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Genetic Privacy in the Age of Commercial DNA Testing

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Introduction

Over the past decade, Americans have become familiar with the promise of commercial genetic testing services. Television advertisements feature smiling customers who discover unknown relatives or places of ancestry through the miracle of modern genetics testing.¹ Companies also tout at-home testing kits as an affordable means to access medical information, such as susceptibility to disease.² For these reasons, Americans increasingly give the gift of genetic testing during the holiday season.³ However, in their haste to access valuable information about ethnicity, familial relationships, and health, consumers may not consider larger questions about the consequences of sharing their DNA with commercial entities, such as: What rights can an individual claim to the contents of a saliva sample mailed to a company like AncestryDNA? How do commercial testing companies share or sell their customers' DNA data? Could genetic information become the basis for discrimination in housing, employment, or insurance? Could it lead to the arrest of a family member?

Recent events have prompted concerns about the ways that technology companies collect and exchange sensitive data, which have encouraged their customers to consider the risks of sharing information about themselves on social media platforms like Facebook. Yet the same people may not recognize the risks of sharing DNA, which stands apart as exceptionally personal data. Meanwhile, commercial genetic testing companies face few meaningful restrictions with respect to their handling of customers' genetic information. Legislators across the country have increasingly noticed and attempted to regulate this industry, and in the process, have contemplated whether individuals possess certain fundamental rights over their genetic material.

This publication introduces these regulatory efforts. It begins by providing background information about genetics, describing commercial genetic testing services, and explaining how these services interact with open-source and law enforcement DNA databases. It then outlines privacy concerns related to the commercial exchange of genetic information, traces the evolution of federal laws, and summarizes regulatory approaches adopted in other states.

Background on genetic testing

According to the National Human Genome Institute, deoxyribonucleic acid, or DNA,

1. See, for example, AncestryDNA, "Testimonial: Lezlie" (TV commercial), 2015, <http://www.ispot.tv>; 23andMe, "100% Nicole: Journey" (TV commercial), 2017, <http://www.ispot.tv>.

2. Anne Wojcicki, "23andMe Responds: Empowering Consumers," letter to the editor, *The New York Times*, February 5, 2019. See also, 23andMe, "Meet Your Genes: LDLR" (TV commercial), 2019, <https://www.ispot.tv>.

3. By some estimates, customers purchased over one million at-home testing kits from AncestryDNA over Thanksgiving weekend in 2017. Megan Molteni, "Ancestry's Genetic Testing Kits Are Heading for Your Stocking This Year," *Wired*, December 1, 2017, <https://www.wired.com/>.

functions like a set of blueprints that passes from one generation to another.⁴ The term **genome** refers to “[one] organism’s complete set of DNA,” or all the biological instructions required “to build and maintain that organism.”⁵ Among humans, the genome varies only slightly, with 99.9 percent of all genetic material remaining identical from person to person. Scientists have studied all 3 billion components of the human genome in an attempt to better understand that remaining tenth of a percent, and have gained a greater understanding of how certain genes correspond to distinct biological traits.⁶ Meanwhile, DNA analysis has become an indispensable tool used to identify unknown persons and establish biological relationships between multiple known persons.

Genetic analysis relies on identifying differences between DNA samples, and certain methods of identification produce more detailed results than others. Commercial testing companies typically rely on a method of analysis that yields a great deal of information about the person to whom a genetic sample belongs. This approach entails looking for tiny variations at thousands of locations on the genome. When cells multiply, they copy their DNA, but sometimes err during the process and create typos—**single-nucleotide polymorphisms**, or **SNPs**. Analyzed together, SNPs tell us about someone’s ancestry, appearance, and health.⁷ By contrast, law enforcement agencies generally analyze DNA by looking for patterns of repetition—referred to as **short tandem repeats**, or **STRs**—at 20 or fewer specific places on the genome. At best, these patterns distinguish one individual’s genome from that of another person.⁸ At worst, they may establish an incorrect match with another person, known as a false positive.⁹

Over the past several decades, SNP and STR analyses have been applied in myriad contexts: they can establish paternity, trace familial relationships, discover ethnic origins, predict susceptibility to disease, identify murder victims, or pinpoint suspects from crime scene evidence. In recent years, the rise of the commercial genetic testing industry has drawn attention to the relative advantages of SNP analysis.

4. “[Deoxyribonucleic Acid \(DNA\) Fact Sheet](https://www.genome.gov/)” (website), National Human Genome Research Institute, <https://www.genome.gov/>.

5. “[What is a genome?](https://ghr.nlm.nih.gov/primer/hgp/genome)” (website), U.S. National Library of Medicine, <https://ghr.nlm.nih.gov/primer/hgp/genome>.

6. Kayte Spector-Bagdady and Elizabeth Pike, “Consuming Genomics: Regulating Direct-to-Consumer Genetic and Genomic Information,” *Nebraska Law Review* 92 (2014), 677–745: 685.

7. Sarah Zhang, “[How a Tiny Website Became the Police’s Go-To Genealogy Database](#),” *Atlantic*, June 1, 2018.

8. Previously, the FBI typically relied on STRs at 13 points or loci. Zhang, “How a Tiny Website”; Karen Norrgard, “[Forensics, DNA Fingerprinting, and CODIS](#),” *Nature Education* 1(1): 35 (2008); Terry Taylor, “What Is STR Analysis?” *National Institute of Justice Journal* 267, March 2, 2011; “[Frequently Asked Questions on CODIS and NDIS](#)” (website), Federal Bureau of Investigation, <https://www.fbi.gov/>.

9. Within law enforcement databases, certain disproportionately represented demographic groups may experience “mistaken identification” based on known margins of error. Nanibaa A. Garrison, Rori V. Rohlf, and Stephanie M. Fullerton, “[Forensic Familial Searching: Scientific and Social Implications](#),” *Nature* 14 (July 2013), 445. Additionally, *Wired* reporting cites a British study from 2014 in which “just 17 percent of familial DNA searches ‘resulted in the identification of a relative of the true offender.’” Brendan I. Koerner, “[Your Relative’s DNA Could Turn You Into a Suspect](#),” *Wired*, October 13, 2015.

Genetic testing services and databases

Sequencing a person's genome has become progressively less time-consuming and expensive.¹⁰ This section introduces commercial genetic testing services and the open-source services that have sprung up around them.

Direct-to-consumer (DTC) companies sell mail-in genetic testing kits for \$100 or less. Customers typically purchase a kit, send a saliva sample to the manufacturer, and receive results online within weeks. These results are based on analysis of SNPs at over a half million places on the genome and may include detailed information about health and ancestry.¹¹ Industry leaders AncestryDNA and 23andMe collectively boast about 15 million customers,¹² and by some estimates, more than 25 million people have used DTC services overall.¹³

Many of those people have turned to **open-source genetic databases**—free or low-cost platforms that aggregate results from various DTC companies—to learn even more about their DNA. The most popular open-source platform, GEDmatch, facilitates genealogical research. For example, a 23andMe customer may identify biological relatives who have also sequenced their DNA using 23andMe, but other biological relatives who have sequenced their DNA using a different service—such as National Geographic DNA or AncestryDNA—cannot be identified through 23andMe's platform. Accordingly, this person may upload the raw data from his or her 23andMe findings to GEDmatch to access information and identify biological connections across multiple DTC services.¹⁴

Other open-source platforms are oriented towards different goals. For example, some provide users with more detailed information about the health implications of their DNA. (Federal regulations, discussed later in this publication, prohibit DTC companies from providing this kind of analysis.¹⁵) Others aggregate genetic data for use by scientists, particularly those who lack the resources to conduct large-scale genetic research projects.¹⁶

10. Spector-Bagdady and Pike, "Consuming Genomics," 689.

11. Zhang, "How a Tiny Website." These findings are based on comparisons with other genetic samples in any given company's database, which means that findings may change as each database grows. For a brief explanation of the fluid results of DTC testing kits, see Damian Garde, "'What's My Real Identity?': As DNA Ancestry Sites Gather More Data, the Answer for Consumers Often Changes," *Stat News*, May 22, 2019.

12. Other companies like Illumina and Gene by Gene compete within this industry; however, this publication focuses on AncestryDNA and 23andMe, the two most widely used services. On figures, see Gina Kolata and Heather Murphy, "The Golden State Killer Is Tracked Through a Thicket of DNA, and Experts Shudder," *New York Times*, April 27, 2018.

13. Antonio Regalado, "All the Reasons 2018 was a Breakout Year for DNA Data," *MIT Technology Review*, December 29, 2018.

14. GEDmatch initially functioned without fees, but has since adopted subscription-based services as the costs of hosting the well-trafficked site increase. Zhang, "How a Tiny Website"; Heather Murphy, "How an Unlikely Family History Website Transformed Cold Case Investigations," *New York Times*, October 15, 2018. Notably, the for-profit genomics firm Verogen, Inc. announced its acquisition of GEDmatch in December 2019, which may result in changes to subscription fees and site policies. See Julian Husbands, "GEDmatch Partners with Genomics Firm," press release, Verogen, December 9, 2019, <https://www.verogen.com>; Nila Bala, "We're Entering a New Phase in Law Enforcement's Use of Consumer Genetic Data," *Slate*, December 19, 2019.

15. Genetic Genie, for example, purports to provide detox analysis based on raw DNA data. Promethease provides detailed medical analysis of reports generated by 23andMe, AncestryDNA, and other services.

16. See, for example, "The Harvard Personal Genome Project," Harvard Medical School, accessed November 27, 2019, <https://pgp.med.harvard.edu/>; "Welcome to OpenSNP," OpenSNP, accessed November 27, 2019, <https://opensnp.org/>. For

As a group, open-source databases enable what some advocates call “citizen science,” a democratized means for all people to access the potential of genetics.¹⁷

Third-party access to commercial and open-source data

As DTC testing companies seek to generate more revenue from licensing their customers’ genetic data to third parties for research than from selling testing kits, third parties regularly access the pool of genetic data analyzed by these companies.¹⁸ For example, in mid-2018, the pharmaceutical giant GlaxoSmithKline invested \$300 million in 23andMe, enabling the company to “use 23andMe’s rich database . . . to fuel drug target discovery.”¹⁹ DTC companies generally request customer consent for third-party research, and an overwhelming majority of users grant blanket consent.²⁰ In this way, these companies have directly broadened the scope of pharmaceutical research. They have also indirectly expanded the potential of medical research writ large, as their customers share their genetic data within open-source scientific databases. The Harvard Personal Genome Project, for example, connects genomic scientists with DNA data from over 5,000 voluntary participants, which other scientists may use to test or replicate their colleagues’ findings.

Similarly, DTC companies have transformed law enforcement’s use of genetic data. Traditionally, law enforcement agencies have relied on the **Combined DNA Index System**, or **CODIS**,²¹ a national repository that holds genetic data from convicted offenders,²² certain arrestees,²³ and incarcerated persons seeking exoneration.²⁴ The database also contains “abandoned DNA” found at crime scenes and not definitively linked to any person.²⁵ Profiles within CODIS consist of STRs, which provide less information about the sample source than SNPs. As a result, police investigators can determine whether a crime scene sample matches existing genetic data from CODIS, but cannot identify the

an extensive list of DNA databases, see “[DNA databases](https://isogg.org/wiki/DNA_databases)” (website), International Society of Genetic Genealogy, https://isogg.org/wiki/DNA_databases.

17. Zhang, “How a Tiny Website.”

18. Katie M. Palmer, “Another Personal Genetics Company Is Sharing Client Data,” *Wired*, July 21, 2015; Elizabeth R. Pike, “Securing Sequences: Ensuring Adequate Protections for Genetic Samples in the Age of Big Data,” *Cardozo Law Review* 37 (2016), 1977–2033; 1996.

19. “GSK and 23andMe Sign Agreement to Leverage Genetic Insights for the Development of Novel Medicines” (press release), GlaxoSmithKline, posted July 25, 2018; Jamie Ducharme, “A Major Drug Company Now Has Access to 23andMe’s Genetic Data. Should You Be Concerned?” *Time*, July 26, 2018.

20. Pike, “Securing Sequences,” 1996.

21. For a brief explanation of CODIS, see Pike, “Securing Sequences,” 1997–8.

22. Most states require convicted offenders to submit DNA samples for certain offenses. In Wisconsin, those convicted of both misdemeanors and felonies must submit samples under Wis. Stat. § 973.047, “[Convicted Offenders Required to Submit DNA Samples](#)” (website), National Conference of State Legislatures, last updated 2013.

23. Some states do not mandate DNA samples from arrestees, but in Wisconsin, persons arrested for certain violent crimes must submit a DNA sample under Wis. Stat. § 165.76 (1) (gm). “[DNA Arrestee Laws](#)” (website), National Conference of State Legislatures, last updated 2013.

24. Those convicted in Wisconsin are eligible to request such testing under Wis. Stat. § 974.07. “[Post Conviction DNA Testing](#)” (website), National Conference of State Legislatures, last updated 2013.

25. Pike, “Securing Sequences,” 1997.

sample source without such a match. By contrast, DTC services can identify an anonymous sample by analyzing SNPs and revealing connections to other customers.²⁶

However, most services require clean saliva samples, meaning “police can’t simply upload a DNA profile they have from old crime scenes.”²⁷ Additionally, company policies generally restrict disclosure of customer information in response to requests from law enforcement agencies.²⁸ To overcome these obstacles, police investigators have increasingly submitted DNA data to open-source databases like GEDmatch in the hopes of identifying sample sources through their family trees. This technique has resolved various cold cases, such as the Golden State Killer, a serial rapist active in California in the late 1970s and early 1980s.²⁹ In that case, officers uploaded raw data of the perpetrator’s DNA to GEDmatch to identify biological relatives and make a list of suspects.³⁰ Officers then narrowed that list,³¹ collected DNA from suspects, and matched one suspect’s DNA to the perpetrator’s profile.³²

Few officers receive training in this kind of genetic genealogy, and as a result, law enforcement agencies often contract with third parties to perform these services. One such company, Parabon Nanolabs, submits raw genetic data to GEDmatch and uses the results in tandem with traditional genealogical sources like obituaries and marriage certificates to construct family trees.³³ Parabon Nanolabs also provides a DNA profiling service that predicts physical traits, such as skin, hair, and eye color, as well as age and body mass.³⁴

Privacy concerns

The rapid growth of the genetic testing industry has raised a number of questions about the security and privacy of DNA. Namely, how do DTC companies—as well as the third

26. Zhang, “How a Tiny Website.”

27. “Providing Saliva Sample for DNA Test Kit,” 23andMe, accessed October 9, 2019; Megan Molteni, “The Creepy Genetics Behind the Golden State Killer Case,” *Wired*, April 27, 2018.

28. Most DTC companies outline law enforcement policies and publish annual transparency reports with information about compliance with court orders, subpoenas, or warrants. See, for example: “Ancestry Guide for Law Enforcement” (website), Ancestry.com; “Ancestry 2018 Transparency Report” (website), Ancestry.com; “23andMe Guide for Law Enforcement” (website), 23andMe.com; “Transparency Report” (website), 23andMe.com. All sites last accessed in October 2019.

29. Kolata and Murphy, “The Golden State Killer Is Tracked.” Another example is the cold case murder of April Tinsley. Matthew Haag, “Decades After Killing of April Tinsley, 8, DNA Leads to Suspect,” *New York Times*, July 16, 2018.

30. That data had been retained as crime scene evidence for over three decades. Zhang, “How a Tiny Website.”

31. In at least one instance, that process involved obtaining a warrant to collect DNA from a suspect, who was subsequently ruled out as a result of his DNA. Dion Lim, “DNA Mistake Pegged Oregon Man as ‘Golden State Killer’,” ABC News 7, KGO-TV (San Francisco), April 28, 2018.

32. Melody Gutierrez and Jenna Lyons, “Detectives in Golden State Killer Case Used Genealogical Sites to Nab Suspect,” *SFGate*, April 26, 2018.

33. In this way, the company relies primarily on innovative uses of existing tools, rather than proprietary technology. See, for example, Camila Domonoske, “Suspect in Decade-Old Serial Rapes Arrested, With Help of Genealogy Database,” NPR, August 23, 2018; Kate Snow and Jon Schuppe, “‘This Is Just the Beginning’: Using DNA and Genealogy to Crack Years-Old Cold Cases,” NBC News, July 18, 2018. Haag, “Decades After Killing of April Tinsley.”

34. “Parabon NanoLabs” (website), Parabon Nanolabs, <https://www.parabon-nanolabs.com/>. The company worked with agencies in Wisconsin to produce a “phenotype report” in a Marinette County cold case. Eric Levenson, “Scientists Sketched Out a Suspect’s Face Using DNA from a 42-Year-Old Cold Case,” CNN, July 24, 2018. See also, Amanda Milkovits, “How DNA and a Tattoo Led to Charges in Cold R.I. Murder Case,” *Providence Journal*, July 27, 2018.

parties with whom they share information—control access to DNA data and ensure customer anonymity? What happens if third parties use DNA data improperly?

Above all, DTC companies, like any companies handling personal information, may be subject to data breaches.³⁵ The consequences of such breaches are especially alarming since DNA is inalterable, unlike other personal information such as credit card numbers. Genetic testing companies strip the data they license to researchers of any identifying information to ensure their customers' anonymity. However, researchers have demonstrated the possibility of reidentifying anonymous DNA data.³⁶ The inability to completely anonymize DNA data raises the possibility that third parties—whether authorized researchers or unauthorized hackers—may be able to identify DTC customers without the customers' knowledge or consent.

DTC customers could be vulnerable to discrimination if unintended parties gain access to the genetic information of these customers. Federal law prohibits genetic discrimination within health insurance and employment; however, these protections do not apply to the areas of education, housing, or mortgage lending, to name a few.³⁷ Journalists have already identified people to whom life insurers denied coverage as the result of genetic tests indicating cancer genes.³⁸ As scientists discover the full range of conclusions that may be drawn from DNA—such as IQ or predispositions to addiction or mental illness—discrimination could broaden.³⁹

The problems outlined above touch more than DTC customers. One person's decision to undergo commercial testing or submit results to an open-source database affects the genetic privacy of everyone in his or her family tree.⁴⁰ For example, someone may unwittingly implicate a biological relative in a crime.⁴¹ Filmmaker Michael Usry was wrongly suspected of murder after police traced the perpetrator's DNA to his father, whose improperly deidentified DNA landed on Ancestry.com after that company acquired another

35. Muhammad Naveed, Erman Ayday, Ellen W. Clayton, Jacques Fellay, Carl A. Gunter, Jean-Pierre Hubaux, Bradley A. Malin, and Xiao Feng Wang, "Privacy in the Genomic Era," *ACM Computing Surveys* 48 (August 2015), 2015, 1–44:13–15. Certain services, like Guardiome, do not store user data on the cloud, but are invariably more expensive. Andelka M. Phillips, "Only a Click Away—DTC Genetics for Ancestry, Health, Love . . . and More: A View of the Business and Regulatory Landscape," *Applied & Translational Genomics* 8 (2016), 16–22.

36. Yaniv Erlich, Tal Shor, Itsik Pe'er, and Shai Carmi, "Identity Inference of Genomic Data Using Long-Range Familial Searches," *Science* Vol. 362, Issue 6415, November 9, 2018, 2. For a useful summary, see Gina Kolata, "Poking Holes in Genetic Privacy," *New York Times*, June 16, 2013.

37. U.S. Department of Health and Human Services, "GINA: The Genetic Information Nondiscrimination Act of 2008—Information for Researchers and Health Care Professionals" (fact sheet), April 6, 2009; Sarah Zhang, "The Loopholes in the Law Prohibiting Genetic Discrimination," *Atlantic*, March 13, 2017.

38. Christina Farr, "If You Want Life Insurance, Think Twice Before Getting A Genetic Test," *Fast Company*, February 17, 2016.

39. For a legal discussion of these concerns, see "The Golden State Killer and Genetic Privacy," *We the People* (podcast), National Constitution Center, June 21, 2018.

40. See Avi Selk, "The ingenious and 'dystopian' DNA technique police used to hunt the 'Golden State Killer' suspect," *Washington Post*, April 28, 2018.

41. See Koerner, "Your Relative's DNA Could Turn You Into a Suspect," and Nanibaa' A. Garrison, Rori V. Rohlf, and Stephanie M. Fullerton, "Forensic Familial Searching: Scientific and Social Implications," *Nature Reviews: Genetics* 14 (July 2013): 445.

database.⁴² Though unusual, Usry's case spells out the unintended consequences of DNA databases for the many millions of people who choose *not* to test themselves. Mathematically, a participation rate of 2 percent within any given population could potentially identify any person in that population.⁴³

For their part, DTC companies publicly commit to handling customer data securely and transparently. AncestryDNA and 23andMe provide detailed policy information about consent, privacy, third parties, and disclosure to law enforcement.⁴⁴ But experts suggest that “most policies fall well short of the ideal.”⁴⁵ Compounding the problem, some user agreements enable customers to grant consent without necessarily reading the terms to which they have agreed.⁴⁶ Finally, company policies have changed frequently and, sometimes, imperceptibly. For example, in 2018, FamilyTreeDNA “quietly and voluntarily” launched a collaboration with the FBI without publicly notifying customers, and acknowledged the agreement only after journalists publicized its terms in January 2019.⁴⁷ Likewise, the open-source database GEDmatch has revised its policies multiple times in response to highly publicized law enforcement uses of the site.⁴⁸

DTC companies have pledged to adopt the best practices outlined by the Future of Privacy Forum.⁴⁹ But leaving companies to self-regulate on data privacy means that customers must place their trust in the companies to not abuse or mishandle their personal information and to clearly communicate changes in policy.

Federal regulations

Federal laws regulate certain aspects of the DTC industry, including placing restrictions

42. For more on Usry's case, see Anne Marie Green, “How Safe Is Your DNA?” *CBS News*, June 16, 2018.

43. Erlich, Shor, Pe'er, and Carmi, “Identity inference of genomic data.” For a plain language summary of this study, see Salvador Hernandez, “Using DNA Databases to Find Your Distant Relatives? So Is The FBI,” *BuzzFeed News*, February 7, 2019.

44. “AncestryDNA Research and Collaboration,” “Privacy for Your AncestryDNA Test,” and “Your Privacy” (websites), Ancestry.com, accessed October 10, 2019; “Research Consent Document” “Privacy is in our DNA,” and “Full Privacy Statement” (websites), 23andMe.com, accessed October 10, 2019.

45. James W. Hazel and Christopher Slobogin, “Who Knows What, and When? A Survey of the Privacy Policies Proffered by U.S. Direct-to-Consumer Genetic Testing Companies,” *Legal Studies Research Paper Series No. 18-18*, Vanderbilt University Law School (April 2018): 1. See also Linnea I. Laestadius, Jennifer R. Rich, and Paul L. Auer, “All Your Data (effectively) Belong to Us: Data Practices among Direct-to-Consumer Genetic Testing Firms,” *Genetics in Medicine* 19 (May 2017), 513–520.

46. Phillips, “Only a Click Away,” 16–17.

47. Mathew Haag, “FamilyTreeDNA Admits to Sharing Genetic Data With F.B.I.,” *New York Times*, February 4, 2019; Salvador Hernandez, “One of the Biggest At-Home DNA Testing Companies Is Working With The FBI,” *BuzzFeed News*, January 31, 2019.

48. After the Golden State Killer's arrest, GEDmatch issued a statement reminding users of the “non-genealogical uses” of site data, “including identification of relatives that have committed crimes.” See Kolata and Murphy, “The Golden State Killer Is Tracked.” As of August 2018, site policy restricted disclosure to law enforcement only in investigations of violent crimes. Journalists later revealed that the site had broken its own policies, and in the aftermath, GED adopted a revised policy that granted users the right to be excluded from law enforcement searches. “GEDmatch.Com Terms of Service and Privacy Policy,” GEDmatch.com, revised May 18, 2019; Natalie Ram, “The Genealogy Site That Helped Catch the Golden State Killer Is Grappling With Privacy,” *Slate*, May 29, 2019.

49. Carson Martinez, “Privacy Best Practices for Consumer Genetic Testing Services,” *Future of Privacy Forum*, July 31, 2018; Mallory Locklear, “23andMe, Ancestry and others agree to genetic privacy guidelines,” *Engadget.com*, July 31, 2018.

on marketing claims and establishing some protections against genetic discrimination. However, they do not define individual rights with respect to DNA data or restrict DTC companies from sharing or selling that data.

As the genetic testing industry expanded in the early 2000s, federal officials worried that health-related results that were tenuous at best might nevertheless inform serious medical decisions. The Government Accountability Office (GAO) first investigated the DTC industry in 2006 and determined that certain health results were “so vague as to be virtually useless.” A subsequent GAO investigation in 2010 produced similar results.⁵⁰ That same year, the Food and Drug Administration (FDA) announced plans to require agency approval for DTC services providing health-related claims; several companies subsequently reoriented their services around genealogy.⁵¹ The FDA has since scaled back these restrictions, approving certain 23andMe tests relating to the risk of colorectal cancer and Alzheimer’s disease, among others.⁵² Meanwhile, other federal agencies have exercised minimal oversight over general DTC marketing claims, despite the fact that rival services often produce conflicting reports based on the same DNA sample.⁵³

In addition to concerns about marketing claims, the growth of the DTC industry also prompted fears that employers and insurers might misuse genetic data to discriminate against prospective employees or customers.⁵⁴ The mobilization of a broad range of stakeholders in the early 2000s resulted in the passage of the Genetic Information Nondiscrimination Act of 2008 (GINA), which prohibits employment discrimination based on genetic information. This legislation also defined genetic information as “protected health information” under the Health Insurance Portability and Accountability Act (HIPAA).⁵⁵ Accordingly, GINA barred health insurers from “using [genetic information] for decisions regarding coverage, rates, or preexisting conditions.”⁵⁶ Two years later, the Affordable Care Act (ACA) bolstered antidiscrimination provisions created under GINA.⁵⁷

50. Spector-Bagdady and Pike, “Consuming Genomics,” 693.

51. 23andMe reoriented its services in 2013 at the request of the FDA. Spector-Bagdady and Pike, “Consuming Genomics,” 680–1, 712.

52. Jack Murtha, “23andMe Genetic Tests for Colorectal Cancer Syndrome Gets FDA Clearance,” *Healthcare Analytics News*, January 22, 2019; Anne Wojcicki, “A Note to Our Customers Regarding the FDA,” 23andMe, February 19, 2015; Ellen Wright Clayton, Barbara J. Evans, James W. Hazel, and Mark A. Rothstein, “The Law of Genetic Privacy: Applications, Implications, and Limitations,” *Journal of the Law and the Biosciences* (2019), 1–36: 17.

53. For its part, the Federal Trade Commission has not policed marketing claims as “deceptive’ business practices,” and has taken only one “meaningful enforcement action” against a DTC company. Clayton, Evans, Hazel, and Rothstein, “The Law of Genetic Privacy,” 19. See, for example, Phil Rogers, Lisa Capitanini, and Courtney Copenhagen, “Home DNA Kits: What Do They Tell You?,” NBC 5 Chicago, April 30, 2018; Stephany Tandy-Connor, Jenna Gultinan, et al., “False-Positive Results Released by Direct-to-Consumer Genetic Tests Highlight the Importance of Clinical Confirmation Testing for Appropriate Patient Care,” *Genetics in Medicine* [advance online publication], March 22, 2018.

54. In 1997, a broad range of groups, from the American Society of Human Genetics to the United Auto Workers, formed the Coalition for Genetic Fairness, which lobbied successfully for the passage of federal legislation. “About the Coalition for Genetic Fairness,” Coalition for Genetic Fairness, accessed August 27, 2018.

55. Genetic Information Nondiscrimination Act of 2008, H.R. 493, 110th Congress, <https://www.congress.gov/bill/110th-congress/house-bill/493/text>.

56. U.S. Department of Health and Human Services, “GINA: The Genetic Information Nondiscrimination Act of 2008.”

57. Under GINA, only “asymptomatic individuals” were protected. The ACA prohibited health insurers from declining

However, critics have identified gaps in the intersecting protections of GINA, HIPAA, and ACA. For example, HIPAA does not prevent the disclosure of deidentified genetic data or require notification of such disclosure despite the known risks of reidentification.⁵⁸ Moreover, many DTC companies are not subject to privacy regulations under HIPAA or federal regulations governing genetic testing labs.⁵⁹ Legislators have introduced measures to create more safeguards for genetic data, but few proposals specifically address DTC companies.⁶⁰ Meanwhile, DTC companies have vigorously lobbied Congress individually and through the Coalition for Genetic Data Protection, a group that opposes genetic privacy regulations in favor of a “one-size-fits-all” model for personal data.⁶¹

State regulations

Over the past decade, states have taken steps towards regulating the genetic testing industry.⁶² Notably, legislatures have attempted to define the rights individuals can exercise over their DNA data after sharing it with DTC companies. Many state statutes employ the term “genetic privacy” to refer to these rights, which amount to “[the] right to control the use of one’s data.”⁶³ This term also encompasses the right to protection against the unforeseen consequences of sharing DNA, such as discrimination. Generally, these laws single out DNA as a particularly sensitive form of personal data that warrants protections separate from general data privacy laws.⁶⁴

coverage based on preexisting conditions, as determined from genetic tests. See Clayton, Evans, Hazel, and Rothstein, “The Law of Genetic Privacy,” 9.

58. Clayton, Evans, Hazel, and Rothstein, “The Law of Genetic Privacy,” 12.

59. For a brief description of CLIA, see U.S. National Library of Medicine, “[How Can Consumers Be Sure a Genetic Test Is Valid and Useful?](#)” accessed October 18, 2019. See also, Clayton, Evans, Hazel, and Rothstein, “The Law of Genetic Privacy,” 14–18.

60. One exception is S. 1842, 116th Congress, introduced in June 2019. It proposes a report on potential regulations for certain companies that collect consumer health data, as well as a national task force that would provide recommendations “[advising] consumers about the basics of genetics and direct-to-consumer genetic testing, and the risks, benefits, and limitations of such testing.”

61. Alex Gangitano, “[DNA Testing Companies Launch New Privacy Coalition](#),” *The Hill*, June 25, 2019; David Lazarus, “[DNA-Testing Firms Are Lobbying to Limit Your Right to Genetic Privacy](#),” *Seattle Times*, July 8, 2019. One prominent example of such a policy is Europe’s General Data Protection Regulation (GDPR), made effective in May 2018. The GDPR requires businesses with European customers to develop “clear, straightforward” privacy policies, obtain “affirmative consent” from customers to share data, notify customers of data transfers, and inform customers about data breaches. Pam Greenberg, “[A Higher Profile for Data Privacy](#),” NCSL *LegisBrief* Vol. 27, No. 7 (February 2019); for a straightforward description of changes under the GDPR, see European Commission, “[A New Era for Data Protection in the EU: What Changes After May 2018](#),” n.d.

62. States have enacted legislation relating to the collection and use of genetic data within the context of scientific research and law enforcement, but this publication does not address those laws. For more information, see Pike, “Securing Sequences,” and Megan Molteni, “[Should Cops Use Family Tree Forensics? Maryland Isn’t So Sure](#),” *Wired*, February 6, 2019.

63. Clayton, Evans, Hazel, and Rothstein, “The Law of Genetic Privacy,” 2–3. For an example of genetic privacy codified in statutes, see 410 Illinois Compiled Statutes 513.

64. Examples include the California Online Privacy Protection Act (CalOPPA) of 2003, under §§ 22575 to 22579, California Business and Professions Code, and the California Consumer Privacy Act of 2018, under §§ 1798.140 and 1798.145, California Civil Code, which broadly authorized consumers “to opt out of the sale of personal information by a business.” Although this legislation includes DNA under the definition of biometric data, a subset of personal information, it creates an exception for deidentified DNA. See also 740 Illinois Compiled Statutes 14; § 503.001, Texas Business and Commerce Code; § 19.375.010, Revised Code of Washington. For a discussion of these laws, see Kashmir Hill and Aron Krolik, “[How Photos of Your Kids Are Powering Surveillance Technology](#),” *New York Times*, October 11, 2019. See also, Pam Greenberg, “[A Higher](#)

Overall, state genetic privacy laws may be divided into the following general categories:

- **Consent**—whether and how DTC customers must agree to data sharing with third parties.
- **Transparency**—the extent to which DTC companies must inform customers of data policies, as well as the potential consequences of their participation.
- **Antidiscrimination**—protections against use of genetic information by third parties to discriminate against past or present DTC customers.
- **Ownership**—whether or how genetic data may be considered an individual’s property.
- **Security**—requirements that DTC companies protect DNA data from data breaches and other threats.
- **Guidance**—state entities created to inform legislative bodies on genetic privacy issues.

Consent. Many state laws codify standards of informed consent for disclosure of DNA data to third parties, especially researchers. Typically, these laws create exceptions for law enforcement, and thus do not affect police use of DTC testing services or open-source databases.

Overall, few of these laws establish higher standards of consent than those already in use by DTC companies. For example, under § 760.40, Florida Statutes, DNA tests require “informed consent” and subsequent results “may not be disclosed without the consent of the person tested.” Likewise, § 192.537, Oregon Revised Statutes, requires “informed consent” for use of an individual’s DNA in “specific anonymous research,” as well as blanket consent for “research generally.” Recent bills in other states have proposed similar rules.⁶⁵ But DTC companies already comply with these standards.

Rather than codify the status quo, some state laws establish even lower standards of consent. More precisely, they carve out exceptions to consent requirements for disclosure of anonymized or deidentified data. For example, ch. 111, § 70G, Massachusetts General Laws, prohibits disclosure of genetic test results without consent, “except where the results disclosed will be used only as is confidential research information for use in epidemiological or clinical research.” Section 629.151, Nevada Revised Statutes, permits obtaining genetic information without consent “for use in a study” if the information remains anonymous. Likewise, § 10:5-45, New Jersey Statutes, and § 35-31-101, Wyoming Statutes, create exceptions to informed consent for “anonymous research.”

Transparency. Along similar lines, some states require DTC companies to provide straightforward information to customers about company policies, or the consequences of participation. For example, under § 51.3151, Louisiana Revised Statutes, DTC companies must provide information about company policies that address the following in

Profile for Data Privacy”; Tim Henderson, “States Battle Big Tech Over Data Privacy Laws,” *Stateline*, July 31, 2019.

65. Under 2017 New York Assembly Bill 8847, for example, “no direct-to-consumer genetic testing company . . . shall distribute to any third party a consumer’s DNA profile without first receiving the consent of such consumer or removing all identifying information from such consumer’s DNA profile.” (The bill died before the session adjourned.)

“easy-to-read” terms: whether the customer’s DNA may be shared or sold to researchers or other third parties, whether the customer may withhold consent for certain research, whether the customer may request the destruction of his or her DNA, and whether the customer “relinquishes ownership of his [or her] DNA by submitting [it] for testing.”⁶⁶ Similarly, § 34-14-22, South Dakota Statutes, requires “informed consent” as a condition of “predictive genetic testing.” At minimum, customers must possess information about the nature of the test, its effectiveness and limitations, potential uses of test results, and parties with access to test samples and results. Other proposed but unenacted bills have incorporated similar measures.⁶⁷

Antidiscrimination. Other state laws prohibit certain third parties from using genetic information in discriminatory ways. Generally, these laws affirm GINA protections related to health insurance, or extend them to cover disability insurance, life insurance, and long-term care insurance.⁶⁸ California leads in this area, having enacted legislation in September 2011 to broadly prohibit genetic discrimination.⁶⁹ To this end, the law extends existing civil rights protections to genetic information within housing, employment, and other areas. For example, § 12955, California Government Code, expressly prohibits the use of genetic information as a condition of financial assistance to purchase a home or as a condition of renting, purchasing, or leasing a home. On this basis, organizations like condominium associations or retirement communities cannot require genetic testing as a precondition of acceptance.⁷⁰

Other states have enacted more limited legislation to prohibit certain uses of genetic information among insurers. Under 410 Illinois Compiled Statutes 513/20,⁷¹ as amended in July 2019, DTC companies may not “[share] any genetic test information or other personally identifiable information about a consumer with any health or life insurance company without written consent from the consumer.” Additionally, insurers are prohibited from seeking genetic information “for use in connection with a policy of accident and health insurance.” Maine’s laws include similar provisions enacted in September 2019.⁷² Under Title 24-A, § 2159-C, Maine Revised Statutes, certain insurers—including disability, long-term care, and life—may not request, require, or obtain information from DTC genetic testing companies without customer consent.

66. These provisions were created under 2018 La. SB 442.

67. For example, under 2016 Md. HB 1392, DTC companies must recommend that the consumer “talk to the consumer’s health care provider or genetic counselor about the results of the consumer’s genetic test,” and warn the consumer that the test could result in denial or cancellation of life insurance coverage. Unusually, 2011 Vermont House Bill 368 proposed a different kind of transparency. Under the bill, companies would be required to notify any consumer “that his or her donation is a commodity and is of some material value.” Additionally, it required companies to compensate customers for sale of their data under certain circumstances. The bill was not enacted.

68. Zhang, “The Loopholes in the Law Prohibiting Genetic Discrimination.”

69. See 2011 Calif. SB 559.

70. Megan Molteni, “The US Urgently Needs New Genetic Privacy Laws,” *Wired*, May 1, 2019.

71. See 2019 Ill. HB 2189.

72. See 2019 Maine HB 949.

Other state laws expressly prohibit employers from discriminating on the basis of genetic information. For example, § 26-45-103, Utah Code, states that employers may not access, request, or require genetic information “in connection with hiring, promotion, retention, or other related [decisions].”⁷³ Michigan law establishes similar protections, but limits them to “genetic information that is unrelated to the individual’s ability to perform the duties of a particular job or position,” under § 37.1202, Michigan Compiled Laws. Other states, including Delaware and Louisiana, extend these protections to members of labor organizations as well.⁷⁴ Broader still, § 24-21-4, New Mexico Statutes, states, “It is unlawful for a person to use genetic information in employment, recruiting, housing or lending decisions or in extending public accommodations and services.”

Ownership. A handful of state laws assert genetic data as a form of property. These provisions attempt to address confusion surrounding individuals’ ownership of data analyzed by DTC companies, and whether ownership implies certain rights over the disposition of that data.⁷⁵

Under a chapter entitled “Genetic Privacy,” § 18.13.010, Alaska Statutes, states that “a DNA sample and the results of a DNA analysis performed on the sample are the exclusive property of the person sampled or analyzed.” Subsequent provisions under §§ 18.13.020 and 18.13.030, Alaska Statutes, create a private right of action and criminal penalties relating to violations of genetic privacy.⁷⁶ Likewise, § 760.40 (2) (a), Florida Statutes, characterizes these results as “the exclusive property of the person tested.” Similarly, § 10-3-1104.7 (1) (a), Colorado Revised Statutes, and § 33-54-1 (1), Official Code of Georgia, refer to genetic information as “the unique property” of the individual, and justify restricting access to this information as a means to “protect individual privacy” and “preserve individual autonomy.” Louisiana law refers to genetic information simply as “property” under § 22:1023 (E), Louisiana Revised Statutes.⁷⁷

Security. A handful of states have passed laws requiring companies that deal in DNA data or other kinds of biometric data to ensure that these types of information are not vulnerable to hackers. For example, Illinois recently enacted the Personal Information Protection Act, or 815 Illinois Compiled Statutes 530/1. This law generally requires “data

73. For examples of similar laws, see § 41-1463, Arizona Revised Statutes, § 11-5-403, Arkansas Code, and §§ 39-8303 and 39-8304, Idaho Code.

74. See, for example, 19 Delaware Code, § 711, and § 23:368, Louisiana Revised Statutes.

75. Professor Jessica Roberts (University of Houston Law Center) notes that DTC companies themselves nod to their customers’ possible ownership, with statements like “[y]ou always maintain ownership of your DNA and DNA data” (Ancestry) or requests to acknowledge “Waiver of Property Rights” (23andMe). Jessica Roberts, “Progressive Genetic Ownership,” *Notre Dame Law Review* 93 (2018), 1105–1128: 1129.

76. These and other provisions were created under 2003 Alaska Senate Bill 217. At least one DTC company—Gene by Gene, known as Family Tree DNA—has challenged this law, arguing that it is unconstitutionally vague. Jennifer K. Wagner, “A Constitutional Challenge to Alaska’s Genetic Privacy Statute,” *The Privacy Report*, July 18, 2017; Reed Smith, “Ninth Circuit Affirms Class Certification Denial in Genetic Information Privacy Case,” *Technology Law Dispatch* (blog), Lexology, August 24, 2018.

77. Similar laws have been proposed in other states. See, for example, 2019 Vt. HB 370, which would “identify a DNA sample and the results of a DNA analysis performed on the sample as the exclusive property of the person sampled.”

collectors” to implement “reasonable security measures” to protect against unlawful data breaches and notify Illinois residents of any breach that might expose their data. Although the law does not specifically mention genetic information, such information likely falls under the category of “unique biometric data” covered under the law. Other states have considered similar bills during the most recent legislative session.⁷⁸

Guidance. Oregon stands apart in having enacted legislation to establish the Advisory Committee on Genetic Privacy and Research in 2001. It exists under § [192.549](#), Oregon Revised Statutes, and provides recommendations to the legislature biennially.⁷⁹ Earlier this year, [2019 Connecticut Senate Bill 1108](#) was enacted to create a task force to study consumer privacy more broadly.⁸⁰

These categories of concern—and legislative responses to them—will likely evolve as the public becomes more aware of the DTC industry and its implications. Accordingly, organizations like the National Human Genome Research Institute track legislation in this area so that stakeholders may access up-to-date information.⁸¹

Wisconsin law

Most provisions of the Wisconsin Statutes relating to DNA pertain to its use within the context of criminal investigations and prosecutions.⁸²

Beyond these provisions, other statutes mirror federal protections against genetic discrimination in employment and health insurance. Under Wis. Stat. § [631.89](#), insurers, the state, and various political subdivisions that provide health care services on a self-insured basis are generally prohibited from requiring or requesting any member to obtain a genetic test. The same entities are also prohibited from requesting or requiring members or health care providers to reveal test results, conditioning insurance coverage or health care benefits on test results, and determining rates or other aspects of coverage based on test results. Subsequent provisions under the statute specify that these prohibitions do not apply to life insurance coverage or income continuation coverage.

Additionally, Wis. Stat. § [111.372](#) generally prohibits genetic testing by employers, employment agencies, labor organizations, and licensing agencies. Under this statute, ge-

78. Examples include companion proposals [2019 Iowa HB 14](#) and [SB 1071](#); companion proposals [2019 Md. HB 1127](#) and [SB 786](#); companion proposals [2019 Minn. SB 2912](#) and [HB 2917](#); and [2019 Pa. HB 245](#).

79. “[Oregon Genetic Research Policy and Laws](#)” and “[History of Oregon’s Genetic Privacy Law](#),” Oregon Health Authority, accessed October 15, 2018.

80. A similar measure in New York, [2019 N.Y. SB 5140](#), has not passed.

81. “[Genome Statute and Legislation Database](#),” National Human Genome Research Institute, last updated January 10, 2019. See also University of Minnesota, “[LawSeq](#),” <https://lawseq.umn.edu/>.

82. For example, under Wis. Stat. § [939.74 \(2d\)](#), the state may commence prosecution of a person whose DNA matches genetic material collected as evidence of the identity of the person who committed the felony in question. Under Wis. Stat. § [973.047 \(1f\)](#), a court must require a genetic sample for analysis from a person sentenced or placed on probation. Any person determined to be a sexually violent person must also submit a genetic sample for analysis under Wis. Stat. § [980.063 \(1\) \(a\)](#). Under Wis. Stat. § [974.07 \(2\)](#), certain persons who are convicted of a crime, adjudicated delinquent, or found not guilty by reason of mental disease or defect may petition for postconviction DNA testing.

netic testing may not be used as a condition of employment, labor organization membership, or licensure, and may not affect the terms, conditions, or privileges of the same.

Finally, Wis. Stat. § 134.98 (1) (b) defines “personal information” as “an individual’s last name and the individual’s first name or first initial” in combination with certain other information, which includes DNA data.⁸³ Generally, Wis. Stat. § 134.98 requires certain entities that “maintain or license” personal information to “make reasonable efforts” to notify persons whose information has been acquired by unauthorized parties, per Wis. Stat. § 134.98 (2) (a). These provisions establish some protections related to data privacy; however, they do not apply to deidentified DNA.⁸⁴

No provision of the Wisconsin Statutes directly addresses commercial genetic testing companies.

Conclusion

In 2013, the U.S. Supreme Court authorized law enforcement officers to take DNA samples from suspects without their consent in *Maryland v. King*. In his dissent, Justice Antonin Scalia issued a stern warning about the dangerous implications of this decision, which he believed laid the foundation for a society of total genetic surveillance, or a “genetic panopticon.”⁸⁵ Years later, millions of Americans have voluntarily forfeited their genetic privacy by submitting DNA samples to DTC companies. As journalist Matt Fort wrote of Scalia’s dissent, “it turns out the American people may have built that genetic panopticon themselves.”⁸⁶

Is it too late to turn back the clock? How can Americans access the benefits of genetic analysis without compromising their privacy? State legislatures have attempted to find a middle ground through proposals that address consent, ownership, and protections against discrimination. However, few proposals do more than codify practices already implemented by DTC companies.

Looking forward, policymakers must consider not only the privacy of DTC customers, but also the privacy of individuals who choose not to undergo testing but are nonetheless identifiable using commercial or open-source databases. They must also strike a balance between privacy interests and scientific progress. Critics warn that an overly cautious approach to DNA data may stall genetic research. In China, for example, laws prohibit transfer or publication of DNA data outside the country without prior government

83. Wis. Stat. § 134.98 (1) (b) 4.

84. 2005 Wis. Act 138 (2005 SB 164).

85. *Maryland v. King*, 569 U.S. at 482. For a brief but helpful introduction to eighteenth-century thinker Jeremy Bentham’s concept of the panopticon, see Ronald Collins, “Panopticon?—Keep Your Eyes on the Word!” *SCOTUSblog*, Supreme Court of the United States Blog, June 5, 2013.

86. Matt Ford, “How the Supreme Court Could Rewrite the Rules for DNA Searches,” *New Republic*, April 30, 2018.

approval.⁸⁷ On the other end of the spectrum, self-regulation may promote progress, but the benefits of progress may accrue unevenly. Americans who purchase testing kits today may someday depend on expensive drugs discovered (and patented) using their own genetic material. More troubling, they may suffer unanticipated consequences—denial of life insurance, home loans, or private school entrance—simply because they sought to satisfy their curiosity about DNA. ■

87. David Cyranoski, “China’s Crackdown on Genetics Breaches Could Deter Data Sharing,” *Nature*, November 13, 2018.