D-N-ABLEISM: THE EVOLUTION OF DATA-BASED DISCRIMINATION WITH HOME DNA KITS

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I. Introduction

For anyone who’s ever been curious about their family history, their genetic predisposition for certain traits or diseases, or even how to tailor a diet to fit their biological makeup, at-home DNA kits can seem like the perfect product.\(^1\) For a relatively low cost, customers can purchase a kit from companies such as 23AndMe or Ancestry.com, mail in a saliva sample or cheek swab, and receive comprehensive reports regarding anything from their personal ethnic heritage to possible relatives.\(^2\) Despite their accessibility and widespread use, however, these kits aren’t necessarily innocuous; the data obtained by

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\(^1\) See Maggie Fox, *What you’re giving away with those home DNA tests*, NBC NEWS (Nov. 18, 2018), archived at https://perma.cc/CJ6U-WNDQ (asserting that some DNA kits can provide information about one’s ancestors and an individual’s perfect diet based on genetic information); Edward Baig, *DNA testing can share all your family secrets. Are you ready for that?*, USA TODAY (July 4, 2019), archived at https://perma.cc/V63J-6NNX (claiming that these tests can provide information regarding genetic markers which may show a predisposition for disease); Cheryl Erwin, *Legal update: living with the Genetic Information Nondiscrimination Act*, 10 AM. J. MED. GENET. 869, 869 (2008) (detailing how “[t]he information about one’s family may provide significant insight into the likely propensities of an insured or employee, including the likelihood of alcoholism, depression, risk-taking behavior, mental health, and other health experiences.”).

\(^2\) See Baig, supra note 1 (detailing the low cost of these kits and how samples are collected); Julian Segert, *Understanding Ownership and Privacy of Genetic Data*, HARV. SCI. NEWS BLOG (Nov. 28, 2018), archived at https://perma.cc/K8HC-GKAE (expanding upon the assertion that these services are low-cost); Scott Simon, *Privacy and DNA Tests*, NPR (Nov. 9, 2019), archived at https://perma.cc/NG5H-3HXV (demonstrating that these tests can provide “data on [one’s] ethnic heritage” or aid in “getting] connected with long lost cousins.”

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these companies is retained and stored, and presents the public with a series of different concerns regarding access to that data by third parties, including law enforcement or potential employers.3

While many of these testing companies have robust privacy policies in place which supposedly inform and protect users, they are neither airtight nor easy to comprehend for most consumers.4 The speed of technological evolution in this field has stunted attempts to regulate the industry, and while larger companies such as Ancestry have been amenable to increased regulation regarding the parties with whom their data can be shared, that sentiment is not uniform throughout the trade.5 While leading brands cash in on their position in the market with high sales, smaller brands may need to monetize the data that they collect in order to stay afloat by selling this information to third parties.6 Any of these companies may also be subject to court

3 See Fox, supra note 1 (listing some possible third parties which might be able to access this information, including law enforcement and employers); Mark A. Rothstein, Discrimination Based on Genetic Information, 33 Jurimetrics 13, 13 (1992) (presenting employers’ access to genetic information as a potential risk to individuals’ privacy rights); Amy L. McGuire et al., DNA data sharing: Research participants’ perspectives, 10 Nat’l Inst. Health 46, 50 (2008) (relaying the results of a study in which “[m]ost of the participants . . . [felt] that it is either very important or extremely important that they be informed about the possibility that their DNA data may be shared with others.”).

4 See Baig, supra note 1 (explaining Ancestry’s approach to a privacy policy and the risk of consumer confusion when faced with complex legal jargon).

5 See Fox supra note 1 (providing that Ancestry is open to regulation which is in line with what is already in their own privacy policies, which their executives see as being comprehensive). Senator Chuck Schumer requested that the Federal Trade Commission, “take a serious look at this relatively new kind of service and ensure that these companies can have clear, fair privacy policies.” Id. Ancestry responded in a public statement: “We respect and agree with Sen. Schumer’s concern for customer privacy and believe any regulation should match the commitments we make to our customers . . . . We do not sell your data to third parties or share it with researchers without your consent.” Id. See Baig, supra note 1 (describing claims by Ancestry and 23AndMe). Ancestry, through its chief privacy officer Eric Heath, emphasizes that it “insists on a search warrant or court order if investigators request DNA data on a customer,” and they may seek to challenge such an order if Ancestry does not believe the order is lawful. Id. Ancestry claims it has only ever received ten valid requests for user data and provided information only in seven of those instances. Id. 23AndMe similarly claims that it resists law enforcement pressure to provide consumer data whenever it is lawful to do so. Id.

6 See Baig, supra note 1 (positing that some genetic testing companies may attempt to monetize the data that they are provided to turn a profit).
orders and other law enforcement pressure to divulge user data for investigative purposes.\(^7\)

The direct-to-consumer (“DTC”) genetic testing industry is in desperate need of increased regulation to protect the privacy and civil rights of consumers from law enforcement overreach and potential discrimination by third-party employers. This means creating firm guidelines regarding if, when, and how user data is shared with third parties, as well as providing more transparent and easy-to-read terms and conditions to their users. While there are some safeguards in place, including the few cases which have touched on the subject to date, as well as landmark legislation preventing genetic and disability-related discrimination, there is currently too much discretion afforded to individual companies. The information compiled by genetic testing companies is incredibly sensitive and creates significant risk of harm to consumers when that information is shared. If handled inappropriately, this information puts any number of populations at risk, perhaps none more than those with specific genetic markers indicating presence of or likelihood of developing some disease, disorder, or disability. Thus, more comprehensive law must be enacted to fill these gaps left in broad federal legislation and litigation so that companies are not afforded the opportunity to turn a profit by exposing consumers to discrimination in employment and criminal justice.

II. History

The development of law surrounding at-home genetic testing and the consequences of their use had its groundwork laid in the 1990s with the enactment of laws which serve to protect the civil rights of people with disabilities, and more specific rights to privacy and protection have been carved out through recent litigation.\(^8\) Presently,

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\(^7\) See Simon, supra note 2 (detailing how law enforcement has at times sought cooperation from genetic testing companies in turning over sensitive genomic information for investigative purposes).

\(^8\) See Americans with Disabilities Act of 1990, 42 U.S.C.S. §§ 12101–12213 (LEXIS through Pub. L. No. 117-285 (excluding Pub. L. No. 117-263)) (establishing law around discrimination against people with disabilities in certain types of public accommodation, including employment). The Act broadly states, regarding employment discrimination, that “[n]o covered entity shall discriminate against a qualified individual with a disability because of the disability of such individual in regard to job application procedures, the hiring, advancement, or discharge of employees, employee compensation, job training, other terms, conditions, and
these measures work together to provide a thin shield of protection to users, though many concerns about consent, third-party sharing, and an overall lack of industry-specific regulation still plague its users.\(^9\)

\textbf{A. Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)}

One of the earliest efforts to protect medical information in the modern regulatory environment was the Standards for Privacy of Individually Identifiable Health Information, which was passed as a part of the 1996 legislation known as HIPAA.\(^10\) Subject to this rule were a series of health-related entities including health providers and insurers, which were barred from disclosing specific identifiers of the

\textit{privileges of employment.”} \textit{Id. at} § 12112(a). It defines employment discrimination as:

- limiting, segregating, or classifying a job applicant or employee in a way that adversely affects the opportunities or status of such applicant . . . [or] participating in a contractual or other arrangement . . . subjecting a covered entity’s qualified applicant or employee with a disability to the discrimination prohibited by this title.

\textit{Id. at} 12112(b)(1)–(2). Prohibited discrimination can also occur via actions which have the effect of disability-based discrimination if not the intent, or those which perpetuate discrimination. \textit{Id. at} 12112(b)(5)(A). Failing to make reasonable accommodations for an employee with a disability also constitutes discrimination under the ADA. \textit{Id.} \textit{See also} Sessa v. Ancestry.com Operations, Inc., 561 F. Supp. 3d 1008, 1016 (D. Nev. 2021) (outlining litigants’ objections to Ancestry.com’s use of their yearbook photographs and other personal information).

\(^9\) See Fox, supra note 1 (naming consent issues as a possible concern for consumers); Simon, supra note 2 (highlighting third-party sharing with law enforcement as a potential risk to consumer civil rights, and that little regulatory standards yet exist in the field).

\(^{10}\) See generally Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C.S. § 1320(d) (LEXIS through Pub. L. No. 117-285 (excluding Pub. L. No. 117-263)) (providing the language of the Act). \textit{See also} Xinhua Shi & Xintao Wu, \textit{An overview of human genetic privacy}, 1387 \textit{Ann. N.Y. Acad. Sci.} 1, 18 (2017) (outlining the milestone regulation). Shi and Wu describe HIPAA’s Privacy Rule as “address[ing] the use and disclosure of individuals’ health information . . . by covered entities . . . and provid[ing] standards for individual privacy rights to understand and control the use of their health information.” \textit{Id. at} 6. They add that “covered entities of the Privacy Rule include health providers, insurers, data clearinghouses, and their business partners,” but that “information not originated from these covered entities are not covered by HIPAA.” \textit{Id.}
individual. As of 2013, HIPAA actively protects genetic information, but only when that information can be identified with an individual and is in the custody of a covered entity, such as a hospital or insurer. However, direct-to-consumer testing services are not covered by HIPAA unless they are owned by a covered entity. This means that while covered entities like health care practitioners and insurance companies cannot share genetic information with genetic testing companies, those same genetic testing companies are not subject to the protections provided by HIPAA, and as such can make disclosures of the same information without any violation of HIPAA. 

B. The Americans with Disabilities Act & Employment Discrimination

The Americans with Disabilities Act ("ADA") was enacted with the goal of prohibiting discrimination against people with disabilities, including in places of public accommodation and employment. Title

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11 See Shi & Wu, supra note 10 (listing the covered entities under the Privacy Rule); Marco D. Sorani et al., Genetic Data Sharing and Privacy, 13 NEUROINFORMATICS 1, 6 (2015) (noting that HIPAA “enumerates 18 identifiers that must be suppressed.”).


13 See Kim Hart, Genetic testing firms share your DNA data more than you think, AXIOS MEDIA (Feb. 25, 2019), archived at https://perma.cc/48ZS-MTAF (explaining that “[c]ommercial DNA-testing services aren’t specifically covered by federal privacy rules, such as HIPAA, because they aren’t health providers or insurers.”).

14 See Carolyn Riley Chapman et al., Genetic discrimination: emerging ethical challenges in the context of advancing technology, 7 J. L. & BIOSCIENCES 1, 23 (2019) (emphasizing that HIPAA protections do not extend to “direct to consumer genetic testing companies and health apps”).

15 See Americans with Disabilities Act of 1990, 42 U.S.C.S. § 12112 (prohibiting discrimination against individuals in several areas of public accommodation, including employment). This law also clarified legal definitions of disability, accommodations, and discrimination vital to understanding the scope of antidiscrimination regulation in the ADA and successive legislation. Id. at §§ 101–
I and Title II of the ADA deal specifically with employment discrimination, including both current and prospective employees.\textsuperscript{16} Title I sets forth requirements for employers to accommodate applicants and employees who have disabilities, while Title II outlines requirements for covered entities to ensure that people with disabilities can participate in programs and activities which are regularly accessible to non-disabled people.\textsuperscript{17} Complaints against an employer or potential employer for a specific violation of the ADA are typically filed directly with the U.S. Equal Employment Opportunity Commission (“EEOC”), which is responsible for bringing suits against private employers; if the employer is a governmental entity, the Department of Justice (“DOJ”) can bring suit instead.\textsuperscript{18} Many of the cases filed against employers by the EEOC and DOJ involve employees who were denied reasonable accommodations requests upon disclosing that they had a disability, termination due to the onset of a disability, and screening people with disabilities out of the hiring process.\textsuperscript{19} One such complaint even alleged that hiring practices within a Minneapolis, MN police department would require applicants

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\textsuperscript{16} See Fighting Discrimination in Employment Under the ADA, ADA.GOV. (Oct. 24, 2021), archived at https://perma.cc/A6DD-ZD8U [hereinafter Fighting Discrimination in Employment] (outlining Title I and Title II hiring practices protections which serve to protect people with disabilities, as well as providing a list of landmark complaint summaries and their corresponding outcomes in favor of the complainant).
\textsuperscript{17} See THE AMERICANS WITH DISABILITIES ACT: A BRIEF OVERVIEW, Job Accommodation Network (July 26, 2012), archived at https://perma.cc/HD27-NTXL (summarizing the five sections of the ADA, including Titles I and II described above).
\textsuperscript{18} See Fighting Discrimination in Employment, supra note 16 (detailing the process of alleging ADA violations against an employer, as provided by the division of the DOJ responsible for following through on any such filings).
\textsuperscript{19} See id. (describing some of the cases that the EEOC and DOJ have fought involving employment discrimination on the basis of disability and genetic information). These include several cases spanning from 2017 to 2020, against both private and governmental entities, most all of which were eventually settled out of court with monetary compensation and requirements that the companies or institutions make changes to policies and patterns of behavior. Id.
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to provide their genetic information to be considered for employment.\textsuperscript{20}

Prior to the enactment of the ADA, there was little recourse for people with disabilities who had experienced discrimination in employment.\textsuperscript{21} People with disabilities were often underemployed and underpaid compared to non-disabled peers of similar education levels.\textsuperscript{22} The ADA set forth a prohibition on discrimination against qualified individuals because of a disability and required that reasonable accommodations be made for people with disabilities in places of employment.\textsuperscript{23} Discrimination here, in part, refers to any limitation or adverse impact on an employee’s opportunities, benefits, or status of employment based off of the employee’s disability status.\textsuperscript{24} Further, except in specifically enumerated circumstances under the ADA, employers are prohibited from making inquiries into the medical background of any individual employee.\textsuperscript{25} Consequences for

\textsuperscript{20} See id. (referencing a pattern of hiring discrimination within the City of Minneapolis, Minnesota wherein applicants for police officer jobs were expected to provide their genetic information as a part of pre-employment screening). This case was settled out of court, but this settlement included a series of consequences for the department, including measures to prevent any future instances of this practice in that department. \textit{Id.}

\textsuperscript{21} See Americans with Disabilities Act of 1990, 42 U.S.C.S. § 12101(a)(4) (enumerating Congress’s findings as a part of the ADA, including that “unlike individuals who have experienced discrimination on the basis of race, color, sex, national origin, religion, or age, individuals who have experienced discrimination on the basis of disability have often had no legal recourse to redress such discrimination[.]”). The ADA defines the term disability as someone having “a physical or mental impairment that substantially limits one or more of the major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment.” \textit{Id.} at § 12102(1).


\textsuperscript{23} See Americans with Disabilities Act of 1990, 42 U.S.C.S. § 12101(b) (declaring that the purpose of the ADA is to “provide a clear and comprehensive national mandate for the elimination of discrimination against individuals with disabilities[.]”).

\textsuperscript{24} See id. at § 12101(5) (defining discrimination under the ADA).

\textsuperscript{25} See id. at § 12112(d) (prohibiting the use of medical examinations or disability inquiries except when used to provide specific, requested accommodations, or in a set of specific circumstances relating to an individual’s physical or mental ability to substantially perform the job as described). The ADA also specifically carves out certain instances where medical examination may be acceptable, including to ensure
ADA violations fall in line with requirements set forth in the Civil Rights Act of 1964, and also set out monetary penalties for offenders depending on how many offenses the organization has committed; however, as many of these cases settle out of court, some measures intended to remediate the behavior may instead be incorporated into settlement agreements.  

C. The Genetic Information Nondiscrimination Act of 2008 & Employment Discrimination

The Genetic Information Nondiscrimination Act of 2008 (“GINA”) expanded on the directives of the ADA to prevent employers from specifically using genetic information to make employment decisions, intentionally obtaining genetic information from a potential or current employee, or use that information for harassment or retaliation.  

For example, a company would be barred from requiring applicants to submit genetic tests as part of its employment screening process. Additionally, employers are prohibited from evaluating an individual’s genetic test results or other genetic information to make hiring, firing, promotion, or other employment decisions. This includes using genetic information to determine an individual’s predisposition to a disease or disorder.  

Individuals meeting certain qualifications to maintain safety in the workplace, to permit religious institutions to give preference in employment to practitioners of that religion, to prevent the passage of communicable diseases, or to prohibit the usage of illicit substances by employees.

26 See id. (directing the reader to information regarding the consequences for an employer’s violation of the ADA). See generally Genetic Information Nondiscrimination Act of 2008, 42 U.S.C.S. §§ 2000ff–2000ff-11 (LEXIS through Pub. L. No. 117-285 (excluding 117-263)) (providing the definitions for the Act); The Genetic Information Nondiscrimination Act of 2008: “GINA,” U.S. DEP’T LAB. (Feb. 14, 2023) archived at https://perma.cc/4N4G-L87R [hereinafter Dep’t of Labor on “GINA”] (defining genetic information as information including “disease or disorder in family members . . . an individual’s genetic tests . . . or any participation in genetic testing or genetic counseling . . . .”); Fighting Discrimination in Employment, supra note 16 (indicating that most of the notable complaints made to the EEOC/DOJ in recent years are settled rather than disputed in court). See also Fighting Discrimination Against Disabled People in America, CASEGUARD (Nov. 18, 2021), archived at https://perma.cc/85RB-ZDAQ (noting the possible monetary penalties as well as the right of state and local governments to impose increased penalties beyond the ADA requirements); What is The Genetic Information Nondiscrimination Act of 2008?, CASEGUARD (Sept. 13, 2021), archived at https://perma.cc/SXR2-T84J (highlighting the differences in monetary penalties for cases of unintentional versus intentional non-compliance with GINA).

27 See Dep’t of Labor on “GINA,” supra note 26 (delineating the specific prohibitions contained within the 2008 legislation). See also Kathy L. Hudson et al., Keeping Pace with the Times – The Genetic Information Nondiscrimination Act of 2008, 358 N. ENGL. J. MED. 2661, 2661 (2008) (outlining the legislation). But see Angela Chen, A House committee thinks your boss should be able to see your genetic information, THE VERGE (Mar. 20, 2017), archived at https://perma.cc/YCK5-PVFB.
from firing or otherwise retaliating against an employee should it discover its employee’s genetic code contained a gene which predisposed that employee to having a disease which is expensive to treat or could potentially cause an employee to have limited capacity in the scope of their duties, schedule, or other areas which might require accommodations.\textsuperscript{28}

Though GINA forbids employers from actively seeking out applicants’ and employees’ genetic information, it is possible that this information could be obtained inadvertently.\textsuperscript{29} The law here prohibits (suggesting that GINA’s protections are very limited). See also \textit{Genetic Information, U.S. Dep’t Health & Hum. Servs.} (June 16, 2017), archived at https://perma.cc/8ZGQ-C4UF (noting that there have been efforts made to clarify what GINA covers). See also Louise Slaughter, \textit{Genetic Information Non-Discrimination Act}, 50 HARV. J. LEGIS. 41, 49 (2013) (highlighting how the process of approving GINA in Congress significantly narrowed the scope of its coverage). See also Mark A. Rothstein, \textit{Putting the Genetic Information Nondiscrimination Act in context}, 10 AM. COLL. MED. GENETICS 655, 655 (2008) (adding that GINA only applies to people who are asymptomatic rather than demonstrating symptoms of a disease or disorder). \textit{Contra} Phillip K. Vacchio & Joshua L. Wolinsky, \textit{Genetic Information Nondiscrimination Act of 2008: It’s in Title VII’s Genes}, 29 HOFSTRA LAB. EMP. L. J. 229, 233 (2011) (detailing how “[s]ome groups representing businesses argue that GINA is an ‘unnecessary and costly burden on employers’”). See also \textit{What is genetic discrimination?}, MEDLINEPLUS (July 28, 2021), archived at https://perma.cc/3ZUT-ANUK (pointing to the fifteen-employee floor on employers before GINA applies).

\textsuperscript{28} See Fox, supra note 1 (discussing the Genetic Information Nondisclosure Act and possible examples of its application in the workplace). See also Lucy Erickson, \textit{Consent in the context of genetic information: Does it really only belong to you?}, AAAS (Apr. 16, 2019), archived at https://perma.cc/ET4H-QTPR (asking “[w]hat if a potential employer refuses to hire you for a high-pressure job because your medical records indicate a predisposition to heart disease?”). \textit{Contra} ANGUS JOHN CLARKE, EMERY AND RIMOIN’S PRINCIPLES AND PRACTICES OF MEDICAL GENETICS 799 (Rimoin, D.L. et al., eds., 6th ed. 2007) (asserting that these tests are not sensitive enough to detect the risk of developing some disease or disorder, making their use inefficient in predicting predisposition).

\textsuperscript{29} See \textit{Genetic Information Nondiscrimination Act} (GINA) of 2008, 42 U.S.C.S. § 2000ff–1(b) (LEXIS through Pub. L. No. 117-285 (excluding 117–263)) (explaining the circumstances under which an employer may inadvertently come into possession of the genetic information of their employees). This may occur, for example, in instances where the employer offers voluntary genetic services as a part of a health program, the employee provides authorization voluntarily with or without limitations on who may access this information, in compliance with other regulations such as the Family and Medical Leave Act of 1993, when that information is commercially and publicly available (not including medical databases or court records). \textit{Id. See also Genetic Information Discrimination, U.S. EQUAL EMP. OPPORTUNITY COMM’N
the use of any information obtained by inadvertent means; however, there are likely barriers to proving that an employer obtained and used that information in a discriminatory fashion.\textsuperscript{30} This can substantially inhibit an employee or applicant’s ability to challenge any actions taken against them, which significantly hinders the scope of this regulation’s applicability.\textsuperscript{31} Further, a report by the Government Accountability Office asserted that as of 2010, the reliability of these tests in both accurately predicting a consumer’s risk for a certain disease and correctly returning the results belonging to the specific consumer were questionable at best.\textsuperscript{32}

\textit{D. Third-Party Sharing with Law Enforcement}

While law enforcement has access to their own databases of DNA collected pursuant to state law and federal oversight, some law enforcement organizations have sought out alternative means of...

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\textsuperscript{30} See Genetic Information Discrimination in the Workplace, supra note 29 (describing the restrictions on the use of inadvertently obtained data). See also Fox, supra note 1 (describing how GINA “forbids discrimination based on genetic information[,]” but that, per Peter Pitts of the Center for Medicine in the Public Interest, “it would also be hard to prove an employer did that”).

\textsuperscript{31} See Fox, supra note 1 (stating the difficulty of proving employer misconduct).


A 2010 report by the Government Accountability Office (GAO) studied four major DTC genetic test companies and came to the conclusion that the tests are “misleading and of little or no practical use.” After submitting samples from the same donors to different companies, the investigators found a single person could be told he was at below average, average, and above average risk for a single disease, depending on which company was used. Another blow to the industry’s credibility occurred in June 2010, when a sample swap at 23andMe resulted in 96 customers receiving data that did not belong to them, leading to confusion, distress, and privacy concerns.
comparing stored genetic sequences to crime scene DNA. Among the most famous instances of DTC genetic databases being used for law enforcement purposes involves the discovery of the identity of the Golden State Killer, who perpetrated a series of killings across California in the 1970s and 1980s, which went unsolved until recent breakthroughs. That case involved one genealogical site called GEDmatch, which compiled a database of over a million users’ genetic information. When they signed up for the service, users agreed that the information was to be publicly available. California law enforcement used the information contained therein to match distant relatives of the killer with DNA which was found at the site of the murders, and build family trees from those matches to identify possible suspects.

Even more recently, Florida law enforcement sought a warrant to use this database specifically because that data was not thoroughly protected by extensive privacy policies from the company. When the

33 See James W. Hazel & Ellen Wright Clayton, Law Enforcement and Genetic Data, HASTINGS CTR. (Jan. 20, 2021), archived at https://perma.cc/H8ZD-8D5R (discussing law enforcement use of CODIS, a genetic database maintained by law enforcement). See also Nila Bala, We’re Entering a New Phase in Law Enforcement’s Use of Consumer Genetic Data, SLATE (Dec. 19, 2019), archived at https://perma.cc/2XX4-DEVR (stating that the use of genetic genealogy by law enforcement has reached significant numbers, including an estimated 200 instances in 2018); Lindsey Wade, Notes From the Field: Expanding the DNA Database to Solve Cold Cases, NAT’L INST. JUST. (Nov. 12, 2019), archived at https://perma.cc/T4Q5-82NT (detailing regulation of police DNA databases).

34 See Simon, supra note 2 (noting that one prominent instance where publicly available data from the database GEDmatch was used for a criminal investigation). See also Jesse Schwab, New DOJ Policy Gives Genealogy Website Users Weak Privacy Protections From Law Enforcement, HARV. CIV. RTS. - CIV. LIBERTIES L. REV. (Oct. 3, 2019), archived at https://perma.cc/EG6G-T8HV [hereinafter New DOJ Policy] (noting that there were no regulations in place to dictate how law enforcement could use publicly available DNA information).

35 See Simon, supra note 2 (stating that the GEDmatch database included approximately 1.2 million users’ genomic information).

36 See id. (discussing the consent agreement GEDmatch users signed when submitting their data, which permitted the company to share their information with the public).

37 See id. (explaining how the database was used to identify the Golden State Killer). See also Fox, supra note 1 (expounding further on how DNA from the crime scene was matched to distant relatives of the killer).

38 See Simon, supra note 2 (detailing law enforcement use of this database in another instance in Florida). See also Baig, supra note 1 (noting the nearly half of the 90 top
public became aware of this database’s use in an investigative capacity for a case without the notoriety of the Golden State Killer, pushback against the company’s lack of privacy policies caused the company to eliminate public access to this information. After contemplating public access to its data, GEDmatch changed their policies to require individuals to opt in to share information with law enforcement officials. Many companies, Ancestry included, have insisted that they have robust privacy policies and do not share genomic information with law enforcement unless ordered by a court. However, a precedent of companies flouting their privacy policies has been set by Family Tree DNA, which cooperated with the FBI on several occasions, and received an onslaught of public backlash in response.

E. Case Law

There is little precedent to work with in this area of law, perhaps owing to arbitration clauses within consumer contracts that would force consumers into private proceedings. Even in light of these genetic testing companies which “had either no policy available to consumers on their website or policies that did not even mention genetic testing or genetic data.”). See Simon, supra note 2 (postulating that public outcry likely prompted the company’s decision to privatize the once-publicly-accessible genomic data of its users).

See Baig, supra note 1 (providing that GEDmatch, among other companies, has made changes to account for consumer pressure to alter privacy policies).

See id. (quoting Ancestry representatives’ claims that their privacy policies are comprehensive and that they do not readily provide information to law enforcement unless obligated to under court order).

See id. (asserting that Family Tree DNA defied their own policies in order to cooperate with law enforcement agencies, a fact which was leaked to the public). Family Tree DNA, like GEDmatch, has made changes to its policies regarding sharing information with law enforcement. Id. See also Diahan Southard, DNA Testing, Law Enforcement Access and Privacy, YOUR DNA GUIDE (Aug. 22, 2019), archived at https://perma.cc/435K-B2X4 (discussing how it appears that Ancestry, 23andMe, and MyHeritage actively attempt to prevent law enforcement use of their data, while Family Tree DNA automatically opted-in users to law enforcement access). But see Kristen V. Brown, Major DNA testing company is sharing genetic data with the FBI, SEATTLE TIMES (Feb. 1, 2019), archived at https://perma.cc/3B5D-PVHL (sharing that Family Tree DNA asserts that it prioritizes privacy and confidentiality).

See Hughes v. Ancestry.com, 580 S.W.3d 42, 45 (Mo. Ct. App. 2019) (detailing the court’s reversal when Ancestry.com was denied its right to compel arbitration
and explaining that all users of Ancestry’s product are subject to terms and conditions granting Ancestry that right).


45 See generally Sessa, 561 F. Supp. 3d at 1016 (denying claims from a class of plaintiffs whose yearbook photos were published by Ancestry.com on the theories of copyright preemption, unjust enrichment, intrusion upon seclusion, and others); Callahan, 2021 U.S. Dist. LEXIS 112036, at *2 (holding that Art. III standing rules prevent plaintiffs from having their case heard as they did not demonstrate that they suffered some real injury).

46 See generally Cole, 2017 U.S. Dist. LEXIS 101761, at *9 (ruling that the sharing of genetic information with third parties can be prohibited under state law).

47 See id. (explaining that the plaintiff’s rights may have been violated by inadequate disclosures about how his information would be made public). “[T]he Court concludes that although Mr. Cole’s alleged injury—the dissemination of his DNA test results without his consent—may not have resulted in tangible economic or physical harm, the injury is sufficiently ‘concrete’ so as to confer Article III standing.” Id.

48 See id. (suggesting that failure to protect genomic data on users’ behalf could constitute a harm to the user).
III. Facts

Presently, the breadth of opinion about the use and protection of genetic information is about as wide as the difference in potential uses. Suggestions for combatting privacy risk and misuse vary anywhere from personal accountability to following other countries’ lead in setting stricter regulations. While there is no administrative entity regulating the activity of the DTC genetic testing industry, there is some movement toward both self-regulation and regulation by other governmental entities such as the Food & Drug Administration. Further, some bills before Congress and developing case law suggest progress toward increasing oversight.

A. Data Uses & Debate

Despite potential privacy concerns, there are a vast array of arguments in favor of increasing the availability of genetic information

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50 See Dana McCullough, Genealogist’s Guide to Protecting Online Privacy, FAMILYTREE (Nov. 21, 2021), archived at https://perma.cc/V582-93DD (suggesting user behavior which will protect privacy in personal use of DTC genetic testing and genealogical services); MARY FRAKER & ANNE-MARIE MAZZA, DIRECT-TO-CONSUMER GENETIC TESTING: SUMMARY OF A WORKSHOP, Appendix B, 47 NAT’L ACADEMIES PRESS (2010) (discussing regulatory action in other countries).


to third party organizations, not all of which are created equal.\textsuperscript{53} When provided to hospitals or research organizations, which users may already opt into, this data can provide significant educational or research opportunities.\textsuperscript{54} The externalities resulting from the communication between DTC testing companies and these types of organizations can include combating epidemics and reducing healthcare costs to consumers.\textsuperscript{55} Low-cost genetic sequencing, which might otherwise be costly through a health care provider, can also increase efficiency in healthcare by aiding in determining a patient’s likely response to a medication or even appropriate dosages.\textsuperscript{56} Genetic sequencing every child at birth has even been posited in order to alert parents to the child’s risk of developing certain disorders.\textsuperscript{57}

But despite potential benefits in healthcare, the risk of that data, even anonymized, being stored indefinitely is a cause of concern for many.\textsuperscript{58} For skeptics, it’s often frustrating that the individual companies’ privacy policies governing the sharing of information can change drastically with little notice to consumers.\textsuperscript{59} The broad scope of consent agreements, their length and complexity, and consumer propensity to simply click “accept” can often result in underinformed consent to the sharing and retention of significant pieces of sensitive

\textsuperscript{53} See Sunderman, \textit{supra} note 49, at 361–67 (weighing the cost and benefits of DTC testing).

\textsuperscript{54} See id. at 362 (describing options for the use of genetic information for more positive purposes).


\textsuperscript{58} See id. (discussing the risks of storing newborn genetic information).

\textsuperscript{59} See Jacqueline Bain, \textit{Genetic Testing HIPAA Warning: Legal Considerations}, FLA. HEALTHCARE L. FIRM (Jan. 14, 2019), archived at https://perma.cc/Y9W4-GFR6 (indicating that DTC genetic companies are only obligated to post the changes within the policies listed on their website); Ancestry.com Changes Privacy Agreement, \textit{ANCESTRY INSIDER} (June 30, 2015), archived at https://perma.cc/2D3F-HJYB (outlining changes enacted by Ancestry, which includes the provision that data can be sold to a third party if the company is sold).
information. However, some individuals do not even have the opportunity to choose to consent to the collection of their data; genetic information submitted by one person can expose details of the genetic information of a broad array of blood relatives including distant cousins. Statistical studies have also shown that a database containing three million or more samples from different individuals can effectively create “genetic transparency” for a demographic population. This could mean that a database meeting these specifications could universally identify genetic information about any person within a demographic population, such as all Americans of European descent. A recent report suggests that nearly two thirds of

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60 See Inst. of Med., Committee on Assessing Genetic Risks, Assessing Genetic Risks: Implications Health & Soc. Pol’y, 247, 249 (Lori B. Andrews et al., 1994) (emphasizing the importance of informed consent in sharing genetic information); Fox, supra note 1 (claiming that “a broad consent is part of the initial contract a consumer makes with a company when he or she submits the test for analysis,” but that consumers are accustomed to simply agreeing to the terms and conditions without reading them thoroughly). These agreements may “go on for pages [and] you may not understand what you’re giving the company permission to do[,]” Id. See also Data Sharing Policies and Expectations, Nat’l Hum. Genome Rsch. Inst. (Jan. 9, 2023), archived at https://perma.cc/UMX9-2RKT (encouraging DTC testing companies to use broad language in constructing their consent agreements).

61 See Baig, supra note 1 (explaining how submitting one’s own genetic information effectively exposes even distant blood relatives to possible identification via these databases). Asserts director of consumer privacy at Stanford Law School’s Center for Internet and Society, Jen King: “You decide to contribute your DNA to one of these services and you have by default included your parents, your siblings if you have any, your kids if you have any or your future kids, and future nieces, nephews and everybody else[.]” Id. Privacy advocates worry that “by permitting law enforcement to poke around such DNA databases, a legal shadow may be cast over innocent family members, some of whom never even submitted their DNA anywhere, much less gave their blessing to be searched by the police.” Id.

62 See Simon, supra note 2 (discussing genetic transparency across demographic populations created with the amassing of three million genetic samples).

63 See id. (providing an example of a demographic group which could be exposed to genetic transparency); Privacy in Genomics, Nat’l Human Genome Rsch. Inst. (Apr. 27, 2021), archived at https://perma.cc/Z5Y8-XTWS (discussing how these risks are heightened among certain groups). For example:

Genomic research in identifiable populations (i.e., specific racial or ethnic groups, geographically defined communities and members of ultra-rare disease groups) presents unique privacy concerns due to a diminished ability to protect the privacy of these individuals or groups. For example, members of an identifiable population may experience stigmatization or discrimination if
all Americans who have some European ancestry are already identifiable using these databases, a number which may continue to grow as consumers add to the pool of genetic information.\textsuperscript{64}

Consent of an individual to choose whether to submit their data can also be surpassed if one’s DNA is submitted by another person with access to their genetic material, as seen in the Golden State Killer case.\textsuperscript{65} Some companies permit consumers to submit DNA which is not their own in order to, for example, catch a cheating partner or determine paternity of a child.\textsuperscript{66} In these instances, the consumer who submits another’s DNA overrides that individual’s choice whether to submit genetic information for analysis, digitization, and retention by the company, as well as exposing that individual and their blood relatives to the inherent risks of that data being submitted for testing and storage.\textsuperscript{67} Law enforcement has submitted genetic material as well, such as in the Golden State Killer case, where police provided a DNA sample to GEDMatch under a fake name and were provided a list of the alleged killer’s potential relatives.\textsuperscript{68}

While genetic testing sites often attempt to anonymize data in order to strip it of its identifiers, and make bold assertions about their attempts to do so, the specificity of the genetic information available in a person’s entire genetic sequence may expose an individual to being identifiable even without their name, address, or any other

\textit{Id.}\textsuperscript{64} See Fox, supra note 1 (stating that “[m]ore than 60 percent of Americans who have some European ancestry can be identified using DNA databases, according to a recent report in the journal Science. Not only could police use this information, but so could other people seeking personal information about someone . . . .”).\textsuperscript{65} See Baig, supra note 1 (discussing some companies’ policies of permitting the submission of DNA which does not belong to the end user).\textsuperscript{66} See \textit{id.} (exemplifying one manner in which the consent of an individual to control what DNA submissions to databases are made can be circumvented).\textsuperscript{67} See \textit{id.} (reiterating that several individuals’ ability to consent has been overridden by companies which allow non-end-user DNA to be submitted).\textsuperscript{68} See Quentin Fottrell, \textit{Genealogy sites are Wild West of privacy – here’s what you give away with your DNA}, MARKETWATCH (May 5, 2018), archived at https://perma.cc/3EBJ-GXZL (highlighting law enforcement’s use of GEDMatch to submit a sample under a fake name).
additional information.\(^{69}\) When these sites fail to adequately anonymize data, even more revelatory information provided in questionnaires such as those administered by 23AndMe could make individuals even more vulnerable to privacy concerns.\(^{70}\)

There are valid arguments for law enforcement use of these tests, such as to aid in efficiently identifying murder victims, or determining a perpetrator of a crime like murder or sexual assault, which often appeal to the public.\(^{71}\) Questions of equity in law enforcement may arise, however, as law enforcement use of this data can present a risk of disparate impact against people with disabilities.\(^{72}\)

**B. Suggested Solutions**

\(^{69}\) See Fox, *supra* note 1 (expressing that anonymization of data by these companies is “far from foolproof.”). Greely asserts: “Especially if it is coupled with health information, you can say this is a 39-year-old woman from Westchester County who is five feet, seven inches tall, who has blue eyes and has cystic fibrosis — it wouldn’t be that hard for somebody to find you.” *Id.*

\(^{70}\) See *id.* (observing that “23andme has an extensive questionnaire about health, lifestyle habits and preferences and while it allows customers to skip any questions they choose to, they can be contributing a lot of personal detail with their DNA sample.”).

\(^{71}\) See Ellen Wright Clayton et al., *The law of genetic privacy: applications, implications, and limitations*, 6 J. L. & BIOSCIENCES 1, 3 (2019) (mentioning the use of DTC tests in identifying victims in mass casualty events); Simon, *supra* note 2 (emphasizing consumers’ willingness to allow law enforcement access to solve murders and sexual assaults); Andrew Perrin, *About half of Americans are OK with DNA testing companies sharing user data with law enforcement*, PEW RSCH. CTR. (Feb. 4, 2020), archived at https://perma.cc/BCK2-4F37 (observing that a plurality of Americans support sharing certain user data with law enforcement); Eric A. Feldman, *The Genetic Information Nondiscrimination Act (GINA): Public Policy and Medical Practice in the Age of Personalized Medicine*, 27 J. GEN. INTERNAL MED. 743, 745 (2012) (theorizing that genetic privacy concerns are overblown in proportion to the actual risk of genetic discrimination).

\(^{72}\) See Stephanie Pappas, *Despite the ADA, equity is still out of reach*, AM. PSYCH. ASS’N (Nov. 1, 2020), archived at https://perma.cc/H4SD-DLCW (discussing risks that may arise when people with disabilities interact with the criminal justice system). Experts note “structural barriers to justice for people with disabilities, who are vastly overrepresented” in prisons, where those “with intellectual disabilities are at high risk of victimization” and “serving lengthened sentences.” *Id.* Behaviors common to “some developmental disabilities can make some defendants look less sympathetic to law enforcement officers, judges and juries.” *Id.* Advocates also point to inaccessibility of jail facilities for those with physical disabilities, and communication barriers for inmates who are deaf. *Id.*
Experts suggest that consumers thoroughly read privacy policies, institute technological safeguards, avoid sharing certain data, and monitor personal privacy settings.\(^{73}\) Privacy organizations, however, note that government involvement is essential to closing the gaps which remain, especially because these policies are complex and lengthy, and consumers have little leverage to negotiate more preferable terms.\(^{74}\)

Other proposed solutions include looking to other countries’ legislative efforts for a guide in developing a regulatory structure in the United States.\(^{75}\) One of the more stringent regulations is an outright ban in Germany of the sale of DTC testing kits in efforts to curb Germans’ privacy concerns regarding their employers’ access to their genetic information.\(^{76}\) The UK’s policy is more complex, with a series of laws and advisory bodies which regulate the industry with respect to quality, marketing, and consumers’ informed consent.\(^{77}\) The European Union has been attempting to develop its own regulations since 2009.\(^{78}\)

In recent years, a series of different genetic testing and genealogical companies have formed what appear to be self-regulating

\(^{73}\) See McCullough, \textit{supra} note 50 (providing tips on protecting one’s identity); \textit{DNA and Genetic Data, PRIV. INT’L} (Nov. 21, 2021), archived at https://perma.cc/Q32W-2Y5U (suggesting that technological safeguards be employed for additional data safety); Xinghua Shi & Xintao Wu, \textit{Genetic Privacy: Risks, Ethics, and Protection Techniques} (Jan. 2016) (presentation at the Workshop on Data Science, Learning and Applications to Biomedical and Health) (on file with the College of Engineering at the University of Arkansas) (outlining the development of possible algorithmic solutions for data privacy).

\(^{74}\) See \textit{DNA and Genetic Data, supra} note 73 (positing government restrictions as a potential solution); Baig, \textit{supra} note 1 (explaining that legalese-heavy, lengthy privacy policies run the risk of consumers being unable or unwilling to read what they are signing to).


\(^{76}\) See \textit{Germany Bans Genetic Genealogy Tests, supra} note 75 (discussing the German ban).

\(^{77}\) See \textit{FraKer & MAZZA, supra} note 50, at 48–49 (discussing the actual legislation and the proposed framework for future regulation in the UK).

\(^{78}\) See id. at 49 (referencing a report for the European Commission with legislative documents for EU member nations).
bodies. These entities seek to promote privacy, transparency, and user control, but are still in the process of development. These organizations may also serve as lobbying organizations for the companies’ own interests, which may not line up with consumers’ interests.

Other federal regulatory bodies cover some of the gaps left by a lack of supervision in the industry; notably, the EEOC and DOJ have the authority to bring forth lawsuits over any acts of discrimination in places of employment with regard to the use of genetic information for discriminatory purposes. To date, no external regulatory bodies exist which specifically handle privacy and civil rights concerns relating to this data. Nor are there any federal limitations on what types of cases law enforcement is permitted to use this data; when law enforcement is in possession of this data, their discretion is broad regarding whether to use the data solely for particularly egregious crimes.

C. Present Attempts at State and Federal Regulation

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79 See Baig, supra note 1 (naming the two self-regulating bodies for genetic testing services). Research notes that “[l]ast year, Ancestry, 23andMe, Helix, MyHeritage, Habit, African Ancestry and Living DNA joined up with the non-profit The Future of Privacy Forum around a set of best practices for consumer genetic testing services Ancestry, 23andMe and Helix earlier this month formed The Coalition For Genetic Data Protection.” Id.

80 See id. (identifying the goals of The Future of Privacy Forum). These include “promot[ing] transparency, while also giving consumers control over how their data is collected, accessed, corrected, used in research, and deleted.” Id.

81 See id. (describing The Coalition For Genetic Data Protection as an organization whose role includes lobbying for “reasonable and uniform” privacy regulations to “ensure the responsible and ethical handling of every person’s genetic data.”).

82 See Fighting Discrimination in Employment, supra note 16 (describing the role of the EEOC and DOJ in employment discrimination suits).

83 See Fox, supra note 1 (reiterating Senator Schumer’s request for greater regulation in the industry as made to the Federal Trade Commission). See also Kaye, supra note 75 (adding that there are no regulations around the marketing of these services). Specifically, there are “few regulatory controls in place at [the UK], European, or global levels to first assess the clinical validity of tests before they get to market.” Id. Direct-to-consumer testing specifically “highlights the gaps in the regulatory regimes” by changing the “control of genetic testing from the clinical domain and medical professionals into the hands of consumers.” Id.

84 See Simon, supra note 2 (sharing the perspective of New York University professor Erin Murphy that law enforcement is lacking any guidance regarding the severity of crimes which warrant the use of genetic information).
State efforts have emerged in an attempt to bridge gaps in federal legislation. Leading the charge are Alaska and Nevada, closely followed by Arizona, California, Florida, and Utah. Amid these regulations are provisions requiring express consent before third-party sharing of data, preventing popups from tricking consumers into providing that consent, and opt-out provisions for both sharing data and its continued storage by the company. These regulations at the state level appear to provide an even broader definition of DTC companies than the FDA standard, which suggests a more closely-woven regulatory net in at least some states.

Despite efforts to introduce legislation before Congress on this topic, there is currently little meaningful progress on that front. Two different bills introduced in recent years touched on the topic of DTC genetic testing privacy, though they have since died on the floor in a previous session of Congress. These bills were introduced by opposing parties sitting on the Energy and Commerce Committee in

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85 See STATES INTRODUCE LAWS COVERING THE COLLECTION, USE, AND SHARING OF GENETIC DATA, HIPAA GUIDE (Nov. 17, 2021), archived at https://perma.cc/6XHH-GJ22 (introducing a series of legislative efforts at the state level). These laws were enacted to “protect individuals from misuse of their genetic data, to hold private companies accountable, and ensure they operate using proper data governance practices.” Id. But see Harper Jean Tobin, The Genetic Information Nondiscrimination Act of 2008: A Case Study of the Need for Better Congressional Responses to Federalism Jurisprudence, 35 J. LEGIS. 113, 113 (2009) (discussing probable state attacks on GINA and other federal legislation).
86 See STATES INTRODUCE LAWS COVERING THE COLLECTION, USE, AND SHARING OF GENETIC DATA, supra note 85 (listing which states introduced legislation); State Genetic Privacy Laws, NAT’L CONF. STATE LEGIS. (Nov. 21, 2021), archived at https://perma.cc/9DKC-UH55 (indicating which provisions are in place in which state). Genetic information has been protected by most state legislatures beyond the current scope of federal regulation. Id.
89 See Data Privacy Lawyer, LYON FIRM (Nov. 21, 2021), archived at https://perma.cc/KRJ9-RUZZ (stating that “lawmakers are scrambling to pass consumer data privacy protections.”)
90 See Genetic Information Privacy Act Summary, supra note 52 (summarizing the first bill); American Genetic Privacy Act Summary, supra note 52 (supplying the language of the second bill).
the House of Representatives, demonstrating that concerns about the industry have arisen across the political aisle.91

The first bill, introduced by Democratic Representative Bobby Rush of Illinois, sought to prohibit any disclosure of personally identifiable information to any third party without the consumer’s express consent.92 This would also have allowed consumers the choice to consent to the disclosure of certain information, while withholding the disclosure of other identifying information, as well as prohibiting companies from conditioning their use on consumers’ consent to disclose such information.93 The bill would also have granted access by the Federal Trade Commission (“FTC”) to create further regulations to prevent bad actors’ access to personally identifiable information.94

Republican Representative Tim Burchett of Tennessee introduced a bill to prohibit the third-party sharing with foreign entities of any genetic information belonging to a United States national.95 This legislation would have been much narrower, specifically prohibiting such disclosure to China.96 However, like the prior bill, this legislation would also have empowered the FTC to enforce the provisions therein.97

The sole federal administrative body within the United States government with substantial regulatory supervision over this industry is the FDA, which receives this power through the Federal Food, Drug,

91 See Genetic Information Privacy Act Summary, supra note 52 (noting the party and committee introducing the first bill); American Genetic Privacy Act Summary, supra note 52 (noting the party and committee introducing the second bill).
92 See Genetic Information Privacy Act Summary, supra note 52 (detailing the goal of the legislation and the initiating representative). This bill discusses the treatment “of personally identifiable information . . . [by] genetic testing services[s],” as well as how the law would be enforced, and its impact other laws. Id.
93 See id. (elaborating on the rights provided to the consumer).
94 See id. (empowering the FTC in a regulatory role). The Federal Trade Commission Act was incorporated by reference into this bill in section 3(a)(2). Id. See also Commissioners, FED. TRADE COMM’N (Jan. 30, 2022), archived at https://perma.cc/B3KD-UW9U (outlining the organizational structure of the FTC).
95 See American Genetic Privacy Act Summary, supra note 52 (identifying the goal of the legislation and the initiating representative). This bill prohibits any commercial DNA testing service from disclosing genetic information to China. Id.
96 See American Genetic Privacy Act of 2021, H.R. 5154, 117th Cong. (2021) (outlining more specifically the goals of the bill).
97 See American Genetic Privacy Act of 2021, H.R. 5154, 117th Cong. (2021) (noting the similar role of the FTC in each bill). The Federal Trade Commission Act was incorporated by reference in section 2(b)(2) of the bill. Id.
and Cosmetic Act.\textsuperscript{98} At present, the FDA is authorized to assess the validity of tests in measuring what it purports to measure, whether that measurement is predictive, and how it presents that information to the public.\textsuperscript{99} However, the FDA has limited its scope to only regulating tests which are marketed as kits, rather than those which are marketed as a lab-based service.\textsuperscript{100}

\textit{D. Future Challenges in Court}

As the regulatory environment surrounding data privacy and genetics continues to evolve, future litigation is likely to involve the American Civil Liberties Union (“ACLU”).\textsuperscript{101} The ACLU has forged a path of case law in the genetic privacy realm, including arguing for probable cause warrants before the release of specific medical records and filing briefs to oppose expansion of law enforcement DNA databases to pretrial arrestees.\textsuperscript{102} It has also sought to prevent corporate patents, which would prevent research into genes associated with certain cancers, demonstrating its willingness to fight for either privacy or transparency, depending on the specific circumstances of any case.\textsuperscript{103} Given the long-standing presence of the ACLU in these

\textsuperscript{98} See Wagner, supra note 51, at 451–52 (discussing administrative agencies’ roles in regulation, including the FDA); Regulatory Developments in Genetic Testing in the United States, OECD (Nov. 21, 2021), archived at https://perma.cc/W8L9-AFQU (noting the legislation which approved the FDA’s oversight).

\textsuperscript{99} See Direct-to-Consumer Tests, FDA (Dec. 20, 2019), archived at https://perma.cc/6BH3-TKS8 (sharing the FDA’s efforts in regulating this industry).

\textsuperscript{100} See Neil A. Holtzman, FDA and the Regulation of Genetic Tests, 41 JURIMETRICS J. 53, 53–54 (2000) (referencing the FDA’s choice to only regulate tests which are marketed as “kits”). See also Abraham P. Schwab et al., Genomic Privacy, 64 CLINICAL CHEMISTRY 1696, 1697 (2018) (outlining a proposal to prevent disclosure to entities beyond the FDA and few other approved entities).

\textsuperscript{101} See MEDICAL AND GENETIC PRIVACY, supra note 52 (emphasizing the ACLU’s commitment to protecting data privacy).

\textsuperscript{102} See id. (expanding on the role of the ACLU in prior cases). The ACLU filed a brief in \textit{Maryland v. King} “opposing the drastic expansion of state DNA databases” and in \textit{Griswold v. Connecticut} “opposed attempts to infringe on people’s autonomy in making medical decisions” regarding contraceptives and other medical decisions. \textit{Id.} The ACLU also successfully argued in the Supreme Court in \textit{Association for Molecular Pathology v. Myriad Genetics} that patents on genes associated with cancer should be invalidated. \textit{Id.}

\textsuperscript{103} See id. (identifying the ACLU’s presence on both sides of genetic privacy issues).
matters, and the inextricable bond of genetic privacy and civil rights, it is only natural to anticipate their involvement in future matters.\textsuperscript{104}

IV. Analysis

A. The Problem

Though the risk of discrimination and invasions of privacy may not be immediately evident from the lack of cases on-point which have garnered public attention, it is becoming increasingly clearer that this technology, if unrestrained, poses substantial risk.\textsuperscript{105} The Golden State Killer case may demonstrate what many would consider an acceptable use of this technology, but the distant cousins whose names are now associated with a serial killer might disagree.\textsuperscript{106} An average consumer’s interest in genealogy can result in discriminatory action from law enforcement, employers, or insurance companies, arising from the submission of that consumer’s DNA sample.\textsuperscript{107} If law

\textsuperscript{104} See id. (extrapolating from the historical involvement of the organization).


\textsuperscript{106} See Simon, supra note 2 (recording the opinion of NYU law professor Erin Murphy that while the potential of genetic database access for law enforcement provides an opportunity to solve cases which are “compelling” and of a “strong public interest” that “people [should] decide whether they think that’s valuable.”). She asserts that at present, law enforcement agencies have the discretion to choose to use the database for only certain crimes, as “there’s not a set of rules that law enforcement has signed on to, much less been compelled to follow.” Id. See Bala, supra note 33(asserting that law enforcement must “wade through [potential matches] to attempt to find a match.”).

\textsuperscript{107} See Perrin, supra note 71 (reiterating that concerns continue to abound with regards to consumers’ civil rights).
enforcement has access to the database to which that person submitted their DNA, they can run a sample collected from a crime scene against that database.\textsuperscript{108} If a small percentage of that person’s DNA matches the suspect sample, law enforcement can build out a family tree highlighting suspects whose DNA profiles could possibly match the suspect.\textsuperscript{109} If the suspect sample contained a genetic marker indicating that the perpetrator had sickle cell anemia, law enforcement could use that information in conjunction with the family tree to narrow possible suspects to only those who have or might have sickle cell anemia.\textsuperscript{110} As law enforcement narrows their suspect list, it may lead to the perpetrator; however, it may also expose innocent individuals to intense law enforcement scrutiny on the basis of a genetic disorder.\textsuperscript{111}

Similar risks exist when it comes to employment and insurance.\textsuperscript{112} While GINA protects against employment discrimination by larger employers and some forms of insurance, the same is not true when it comes to small business employers and life, disability, or long-term-care insurance.\textsuperscript{113} Equity in employment suffers when individuals

\textsuperscript{108} See Hart, supra note 13 (reporting that the FBI was provided access to the FamilyTreeDNA database “to test DNA samples from crime scenes against customers’ genetic information to look for family matches.”).

\textsuperscript{109} See New DOJ Policy, supra note 34 (explaining the level at which law enforcement can begin searching for potential suspects within a consumer’s family tree). The article explains:

\begin{quote}
An investigator using genetic genealogy begins the investigation by looking for DNA matches at the level of third cousin or closer. Most people have around 800 people who would fall into this category, meaning that if any one of those 800 relatives choose to submit their DNA to a database, an investigator may be able to identify an individual who has not shared their own DNA.
\end{quote}

\textit{Id.}

\textsuperscript{110} See Vacchio & Wolinsky, supra note 27, at 269 (explaining that the presence of sickle cell anemia can be detected via a genetic test). Sickle cell status has previously been used for discriminatory purposes in denying employment, though no reference is made here to its use to narrow suspects in investigative situations. \textit{Id.}

\textsuperscript{111} See Baig, supra note 1 (alluding to a “legal shadow” that could hang over innocent individuals simply because of their genetic relationship with a perpetrator).

\textsuperscript{112} See \textit{What is genetic discrimination?}, supra note 27 (enumerating limitations on GINA’s application in employment and insurance).

\textsuperscript{113} See \textit{id.} (detailing further which limitations inhibit the application of GINA and other nondiscrimination law).

GINA and other laws do not protect people from genetic discrimination in every circumstance. For example, GINA does not apply when an employer has fewer than 15 employees. GINA also does not protect against genetic discrimination in forms of
with disabilities, or the potential to develop them, are denied the same opportunities as other equally qualified individuals. The same is true of insurance; the economic disadvantages arising from certain insurance providers having access to their members’ genetic information will result in serious inequities in those born with these genetic markers.

While there have been demonstrable attempts to contain the power of DTC genetic companies through litigation, legislation, and administrative regulation, the approach has thus far been patchworked into a hole-riddled regulatory quilt. On-point litigation has not reached the Supreme Court of the United States, legislative attempts lack interstate uniformity and substantial breadth, and administrative agencies’ attempts to intervene stretch their resources and distract from their primary goals.

B. Solutions

At a time when political polarization and corporate power can limit non-incremental changes to the status quo, a multi-pronged approach

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Id.

114 See generally Genetic Information Discrimination, supra note 29 (alluding to the U.S. Equal Employment Opportunity Commission’s mission of enforcing GINA and preventing the use of genetic information for discrimination); Fighting Discrimination Against Disabled People in America, supra note 26 (extolling the principle underlying the ADA and other legislation such as GINA that “American citizens with disabilities should not be discriminated against based on their impairment, as they have the same rights and freedoms as any other citizens of the country.”).

115 See What is genetic discrimination?, supra note 27 (stating that some insurance companies still retain the right to discriminate on the basis of genetic information); Slaughter, supra note 27, at 46 (citing a study in which, prior to the institution of GINA, “a percentage of health insurance applicants were denied coverage, administered a surcharge on premiums, or given limited coverage benefits based on genetic information.”).

116 See Wagner, supra note 51 (asserting that the DTC “genetic testing industry is under considerable scrutiny by federal agencies and by Congress and has been the subject of scholars’ calls for new or increased federal regulations.”).

117 See Mullin, supra note 87 (detailing which individual states have sought to regulate the industry). The author claims that “a growing number of states are adopting genetic privacy laws in an effort to close [the] gaps” left by unregulated privacy policies and nonexistent federal legislation. Id.
which targets all three branches of the United States government could protect against partisan and lobbying attacks.\textsuperscript{118} While commendable efforts have been made at the state level, ensuring uniformity among the states and thereby protecting the population at large will only be achieved with any expedience if done at the federal level.\textsuperscript{119} DTC testing falls into interstate commerce, giving Congress the power to regulate these economic activities under the Commerce Clause of the Constitution.\textsuperscript{120} With little case law to look at, and lobbying groups like the ACLU taking the helm in advocacy, the judiciary’s role should be limited to interpreting current and future law; advocates on behalf of genetic privacy should encourage any judge to interpret the law in a light most favorable to those seeking that privacy.\textsuperscript{121} The primary push for regulation should be done legislatively, but the executive branch would also have a role in solving this problem.\textsuperscript{122}

1. Legislative Branch Solutions

While legislation like HIPAA, the ADA, and GINA have all created a foundation for preventing inappropriate disclosures of genetic information and discrimination on the basis of that information, they do nothing to target DTC genetics companies

\textsuperscript{118} See generally, Slaughter, \textit{supra} note 27 (alluding to a series of partisan challenges to GINA when it was first introduced as a bill and in any attempts to expand or constrict the rights codified therein). While she references some bipartisan support in 2008, including her “Republican colleague, Congresswoman Biggert,” she also details how a Republican senator “put a hold on GINA” to try to quell fears that employers or insurance companies would face discrimination suits, and that at large “Republicans were reluctant to add an employer provision to GINA.” \textit{Id.}

\textsuperscript{119} See Mullin, \textit{supra} note 87 (outlining which states have instituted legislation regulating the DTC genetic testing industry); \textit{State Genetic Privacy Laws, supra} note 86 (indicating which states currently have active legislation and how the DTC genetics industry is regulated). Among the regulatory categories include when consumers must consent to disclosure or retention of their genetic data, as well as who retains the property rights to that information. \textit{Id.}

\textsuperscript{120} See Tobin, \textit{supra} note 85, at 114 (referencing the regulatory powers maintained by Congress through the Commerce Clause of the United States Constitution).

\textsuperscript{121} See \textit{MEDICAL AND GENETIC PRIVACY, supra} note 52 (affirming the ACLU’s commitment to future litigation surrounding genetic privacy and disclosure).

\textsuperscript{122} See Hudson et al., \textit{supra} note 27, at 2661 (emphasizing the role of legislation in “forward looking” action in “health care, research, and policy”); \textit{Genetic Information Privacy Act Summary, supra} note 52 (suggesting that the FTC should have a role in continued regulation of the industry, thus adding in an executive branch-based enforcement of industry regulation).
HIPAA prevents disclosure by healthcare professionals, and the ADA and GINA regulate what information employers and insurance companies can seek out and what they can do with that information. Outright bans on these companies and their products, such as the one instituted in Germany, are unlikely to be accomplished in the United States. Their popularity, combined with political pressures to not overregulate the market, will likely prevent any such legislation from moving forward.

The Democrat-backed bill before Congress demonstrated a greater potential than the Republican-backed bill in terms of broadly regulating disclosures of genetic information to third parties. It would also have empowered an entity in the Executive Branch—the FTC—to handle future issues relating to this industry. However, as


125 See Germany Bans Genetic Genealogy Tests, supra note 75 (demonstrating that outright bans exist in other countries, including Germany).

126 See Mullin, supra note 87 (claiming that “Consumer Reports estimates that around 20 percent of Americans have taken a home test from companies such as 23andMe, Ancestry, MyHeritage, and Family Tree DNA,” exhibiting the degree of popularity of these kits in the United States).

127 See Genetic Information Privacy Act Summary, supra note 52 (summarizing the Democrat-backed bill, which is broader than its Republican-backed counterpart in that it applies to the disclosure of information to several entities as well as would vest power in the FTC to continue to regulate the DTC genetic testing industry); American Genetic Privacy Act Summary, supra note 52 (providing the language of the Republican-backed bill, which is limited in scope to disclosures made to China, with no provision allowing for continued regulation of the DTC genetic testing industry by the executive branch of the U.S. government).

128 See Genetic Information Privacy Act Summary, supra note 52 (asserting that the FTC would take part in the continued regulation of genetic testing companies). The proposed language states, “The Federal Trade Commission (FTC) must promulgate regulations establishing how genetic testing services are required to secure such personally identifiable information against unauthorized access. The bill grants the
it was written, the bill would not obligate these companies to make consumers’ rights clear and conspicuous within their consumer contracts, with language which is easy to understand for the average consumer. Further, the provisions of this bill were almost certainly faced with opposition from critics who would prefer narrower regulation, if any at all, or it would have been so amended at committee that it would no longer provide the same protections for which the bill was introduced. Nonetheless, incremental change can still result in increased privacy rights, so any forthcoming bill that can pass into law which would limit DTC genetic companies’ ability to disclose personal information without consent would be an improvement from the current legislative landscape.

2. Executive Branch Solutions

At present, the only executive branch oversight of DTC genetic testing occurs within the FDA and the FTC. These agencies are not specifically empowered to regulate the DTC genetic testing industry, FTC and state attorneys general powers to enforce compliance with the requirements of this bill.” Id.

129 See id. (failing to include any provisions requiring that consumers’ right to prevent disclosure of “personally identifiable information to third parties without the consumer’s express consent” be made clear and conspicuous, nor does it establish a requirement that this right be stated in a manner which is easy for consumers to understand). However, the grant of authority to the FTC to “promulgate regulations” may allow for the FTC to establish these conditions. Id.

130 See generally Slaughter, supra note 27, at 55 (demonstrating the process required to pass a bill as law). Even a bill with bipartisan support such as GINA underwent significant political negotiation, amendments, and stalls in its progress before it achieved the necessary number of votes to pass. Id.

131 See New DOJ Policy, supra note 34 (referring to the government’s use of DTC genetic testing databases for investigative purposes as a “previously unregulated tactic of law enforcement investigation.”). Schwab further states, “governmental regulation is necessary to protect the privacy of . . . genealogical site users who do not consent to law enforcement sharing, and individuals who do not use the sites but whose genetic information is exposed by their relatives.” Id.

132 See Wagner, supra note 51, at 451 (discussing the role of the FDA in regulation of the DTC genetic testing industry); Regulatory Developments in Genetic Testing in the United States, supra note 98 (noting that the FDA is approved to regulate the DTC genetic testing industry to some extent); Direct-to-Consumer Tests, supra note 99(outlining the FDA’s efforts in regulating the industry); Fox, supra note 1 (discussing Sen. Schumer’s imploring of the FTC to review the current landscape of the DTC genetic testing industry).
however; these tests fall into their purview only incidentally by nature of sometimes being marketed as a “kit” rather than a service.\textsuperscript{133} Without legislation to reference upon which to base privacy claims against these companies, the FDA and FTC face an uphill battle to protect consumers.\textsuperscript{134} By enacting legislation specifically empowering one or both of these entities, along with a legislative baseline from which to regulate, Congress would allow for its coequal branch to protect consumers by enforcing that law.\textsuperscript{135} Protecting necessary regulatory efforts against the changing political perspectives of each presidential administration may make the FTC the clear choice for a regulating body, as the president cannot stack its commission with operatives of a single political party, whereas even the check of Senate advice and consent on the commissioner of the FDA would regularly result in a commissioner of the president’s own party.\textsuperscript{136}

V. Conclusion

Legislative mandates for increased transparency, implementing uniform rules across the market, and ensuring the existence of an enforcement agency are the first steps in creating an environment in which consumers can confidently use DTC genetic testing kits without fearing that their information is at risk. Without such legislation, the risk remains that employers, insurers, or law enforcement could pick through a consumer’s genomic data for genetic markers. This ultimately exposes people with genetic markers for

\textsuperscript{133} See Holtzman, supra note 100, at 58–59 (discussing the limitations on the authority of the FDA). See also Schwab et al., supra note 100, at 1697 (suggesting which governmental entities should have authority over the disclosure of information).

\textsuperscript{134} See Clayton et al., supra note 71, at 11 (noting how other measures enacted by the U.S. Department of Health and Human Services have been needed to stand in for actual legislation on genetic privacy, owing to “Congress’s failure to enact more sweeping and rigorous health and genetic privacy laws and regulations.”).

\textsuperscript{135} See generally Slaughter, supra note 27, at 66 (extolling the benefits of having functional legislation in place). This legislation can guide the executive branch in its enforcement of the law and provide the judiciary with the legal language necessary to interpret the scope of authority granted to each branch of the United States government. Id.

\textsuperscript{136} See Commissioners, supra note 94 (indicating that “[t]he Commission is headed by five Commissioners, nominated by the President and confirmed by the Senate, each serving a seven-year term. No more than three Commissioners can be of the same political party. The President chooses one Commissioner to act as Chair.”).
diseases, disorders, or other disabilities to being denied employment, denied insurance coverage, or even more susceptible to law enforcement interactions. By eliminating DTC genetics companies’ ability to employ their own discretion and instead instituting strict legal guideposts, sensitive information pertaining to the genetic code of the average American would have an added layer of protection against bad actors.