack M. Balkin, *Fixing Social Media's Grand Bargain* 1, 13 (Hoover Inst. Working Grp. on Nat'l Sec., Tech., & Law, Aegis Series Paper No. 1814, 2018), https://www.hoover.org/sites/default/files/research/docs/balkin_webreadypdf.pdf [https://perma.cc/QN2U-W94U].).

275. CAL. CIV. CODE § 1798.140(c)(1) (2018); California Privacy Rights Act of 2020, sec. 14, § 1798.140(d)(1) (modifying the CCPA language).

276. *See* Elizabeth (Liz) Harding & Alex Polishuk, *CPRA – What This Means for Your Business*, NAT'L L. REV. (Nov. 9, 2020), https://www.natlawreview.com/article/cpra-what-means-your-business [https://perma.cc/X4Y5-ZJQ9].

277. Peter Fleischer, *Foggy Thinking About the Right to Oblivion*, PETER FLEISCHER: PRIVACY. . .? (Mar. 9, 2011), http://peterfleischer.blogspot.com/2011/03/foggy-thinking-about-right-to-oblivion.html [https://perma.cc/8TZR-XDPN].

DNA to a company and later want to delete it. Like the third deletion scenario, either another person surreptitiously takes an individual's DNA and sends it to a company for testing, or a relative of a third-party genetic database user may want to delete the user's DNA.

It is clear from the language of the CCPA and CPRA that a consumer who procured the services of a business has the right to request deletion.[278] As noted by Fleischer and other scholars, the first deletion scenario where an internet user wants to delete her own posts—or a consumer wants to delete her own genetic information from a company's database—is the least controversial deletion scenario.[279] In the case of the third deletion scenario, which can be likened to situations involving surreptitious testing or the uploading of data to a third-party genetic database, deletion is more controversial.[280] Based on the prevalence of surreptitious testing and its nonconsensual nature,[281] victims of surreptitious testing should be able to request deletion from DTC genetic testing companies. Some scholars have argued to make nonconsensual genetic collection and testing a crime, and some states have passed laws addressing the issue.[282] However, there should also be a noncriminal avenue to address surreptitious testing for those who do not want to press charges.

According to current CCPA regulations, a consumer that does not have access to a password-protected account with a business may submit a deletion request, but the business must verify the identity of the consumer to a "reasonable or reasonably high degree of certainty depending on the sensitivity of the personal information and the risk of harm to the consumer posed by unauthorized deletion."[283] Further regulations should specify how verification would work in the DTC genetic testing context. The actual process of verifying non-account holders will likely be a conundrum for companies, since these companies require little in terms of initial identity verification when setting up an account and sending in a sample for testing.[284] Even though there may be conflict with the freedom of expression,

278. CAL. CIV. CODE § 1798.105(a); California Privacy Rights Act of 2020, sec. 5, § 1798.105(a) ("A consumer shall have the right to request that a business delete any personal information about the consumer which the business has collected from the consumer.").

279. *See* Rustad & Kulevska, *supra* note 252, at 389; Fleischer, *supra* note 277.

280. *See* Fleischer, *supra* note 277.

281. *See* Christofides & O'Doherty, *supra* note 12; Hazel & Slobogin, *supra* note 12; Phillips, *supra* note 12, at 16–17, 19.

282. Elizabeth E. Joh, *DNA Theft: Recognizing the Crime of Nonconsensual Genetic Collection and Testing*, 91 B.U. L. REV. 665, 670 (2011); Prince, *supra* note 168, at 211–12.

283. CAL. CODE REGS. tit. 11, § 999.325 (2020).

284. For example, a 23andMe account can be created with only a name, email address, birth date, and password. *23andMe Registration Trouble?*, 23ANDME, https://customercare.23andme.com/hc/en-us/articles/204632060-23andMe-Registration-Trouble- [https://web.archive.org/web/20201130015512/https://customercare.23andme.com/hc/en-us/articles/204632060-23andMe-Registration-Trouble-] (last visited Oct. 25, 2021). It is also fairly easy for a consumer to send in a DNA sample and link the sample to an account with false information. *See* Sarah A. Downey, *How to Use 23andMe Without Giving Up Your Genetic Privacy*, VENTUREBEAT (Sept. 20, 2013, 10:19 AM), https://venturebeat.com/2013/09/20/how-to-use-23andme-without-giving-up-your-genetic-privacy

"limiting the right [to delete] to private parties minimizes the chilling impact on speech."[285]

Another wrinkle regarding who can request the deletion of genetic data involves the family members of users who have chosen to take a DTC genetic test. For example, GEDmatch is a popular website that allows users to upload raw DNA data from DTC genetic testing companies like 23andMe and Ancestry, making it possible for people to find distant family members—both on and off the website.[286] Biological family members' genetic identity and privacy "are inherently compromised because of the proliferation of partial DNA matching techniques" in DTC genetic databases and governmental forensic DNA databases.[287] Family members thus may have an interest in requesting the deletion of their relatives' genetic data. However, this falls most closely along the lines of Fleischer's third, and most controversial, scenario, without the nonconsensual element of surreptitious testing.[288] As such, deletion requests by family members of users should not be allowed due to concerns that laws may become difficult to implement and may inhibit free speech and research.[289] Permissible deletion requests should therefore be limited to users who procured services themselves and to the victims of surreptitious testing.

The third consideration regarding a deletion request is whether companies and their affiliates can avoid deletion of personal information if deletion is impossible or involves disproportionate effort.[290] Consumer genetic information is attractive to data brokers, marketing and advertising corporations, pharmaceutical companies, employers, insurers, and law enforcement.[291] Relationships between data subjects and data collectors stemming from the use of internet and mobile services, websites, apps, or major technology platforms like Google, Amazon, Apple, Facebook, and Microsoft mean that "many, if not most, privacy concerns are rooted in a relationship characterized by extreme information and power asymmetries."[292] Companies thus have an incentive to avoid deletion requests, particularly where data is so valuable, as in the DTC genetic testing context.

[https://perma.cc/47NC-M3K5]. Given the difficulty of matching a non-account holder's deletion request with an account, the ironic solution might be that the non-account holder must send another sample of her DNA to the company for it to cross-check its databases.

285. Rustad & Kulevska, *supra* note 252, at 398.

286. Sarah Zhang, *How a Tiny Website Became the Police's Go-To Genealogy Database*, ATLANTIC (June 1, 2018), https://www.theatlantic.com/science/archive/2018/06/gedmatch-police-genealogy-database/561695 [https://perma.cc/KBV2-2NY9].

287. Entrikin, *supra* note 143, at 867–88; *see also* Zhang, *supra* note 286.

288. Fleischer, *supra* note 277 ("I cannot see how such a right could be introduced without severely infringing on freedom of speech. This is why I think privacy is the new black in censorship fashion.").

289. Prince, *supra* note 168, at 208.

290. California Privacy Rights Act of 2020, sec. 5, § 1798.105(c), 2020 Cal. Legis. Serv. Prop. 24.

291. Drabiak, *supra* note 125.

292. Hartzog & Richards, *supra* note 257, at 1745.

Further regulations are needed to define what constitutes impossibility and disproportionate effort. For example, it is foreseeable DTC genetic testing companies may argue de-identified consumer information already in use in internal or external research is impossible to delete or would involve disproportionate effort, even if the data was collected without consent. The CCPA and CPRA allow research with data that has been pseudonymized and de-identified or de-identified and in the aggregate.[293] However, numerous scholars have found that re-identification of de-identified data can be easily done.[294] It is worth exploring whether de-identified data should be deleted in surreptitious testing cases, and if so, whether this should be provided for within the CCPA and CPRA framework or an alternative genetic-privacy statute.

b. The CalECPA Exception

Law enforcement has increasingly turned to genetic genealogy to solve cold cases, which has led to the successful identifications of serial killers such as Joseph James DeAngelo (the Golden State Killer).[295] The Golden State Killer case was the first high-profile case to be solved using genetic genealogy.[296] The capture of DeAngelo after decades of evading the police inspired dozens of other agencies to employ the same methods in solving their violent crimes.[297] Clearly, there is a substantial public-safety benefit to law enforcement's use of genetics databases.[298] However, concerns regarding unwarranted intrusion into innocent parties' privacy are still valid, given that one study found sixty percent of Americans of Northern European descent can be identified using DTC genetic testing sites, whether or not those individuals have used the services.[299]

The interests in protecting genetic privacy and ensuring public safety thus appear to be on a collision course. Under the CCPA and CPRA, businesses and their affiliates do not have to comply with a deletion request where they must

293. CAL. CIV. CODE § 1798.140(s) (2018); California Privacy Rights Act of 2020, sec. 14, § 1798.140(ab) ("[De-identified] information cannot reasonably identify, relate to, describe, be capable of being associated with, or be linked, directly or indirectly, to a particular consumer, by a business.").

294. *See* Koch & Todd, *supra* note 253, at 117–18 (describing a series of studies demonstrating the ease of re-identification); Elizabeth R. Pike, *Defending Data: Toward Ethical Protections and Comprehensive Data Governance*, 69 EMORY L.J. 687, 719 (2020) (arguing the CCPA's allowance of de-identified data is either "so broad as to render nearly all data identifiable or so narrow that large swaths of data [sic] unprotected"); Prince, *supra* note 168, at 207 (describing further studies that show re-identification is possible, and positing that biobank data can identify members of discrete populations).

295. Entrikin, *supra* note 143, at 869–870.

296. Levenson & Murphy, *supra* note 136.

297. *Id.*

298. *Id.*

299. Heather Murphy, *Most White Americans' DNA Can Be Identified Through Genealogy Databases*, N.Y. TIMES (Oct. 11, 2018), https://www.nytimes.com/2018/10/11/science/science-genetic-genealogy-study.html [https://perma.cc/YQ48-SA5K].

comply with CalECPA.[300] When initially reviewing Fourth Amendment jurisprudence regarding police searches and seizures, genetic privacy seems to give way to governmental intrusion for the protection of public safety.[301] Furthermore, the Fourth Amendment's third-party doctrine establishes that there is no reasonable expectation of privacy when information is voluntarily conveyed to a third party.[302] One scholar has hypothesized that because DTC genetic testing customers voluntarily give their biological samples to companies, the third-party doctrine would allow the government to gain access to these companies' genetic databases.[303]

California's enactment of the CalECPA on October 8, 2015, was a turning point in protecting Californians' digital privacy by requiring a warrant for searches of digital records such as emails, text messages, and geographic location.[304] CalECPA prohibits a government entity from compelling "the production of or access to electronic communication information from a service provider."[305] CalECPA thus covers cloud-storage services like Dropbox, social-media sites like Facebook, and email providers like Google.[306] Even though the outer boundaries of CalECPA are unclear,[307] DTC genetic testing companies likely fall within the definition of a service provider because they are entities arguably offering to provide users with electronic-communication capabilities, act as an intermediary in communications, and store communication information.[308]

Additionally, genetic data itself is likely covered under CalECPA. The statute has broad definitions for what counts as "electronic communication," including "the transfer of signs, signals, writings, images, sounds, *data*, or intelligence *of any nature* in whole or in part by a wire, radio, electromagnetic, photoelectric, or

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300. CAL. CIV. CODE § 1798.105(d)(5) (2018); California Privacy Rights Act of 2020, sec. 5, § 1798.105(d)(5), 2020 Cal. Legis. Serv. Prop. 24.

301. *See* Maryland v. King, 569 U.S. 435, 465–66 (2013) (holding that taking a DNA sample from an arrestee via buccal swab did not violate the Fourth Amendment because it is a "routine booking procedure").

302. Smith v. Maryland, 442 U.S. 735, 742 (1979) (rejecting argument that petitioner had a legitimate expectation of privacy in the numbers he dialed on his phone that were recorded by a pen register installed at a telephone company).

303. Ayesha K. Rasheed, *Personal Genetic Testing and the Fourth Amendment*, 2020 U. ILL. L. REV. 1249, 1255.

304. Dave Maass, *Victory in California! Gov. Brown Signs CalECPA, Requiring Police to Get a Warrant Before Accessing Your Data*, ELEC. FRONTIER FOUND. (Oct. 8, 2015), https://www.eff.org/deeplinks/2015/10/victory-california-gov-brown-signs-calecpa-requiring-police-get-warrant-accessing [https://perma.cc/YDH9-PEQH].

305. CAL. PENAL CODE § 1546.1(a)(1) (2015). "Service provider" is defined as "a person or entity offering an electronic communication service." § 1546(j). "Electronic communication service" is defined as "a service that provides to its subscribers or users the ability to send or receive electronic communications, including any service that acts as an intermediary in the transmission of electronic communications, or stores electronic communication information." § 1546(e).

306. Susan Freiwald, *At the Privacy Vanguard: California's Electronic Communications Privacy Act (CalECPA)*, 33 BERKELEY TECH. L.J. 131, 147–48 (2018).

307. *Id.*

308. CAL. PENAL CODE § 1546(j), (e).

photo-optical system."[309] The definition of "electronic communication information" is similarly broad, including "any information about an electronic communication or the use of an electronic communication service."[310]

Lauded as the "most privacy-protective legislation of its kind in the nation,"[311] CalECPA serves as an appropriate barrier to law enforcement intrusion into DTC genetic databases. The finding of probable cause to support a warrant should be the bar that law enforcement must rise above to conduct searches in databases that invade innocent parties' privacy. For states drafting CCPA- and CPRA-like laws that do not also have strong legislation protecting governmental intrusion into electronic communications, it is important to include a provision explicitly stating law enforcement must procure a warrant before searching DTC genetic databases.

c. The Research Exception

The other notable exception applicable to genetic-deletion requests is the research exception under the CCPA and CPRA. The research exception explicitly allows businesses to retain consumer data when engaging in "public or peer-reviewed scientific, historical, or statistical research that conforms or adheres to all other applicable ethics and privacy laws, when the business's deletion of the information is likely to render impossible or seriously impair the ability to complete such research, if the consumer has provided informed consent."[312]

Three main requirements must be met for the exception to apply. First, the exception only covers businesses, service providers, or contractors who engage in "public or peer-reviewed scientific, historical, or statistical research that conforms or adheres to all other applicable ethics and privacy laws."[313] Internal company research is not mentioned. For consumers to have an unfettered right to delete their genetic information from all internal research, regulators must firmly constrain the application of the exception to only public or peer-reviewed research. Furthermore, regulations must be clear that the internal-use exception[314] cannot be used to undermine the research exception.

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309. § 1546(c) (emphasis added).

310. § 1546(d).

311. Freiwald, *supra* note 306, at 133.

312. CAL. CIV. CODE § 1798.105(d)(6) (2018); California Privacy Rights Act of 2020, sec. 5, § 1798.105(d)(6), 2020 Cal. Legis. Serv. Prop. 24.

313. California Privacy Rights Act of 2020 § 1798.105(d)(6).

314. The internal use exception states:

> A business, or a service provider or contractor . . . shall not be required to comply with a consumer's request to delete . . . [t]o enable solely internal uses that are reasonably aligned with the expectations of the consumer based on the consumer's relationship with the business and compatible with the context in which the consumer provided the information.

§ 1798.105(d)(7). In the DTC genetic testing context, a company should not be able to claim that its consumers expect internal research to be conducted and that internal research is compatible with the context of a consumer providing DNA to the company. This is an important distinction to make because companies like 23andMe present themselves to be on the cutting edge of research and encourage consumers to participate in research, despite having numerous private-entity collaborators. *See Research*, *supra* note 23.

Limiting the research exception to public or peer-reviewed research addresses concerns that DTC genetic testing companies lack transparency when it comes to what they do with genetic data in their possession. As seen in one study, seventy-one percent of companies surveyed with readily accessible privacy policies regarding genetic data provided information that indicated a consumer's genetic data could be used internally beyond the original transaction of providing test results for the consumer.[315] Additionally, sixty-two percent of companies indicating such potential uses went further to explicitly state that a consumer's genetic data could be used for internal research and development.[316] Based on findings like these, it is appropriate for the legislature to discourage internal research by allowing consumers to delete their information freely.

Second, the CPRA's research exception applies in situations where deletion "is likely to render impossible or seriously impair the ability to complete such research."[317] Regulations are needed to further define impossibility and serious impairment. At present, it is unclear how many deletion requests would be considered as rendering impossible or seriously impairing a research endeavor. Researchers have affirmed that genetic-association studies with larger numbers of SNP markers require larger sample sizes, and these sample sizes must increase even more for genome-wide association studies.[318] Another issue in research regarding gene-disease associations is the lack of replication of the original research findings, which typically means that the original research contained false positives.[319] Common biases in gene-disease association research include population stratification, misclassification of phenotype, genotyping error, and selection biases.[320] Given these concerns, companies conducting research have an incentive to maximize the number of participants in their studies and may use the research exception to protect their investments at the expense of consumers' genetic privacy. The definitions of impossibility and serious impairment must reflect the dual goals of promoting ethical research and protecting consumers' genetic privacy.

Third, in addition to the requirements of public or peer-reviewed research and the finding of impossibility or serious impairment of that research, a consumer must also have originally provided informed consent for a company to deny the consumer's deletion request.[321] This requirement demonstrates the continuing importance of informed consent in the DTC genetic testing context, despite

315. Hazel & Slobogin, *supra* note 12, at 52.

316. *Id.*

317. California Privacy Rights Act of 2020 § 1798.105(d)(6).

318. Eun Pyo Hong & Ji Wan Park, *Sample Size and Statistical Power Calculation in Genetic Association Studies*, 10 GENOMICS & INFORMATICS 117, 120 (2012).

319. Ramal Moonesinghe, Muin J. Khoury, Tiebin Liu & John P. A. Ioannidis, *Required Sample Size and Nonreplicability Thresholds for Heterogeneous Genetic Associations*, 105 PROC. NAT'L ACAD. SCI. 617, 617 (2008).

320. *Id.*

321. California Privacy Rights Act of 2020 § 1798.105(d)(6).

scholars' acknowledging its inadequacies.[322] Consumers who are truly informed and consent to research are better positioned to preserve their autonomy over their genetic information.[323] Therefore, regulators and consumers must view the right to delete as a tool to augment consumer autonomy and should not consider it as a panacea for genetic-privacy issues.

CONCLUSION

Big data and personalized medicine have spurred the growth of the DTC genetic testing industry into what it is today. The industry, which started out by offering consumers a glimpse into their genealogies, continues to develop in the health-care space and promises to deliver innovative health-related genetic tests and to aid in research efforts across a variety of scientific fields. The fact that DTC genetic testing companies have amassed so much genetic information is concerning. As is often the case, technology outpaces the law, and the legal framework in the United States applicable to DTC genetic testing—and more broadly, privacy—needs to be modernized.

Recent state laws like the CCPA and CPRA[324] seek to do just that, and they may serve as model legislation for other state laws or even a federal data-privacy law. In particular, the right to delete is a promising tool for consumers to utilize in regaining and maintaining their ability to make choices regarding their genetic information. The CCPA and CPRA provide exceptions to the right to delete that are largely in keeping with the necessity to balance deletion with legitimate interests in protecting public safety and promoting research. However, further regulations are needed to parse out the nuances of this new privacy right and its limitations. With legal tools such as the right to delete, consumer autonomy will hopefully be more protected in the DTC genetic testing context and beyond.

322. *See supra* Section IV.B.1.

323. *See supra* Sections II.C, IV.B.1.

324. As a testament to the recent rapid development of California privacy law, California Governor Gavin Newsom signed into law the Genetic Information Privacy Act (GIPA) governing DTC genetic testing companies approximately one month prior to the publication of this Note. Genetic Information Privacy Act, 2021 Cal. Legis. Serv. Ch. 596 (West). Notably, GIPA requires DTC genetic testing companies to honor consumers' revocations of consent by destroying biological samples within thirty days of revocation and deleting consumers' accounts and genetic data, except where genetic data is required to be retained to comply with applicable legal and regulatory requirements. *Id.* GIPA does not provide explicit guidelines on how DTC genetic testing companies are to structure their new policies and practices. *Id.* Furthermore, GIPA does not reduce or eliminate obligations under other laws, including the more broadly applicable CCPA and CPRA. *Id.* I therefore affirm my thoughts and recommendations in Part IV of this Note and would similarly apply them to GIPA.