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Direct-To-Consumer Genetic Testing: Privacy Issues & Impacts on Biological Relatives

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ABSTRACT

Numerous direct-to-consumer genetic testing services now offer individuals genetic sequencing, testing, and ancestry mapping services outside of the traditional healthcare infrastructure and regulatory barriers. The rise of direct-to-consumer testing services presents policy questions on how to best protect consumers while still promoting future innovation. From a data privacy perspective, concerns include who can share other people's genetic information, what entities can use the information, what happens if the information is stolen, and whether law enforcement, or other entities, can request information from a third party. The overarching concern is that once disclosed, genetic information often cannot be unshared or returned. Further, genetic information from biological relatives can provide information on others who have not personally disclosed or authorized disclosure of their genetic information.

In the United States, a patchwork of regulations has been created at the state level that exceeds the minimum requirements created by Congress. In other parts of the world, countries and regional networks have similarly created varying regulations to govern genetic information and its use. This comment reviews various regulations both in the United States and Europe, discusses the implications of the various regulatory schemes, and proposes a regulatory regime. This proposal aims at harmonizing rules across jurisdictions, distinguishing between "faceless" and individually labeled data, and seeks to allow for data use, testing, and development of new technology, while limiting exposure of individuals genetic information.

I. INTRODUCTION

Genetics has long been taught in schools, and over the last seventy years has moved from the study of simple patterns of gene inheritance to one of the five core concepts of biology.[1] Previously, genetics was an academic discipline that studied the effect of genes within the body and how they impact the body's health, potential diseases, and physical expressions.[2] Genetic testing in the clinical setting has long been increasing for both disease research and family planning; however, with the direct-to-consumer options allowing

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1. Michelle K. Smith & William B. Wood, *Teaching Genetics: Past, Present, and Future*, 204 GENETICS 5, Aug. 30, 2016, at 5.

2. *See Genetics Basics*, CDC, https://www.cdc.gov/genomics/about/basics.htm [https://perma.cc/MV5W-NHE3].

anyone to get gene testing, or search their ancestry, the frequency of genetic testing has exploded.[3] The increase in the availability and popularity of direct-to-consumer options means that the regulatory regime and impacts on the industry are becoming more and more relevant to everyday life.[4]

With more scientific breakthroughs, the genetics industry has become an increasingly popular area for study and innovation.[5] In 2019, the industry accounted for $12.6 billion in spending.[6] It is expected to grow 10.1% every year until 2027, when it is projected to be an over $21 billion industry.[7] New technology and innovation have provided numerous direct-to-consumer options for one to obtain gene testing.[8] Some of the more popular direct-to-consumer companies include Ancestry.com and 23&Me.[9] The industry is growing as consumer offerings seek market share, with some companies even bombarding consumers with television ads.[10] These consumer offerings do not appear to be disappearing anytime soon, and the majority of growth favors consumer gene testing over, and rather than, medical gene testing.[11] Interestingly, recent studies have found that Americans are increasingly worried about how private companies and the government use their private data.[12]

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3. *See Genetic Testing, Privacy, and Healthcare*, AM. SOC'Y OF HUM. GENETICS (Jan. 1, 2019), https://www.ashg.org/discover-genetics/testing-privacy/ [https://perma.cc/9LGW-JC36]; *see* Smith & Wood, *supra* note 1, at 8–9.

4. *See* AM. SOC'Y OF HUM. GENETICS, *supra* note 3.

5. Sanjivan Gill & Onkar Sumant, *Genetic Testing Market*, ALLIED MKT. RSCH. (Sept. 2020), https://www.alliedmarketresearch.com/genetic-testing-market [https://perma.cc/2Y2J-V6KA].

6. *Id.*

7. *Id.*

8. Eric Rosenbaum, *5 Biggest Risks of Sharing Your DNA with Consumer Genetic-Testing Companies*, CNBC (June 16, 2018, 2:18 PM), https://www.cnbc.com/2018/06/16/5-biggest-risks-of-sharing-dna-with-consumer-genetic-testing-companies.html [https://perma.cc/7KAR-FUKD].

9. *Id.*

10. Peter Loftus, *23andMe Stops Genetic Test Marketing*, WALL ST. J. (Dec. 2, 2013, 5:14 PM), https://www.wsj.com/articles/SB10001424052702304579404579234503409624522 [https://perma.cc/4EZ6-ULW3].

11. *See id.*

12. Brooke Auxier & Lee Rainie, *Key Takeaways on Americans' Views About Privacy, Surveillance, and Data-Sharing*, PEW RSCH. CNTR. (Nov. 15, 2019), https://www.pewresearch.org/fact-tank/2019/11/15/key-takeaways-on-americans-views-about-privacy-surveillance-and-data-sharing/ [https://perma.cc/FPP7-ZT6R].

With ever growing capabilities, genetics and gene analysis have an increasing ability to discern and impact our lives.[13] Privacy issues in the genetics world touch on numerous issues including who is able to share the information, what entities can use the information, what happens if the information is stolen, and whether law enforcement can request access to the information.[14] Overall, the issue also presents a "pandora's box" type concern where once a person's information is out in the open, it can never be "secret" again.[15] Furthermore, this issue is not limited to the United States.[16] Globally, individuals' genetic data and personal information are exposed to the direct-to-consumer testing market.[17]

Tangentially, genetics is a unique field of study because genes are inherited and shared between familial relatives.[18] Biological relations, or those of close consanguineal lineage, sit in a precarious position of having many of the same genes as their parents, siblings, and other family members.[19] As the world starts to regulate the genetics industry from a user perspective, there is an extended privacy concern for those who could be impacted by the decisions of closely related individuals who choose to have genetic testing done.[20] Biologic familial matches in genes make identification of a close match possible, and identification allows for a connection of the dots and the possible illumination of information about individuals who have not taken a genetic test.[21]

This comment will first discuss the background of the genetics industry before delving into the privacy issues for both those being tested and those related to them. Next, the comment will explore the current federal and state regulations and some of the proposed regulations in the genomics field. It will also consider the regulations in the European Union as well as some individual European Union member states. To finish, the comment will dis-

13. *See generally* J. Lyn Entrikin, *Family Secrets and Relational Privacy: Protecting Not-So-Personal, Sensitive Information from Public Disclosure*, 74 Univ. Mia. L. Rev. 781, 787 (2020).

14. *E.g.*, Rosenbaum, *supra* note 8.

15. *See* Rob Stein, *Easy DNA Identifications with Genealogy Databases Raise Privacy Concerns*, NPR (Oct. 11, 2018, 3:58 PM), https://www.npr.org/sections/health-shots/2018/10/11/656268742/easy-dna-identifications-with-genealogy-databases-raise-privacy-concerns [https://perma.cc/LJ8N-297X].

16. *See id.*

17. *See* Louiza Kalokairinou et al., *Legislation of Direct-to-Consumer Genetic Testing in Europe: A Fragmented Regulatory Landscape*, 9 J. Cmty. Genetics 117, 126 (2018).

18. Entrikin, *supra* note 13, at 888.

19. *Id.*; *see* Stein, *supra* note 15.

20. *See* Stein, *supra* note 15; Entrikin, *supra* note 13, at 888.

21. *See* Stein, *supra* note 15; Entrikin, *supra* note 13, at 888.

cuss the implications of the numerous regulations and provide a proposed regulatory regime to protect the genetics industry, individual customers, and unsuspecting third parties.

II. BACKGROUND

The genetics industry and testing of genes has been a fixture of medical work since the discovery of DNA by Watson and Crick in 1953.[22] Most prior discoveries were centered around the clinical and research-based work of labs to discover the individual gene markers of cystic fibrosis and Huntington's disease.[23] The discovery of the polymerase chain reaction (PCR) process, which led to the discovery of the ordering sequence of DNA bases, generated interest in the gene field in 1983.[24] By the 1990s, the international Human Genome Project culminated in sequencing the entire human genome rather than just individual genes.[25]

Modern efforts in the medical field have somewhat shifted from simply identifying markers for diseases to attempting to use genetics data and knowledge to create medical treatments.[26] The focus on treatment has included developments of vaccines.[27] Additionally, testing genes related to certain diseases for preventative use has increased.[28] This is seen in the work testing genes such as the APOE gene or the BRCA gene, which have been associated with Alzheimer's disease and breast cancer, respectively.[29] These tests were traditionally completed in the medical setting, but new businesses have emerged to serve the direct-to-consumer market.[30] Offerings now range from whole genome, partial genome, and ancestry testing options from companies, such as 23andMe, Ancestry.com DNA, and Family Tree DNA.[31] Their capabilities span from a simple ancestry type of nationality crowdsourcing to more "serious" medical testing intended to identify risks or genetic disorders that in prior years was completed in a medical setting.[32]

22. JORGE L. CONTRERAS & VIKRANT DESHMUKH, GENETICS, ETHICS AND EDUCATION, ch. 13 at 2 (Susan Bourgey et al., eds., 2017).

23. *Id.*

24. *Id.*

25. *Id.*

26. *Id.* ch.13 at 3.

27. *Id.*

28. CONTRERAS & DESHMUKH, *supra* note 22, ch. 13 at 4–5.

29. *Id.*

30. CONTRERAS & DESHMUKH, *supra* note 22, ch. 13 at 6.

31. *Id.* ch. 13 at 6–7.

32. *Id.*

Privacy issues confront these new genetic testing options on numerous fronts.[33] The most glaring issue is what a company is allowed to do with genetic information once it is in the company's possession.[34] These companies are not bound by the HIPPA regulations that restrict most medical providers.[35] First, given that regulation is being developed prospectively, there is a question of whether the company can keep the information or in what scenarios retention is allowed.[36] Retention of this information may give the company monetization opportunities.[37] Recent examples show that some companies use collected data internally and even provide the data to third parties.[38] Many companies include clauses in contracts that allow companies to use the information as they see fit.[39] A consumer may not consider it, but there is chance their genetic information can be bought or sold.[40] The further the genetic information gets from the original collection source, the harder it is to locate the information, control its use, and regulate the impacts on the original subjects.[41] Also, company policies and privacy statements are often not set in stone, so depending on the company leadership and changing priorities, such as profitability or a change in strategy, a company could alter its privacy policies.[42] This means the company an individual trusted based on its policies could shift in strategy at any point without needing an individual's consent.[43] A company may be limited by law from providing or selling genetic information to other entities, but outright purchases of the entire testing company that houses the genetic testing information, however, open an alternative avenue for third parties to acquire the information without it ever "leaving" the initial company's protective internal systems.[44] These loopholes allow third party entities to obtain the data of direct-to-consumer testing providers or servicers through the purchase of the company, thereby

33. Rosenbaum, *supra* note 8.

34. *See* Matthew Haag, *FamilyTreeDNA Admits to Sharing Genetic Data With F.B.I.*, N.Y. TIMES (Feb. 4, 2019), https://www.nytimes.com/2019/02/04/business/family-tree-dna-fbi.html [https://perma.cc/BE2W-X3NR].

35. *See id.*

36. *See id.*

37. *See id.*

38. *Id.*

39. *See id.*

40. Rosenbaum, *supra* note 8.

41. *See id.*

42. *See* Haag, *supra* note 34.

43. *See id.*

44. Rosenbaum, *supra* note 8.

eliminating the third party designation and sidestepping regulations on transfer of information.[45]

A second issue involves hacking and the liability associated with genetic information being stolen.[46] Information is never completely safe online, and there is an increasing threat that genetic information can and will be stolen.[47] Without efforts to safeguard data this valuable information is potentially an easy target.[48] An individual's data may just be waiting for someone to take advantage of a poorly defended servicer's bank of genetic information.[49] As more breakthroughs occur in the scientific arena, this information will likely continue to increase in value, putting an even larger emphasis on the risks of data breaches.[50]

Third, law enforcement has increasingly sought to solve crimes with the DNA information contained in the databases of consumer testing companies.[51] The rules of medical HIPPA protections do not bind direct-to-consumer companies to certain confidentiality rules normally associated with the medical field.[52] Law enforcement has seen success with this approach to get around consent issues because some companies have been willing to share information.[53] This method has allowed law enforcement to obtain individuals' DNA information from companies, while obtaining DNA test directly from an individual normally requires direct consent or a court order.[54] This presents issues similar to the FBI asking for Apple's help to open an iPhone, but with genetic data at stake rather than electronic information.[55] Moreover, a phone may include encryption or other safety measures to protect personal information, while a direct-to-consumer genetic testing company likely has limited controls to internally protect an individual's genetic data.[56] The accessibility of information normally protected by court order presents a consti-

45. *See id.*

46. *Id.*

47. *See id.*

48. *See id.*

49. *See id.*

50. *See* Rosenbaum, *supra* note 8.

51. Haag, *supra* note 34.

52. *See id.*

53. *See* Entrikin, *supra* note 13, at 787.

54. *See generally id.*

55. Russell Brandon, *The FBI Has Asked Apple to Unlock Another Shooter's iPhone*, THE VERGE (Jan. 7, 2020, 11:34 AM), https://www.theverge.com/2020/1/7/21054836/fbi-iphone-unlock-apple-encryption-debate-pensacola-ios-security [https://perma.cc/86NY-ABAU].

56. *See id.*

tutional issue, as the gateway to an individual's data may be through a testing company rather than the individual.[57]

Finally, there are implications for how genetic information can be used in the insurance industry.[58] At some level, this data could be used by actuaries in the health insurance, life insurance, and car insurance markets to triangulate risk factors associated with certain sets of genes.[59] The problem with that is those with recognizable risk factors could be forced to pay more or less depending on the assessment by the insurance companies actuarial department.[60] Though more of a policy issue, this involves some privacy concerns, as legislators will have to decide what information can be used by insurance companies.[61] As a policy question, the concept of risk sharing versus requiring individuals to pay for their enhanced risk factors likely has no clear cut answer.[62] However, it presents an interesting question hovering around the insurance industry as to what information can be requested and used to develop policies for customers.[63] Overall, anyone participating in the direct-to-consumer genetic testing market faces these numerous implications and potential issues today.[64]

There are also impacts for the biological relatives of those who participate in genetic testing.[65] Unlike a social security number, that if given away would just impact oneself, DNA is biologically passed down.[66] Just last year, Joseph DeAngelo, also known as the "Golden State Killer," was caught with the assistance of triangulating his identity through the DNA of a familial connection, a third cousin.[67] Certain studies have found the availably of genetic testing data has made it such that one could potentially triangulate the identities of a majority of individuals in the United States in the next few year with the help of genetic information paired with additional personal in-

57. *See id.*

58. Rosenbaum, *supra* note 8.

59. Jean-Christophe Bélisle Pipon et al., *Genetic Testing, Insurance Discrimination and Medical Research: What the United States Can Learn from Peer Countries*, 25 NATURE MED. 1198, 1198–1204 (2019).

60. *See id.*

61. *See id.*

62. *See id.*

63. *See id.*

64. *See* Rosenbaum, *supra* note 8.

65. Entrikin, *supra* note 13, at 785.

66. *Id.* at 784.

67. JV Chamary, *How Genetic Genealogy Helped Catch The Golden State Killer*, FORBES (June 30, 2020, 5:PM), https://www.forbes.com/sites/jvchamary/2020/06/30/genetic-genealogy-golden-state-killer/?sh=27ce58e5a6d0 [https://perma.cc/5XNM-KTMH].

formation identifiers.[68] This would not be an issue if people had consented to their information being used or obtained.[69] However, a familial connection could be implicated by the actions of an individual without having personally consented, as was the situation in DeAngelo's situation.[70] As a result of a decision made by a familial connection, individuals without their consent could have their information provided to pharmaceutical companies, used in estate matters, tagged by law enforcement, or have personal health issues known by others.[71] Close biological relations face these risks simply by being related to individuals who have provided information.[72] At least one study shows that over 75% of Americans are concerned with how companies and the government use their personal data.[73] It stands to reason that the use or access to one's data through a family member rather than through one's own actions would concern the populous even more.[74]

III. LEGAL BACKGROUND/DEVELOPMENTS AND PROBLEMS

There have been numerous efforts at both the federal and state levels in the United States to provide regulations for the genetics industry, or tangentially in the privacy sphere.[75] A few proposals have been passed and many have been, or are currently being, considered.[76] Other countries around the world, notably those in Europe, have also undertaken efforts to pass regulations or have considered steps to install regulations for the direct-to-consumer genetic testing field.[77]

A. Federal Genetic Information Non-Discrimination Act (GINA)

The U.S. federal government's first attempt at enacting regulation in the genetics space was in 2008 with the passing of the Genetic Information Non-

68. Haag, *supra* note 34.

69. Entrikin, *supra* note 13, at 860.

70. *Id.*; Chamary, *supra* note 67.

71. *See* Entrikin, *supra* note 13, at 864.

72. *Id.*

73. Auxier & Rainie, *supra* note 12.

74. *See* Entrikin, *supra* note 13, at 860.

75. *See* HHS, "GINA" The Genetic Information Nondiscrimination Act of 2008 Information for Researchers and Health Care Professionals 1 (Apr. 6, 2009), https://www.genome.gov/sites/default/files/genomeold/pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf [https://perma.cc/DG38-PTW4] [hereinafter GINA].

76. *See id.*

77. Ashleigh Furlong, *Europe Eyes New Rules for 'Wild West' of DNA Testing*, Politico (Jan. 14, 2020, 1:25 PM), https://www.politico.eu/article/europe-eyes-new-rules-for-wild-west-of-dna-testing/ [https://perma.cc/L2TM-PKAR].

Discrimination Act (GINA).[78] The bill passed almost unanimously in both chambers of Congress and concluded a thirteen-year debate on the measure.[79] First, GINA provides protection to individuals from health insurance providers from discrimination based on genetic information in both eligibility and coverage decision making.[80] This, however, applies only to health insurance and does not regulate other forms of insurance.[81] Second, genetic information cannot be used discriminate in employment situations, such as in hiring and promotion.[82] This is similar to actions taken in the past to prevent discrimination in the workplace regarding other forms of health status.[83] The regulation explicitly places genetic information in the class of information that is not allowed to be considered by employers or health insurer when making their decisions.[84] GINA also outlines numerous penalties for those companies that seek to add genetic information as factor used in algorithms or decision-making processes.[85] These penalties provide some teeth to the regulations rather than just outlining illegality.[86]

Notably, GINA, while expansive in its regulations on most employers and health insurers, leaves out numerous related industries that could readily use genetic information.[87] It specifically exempts employers with fewer than 15 employees.[88] As another exception, companies providing insurance plans including life, long-term care, disability, and types of property insurance that could possibly use the information to discern riskier individuals and force higher payments depending on the perceived risk are not impacted by GINA.[89] In this vein, it was argued, before passage, that GINA could force higher payments for less-risky individuals when high-risk individuals cannot be separated by their genetic information.[90] This could materialize in individuals with specific genetic disorders inflating cost for the overall insurance

78. GINA, *supra* note 75, at 2.

79. *Id.*

80. 29 U.S.C.A. § 1182(a)(1)(F) (2008).

81. *See id.*

82. GINA, *supra* note 75, at 2.

83. *Id.* at 1.

84. *Id.* at 2.

85. *See* 29 U.S.C.A. § 216 (2018).

86. *See id.*

87. *See* NIH, *What is Genetic Discrimination?*, MEDLINEPLUS (Jul. 28, 2021), https://medlineplus.gov/genetics/understanding/testing/discrimination/ [https://perma.cc/4HJ6-9S68].

88. *Id.*

89. *Id.*

90. Jessica D. Tenenbaum & Kenneth W. Goodwin, *Beyond the Genetic Information Nondiscrimination Act: Ethical and Economic Implication of the Exclusion*

pool.[91] With GINA, Congress drew a hard line with health insurance, but left the door ajar in the other insurance spaces that may not be able to use genetic information intelligently in their actuarial processes.[92]

B. United States State Laws

Illinois has compiled some of the strictest genetics privacy laws.[93] Notably, the laws require genetic testing entities to obtain written permission from the test-taker before the results can be shared with any third party.[94] The law passed in 2009.[95] The genesis of the law came from supporters who pushed for a public policy update as the demands and use of genetic data grew.[96]

Utah passed its own Genetic Information Privacy Act in 2021 that is specifically aimed at protecting consumers of direct-to-consumer genetic testing products.[97] The Act created requirements for companies to provide notice, limit data usage, and require consent for usage of genetic data.[98] Interestingly, the plan also required companies to provide a data security plan to protect unauthorized use or access to the bank of genetic data held by the company.[99]

Florida, in 2020, became the first state to extend genetic privacy testing to all insurers, which is in addition to health insurers covered under the Federal GINA.[100] Florida now prohibits insurers from using genetic information

of Disability, Long-Term Care and Life Insurance, 14(2) PER. MED. 153, 154 (2017).

91. *See id.*

92. *See id.* at 156.

93. *See* 410 ILL. COMP. STAT. 513/15 (2021) ("Except as otherwise provided in this Act, genetic testing and information derived from genetic testing is confidential and privileged and may be released only to the individual tested and to persons specifically authorized, in writing in accordance with Section 30, by that individual to receive the information").

94. *Id.*

95. *Id.*

96. Sean Crawford, *New Illinois Privacy Law For Genetic Test Results*, NPR ILL. (Dec. 30, 2019, 9:47 AM), https://www.nprillinois.org/health-harvest/2019-12-30/new-illinois-privacy-law-for-genetic-test-results [https://perma.cc/XVP7-C4H5].

97. UTAH CODE ANN. §13-60-101 (West 2022).

98. *Id.* §13-60-201 (West 2022).

99. *Id.*; Julia K. Kadish, *States Continue to Step in to Safeguard Genetic Information*, XI 88 NAT'L L. REV., Mar. 29, 2021, at 2, https://www.natlawreview.com/article/states-continue-to-step-to-safeguard-genetic-information [https://perma.cc/LL3W-MWB4].

100. FLA. STAT. § 627.4301 (2020); Harry Valetk, *Florida Becomes the First State to Enact DNA Privacy Law Blocking Insurers from Genetic Data*, BAKER MC-

to create prices or offerings in the life insurance, disability insurance, and long-term care insurance markets.[101] Florida also updated its regulations in 2021 by making criminal penalties available for violations of state genetics protection laws.[102]

In October of 2021, California added the Genetic Information Privacy Act to the already-existing Consumer Privacy Act of 2018.[103] This new Act specifically applies to direct-to-consumer genetic testing companies.[104] The key provisions limits access to private data for third parties and institutes procedures for the entire life-cycle of the genetics process.[105] Further, the Act also allows for customers to revoke consent in an action requiring destruction of data within thirty days.[106] Given this requirement, this law will likely set the standard for state laws because of the wide ranging limits on the use of genetic information by testing companies.[107]

Coming down the pipeline, the California Privacy Rights Act and the Virginia Consumer Data Protection Act both passed in 2021 and are scheduled to go into effect soon.[108] The laws mirror the current laws of the European Union under the General Data Protection Regulation, which is aimed at data use widely rather than just genetics.[109] Both Virginia and California laws

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KENZIE (July 11, 2020), https://www.lexology.com/library/detail.aspx?g=66b6b069-27dc-4fe3-91c3-17234ff5212e [https://perma.cc/M5UL-FT3A].

101. FLA. STAT. § 627.4301; Valetk, *supra* note 100.

102. Libbie Canter, *Newly Effective Florida Law Imposing Criminal Sanctions Adds to Developing Nationwide Patchwork of State Genetic Privacy Laws*, COVINGTON (Oct. 6, 2021), https://www.insideprivacy.com/health-privacy/newly-effective-florida-law-imposing-criminal-sanctions-adds-to-developing-nationwide-patchwork-of-state-genetic-privacy-laws/?utm_source=Mondaq&utm_medium=Syndication&utm_campaign=ClinkedIn-integration [https://perma.cc/5235-NWBU].

103. *See* Julia K. Kadish & Harrison Schafer, *California Enacts New Privacy Law for Genetic Data,* XI 285 NAT'L L. REV., Oct. 12, 2021, at 2, https://www.natlawreview.com/article/california-enacts-new-privacy-law-genetic-data#google_vignette [https://perma.cc/Z7VC-Q5K5].

104. *Id.*

105. *See id.* ("[P]rovide a customer with certain information regarding the company's policies and procedures for the collection, use, maintenance, and disclosure, as applicable, of genetic data, and to obtain a consumer's express consent for collection, use, or disclosure of the consumer's genetic data").

106. *Id.*

107. *See id.*

108. Elizabeth Harding & Caitlin A. Smith, *Virginia's New Consumer Data Protection Act*, XI 222 NAT'L L. REV., Aug. 10, 2021, at 2, https://www.natlawreview.com/article/virginia-s-new-consumer-data-protection-act [https://perma.cc/GQ93-EPR4].

109. *Id.*

include genetic information on the list of data covered under the new rules for a number of access, deletion, and control mechanisms that must be followed by businesses when personal data is in their possession.[110] While not as consequential for genetics regulation in California given the recent passage of the Genetics Information Privacy Act, this Act will serve as the basis for most of the regulatory regime in Virginia.[111]

About half of the states in the U.S. have instituted regulations in the areas of consent for either disclosure or performance of a genetic test.[112] A small number of states have gone as far as labeling genetic information as personal property.[113] Similar efforts have resulting in DNA samples being labeled personal property, as personal rights slowly expand into the personal genetics industry.[114]

Not all action, however, has been directed toward regulation. Oregon, in the past twenty years, has eliminated the property right to DNA samples, which demonstrates that despite momentum towards increased regulations, there are still some locations moving in the opposite direction.[115] Outside of usage for personal or medical reasons, usage of genetic testing and genetic information in the employment and the insurance industries, in particular, has generated separate regulatory action.[116] Similar to consent laws, these requirements or bans on the use of genetics to inform an employment or insurance decision are only present in a few states and are not uniform.[117]

C. European Union Regulations

Like the structure of regulations in the U.S., European Union (EU) regulations come in the form of both overarching EU rules for all the member

110. *Id.*

111. *Id.*

112. *State Genetic Privacy Laws*, NAT'L CONF. OF STATE LEGIS. http://pierce.wesleyancollege.edu/faculty/hboettger-tong/docs/hbt%20public%20folder/FYS/State%20Genetic%20Summary%20Table%20on%20Privacy%20Laws.htm [https://perma.cc/B9LL-7B2D] [hereinafter *State Genetic*] ("Laws in 16 states require informed consent for a third party either to perform or require a genetic test or to obtain genetic information. Twenty-four states require informed consent to disclose genetic information. In addition, Rhode Island and Washington require written authorization to disclose genetic information").

113. *Id.*

114. *Id.*

115. *Id.*

116. *See id.*

117. *See State Genetic, supra* note 112.

states as well as country specific rules.[118] The country-specific rules tend to extend beyond the regulations set by the EU.[119]

In the EU, the General Data Protection Regulation dominates the regulatory regime for the member countries.[120] Created in 2016 as an advancement and update to the 1995 European rules, the regulations impose added controls for individuals to dictate how their personal data is used.[121] The goal was to harmonize the member-countries' laws, given the thicket that could emerge if each country were to create its own set of regulations.[122] Similar to the situation in the U.S., however, this left the door open for countries that desired to enact their own national laws.[123] The regulations impose added obligations on controllers and processors of personal data but do little to force consent for given services.[124] These obligations require the data processors and handlers to prove their compliance with the law.[125] The EU's regulatory regime has been described as one of toughest in the world.[126] Fines could reach into the tens of millions of Euros for violations.[127] This is based on penalties of upwards of 4% of a company's global revenues, not profit, for violation just in the EU, which will get the attention of any data handler.[128]

Adding on to the EU regulations, many European countries, including France and Germany, have enacted country-specific regulatory schemes regarding personal data.[129] The strictest regulation that currently exists is the French ban on direct-to-consumer DNA testing.[130] Currently, individuals found guilty of breaking the French rules are liable for a _3,750 fine, which makes France one of the few countries that creates criminal penalties for users of direct-to-consumer DNA tests.[131] The French bioethics rules are up-

118. Ben Wolford, *What is GDPR, the EU's New Data Protection Law?*, EUR. UNION, https://gdpr.eu/what-is-gdpr/ [https://perma.cc/T3CZ-43JZ].

119. *See generally id.*

120. *Id.*

121. *Id.*

122. *See id.*

123. *See generally State Genetic*, *supra* note 112.

124. Wolford, *supra* note 118.

125. *Id.*

126. *Id.*

127. *Id.*

128. *Id.*

129. *See* Eric Boodman, *In France, It's Illegal for Consumers to Order a DNA Spit Kit. Activists Are Fighting Over the Ban*, STAT (Nov. 14, 2019), https://www.statnews.com/2019/11/14/france-consumer-genetic-testing-ban/ [https://perma.cc/F534-NC36].

130. *See id.*

131. *Id.*

dated every seven years, and sizeable pressure exists from industry groups to lift or limit the restrictions; but as of now, the restrictions are still in place.[132] France takes pride in having the strictest regulations of privacy with this specific regulation concerning direct-to-consumer genetics.[133] While strict, the rules in France, including the fine or penalty, have never actually been enforced, and consumers remain largely free to purchase the tests from companies outside the country.[134] Germany's legislation has similarly been considered as targeting direct-to-consumer genetic testing and limiting German consumers' access to this type of testing.[135] Also, Germany is one of the few countries to require post-test counseling to certain individuals based on the test given.[136]

In other European countries, however, there are a less clear-cut lines as to what is a medical test versus what is a recreational product because definitions differ among the countries.[137] The regulations for genetic testing in many countries are aimed at medical professionals but could encompass some of the direct-to-consumer options depending on the specific regulations of the country.[138] Austria, Norway, and Portugal, for example, require written consent for the completion of certain types of genetics tests.[139] In Austria, genetic tests determining a manifested disease based on a germ line mutation, genetic tests determining predisposition to a disease (especially future onset diseases or the determination of carrier status), and genetic tests for prenatal diagnosis may only be performed upon written consent of the person to be tested and after genetic counselling is complete.[140] Informed consent requires the individual indicate that they were informed in advance about the genetic test's nature, consequences, and significance.[141] Portugal similarly restricts genetics testing without written consent for detecting heterozygosity status of recessive diseases, diagnosing monogenic diseases, and testing for genetic susceptibility in healthy individuals.[142] These requirements vary by country because they may depend on the type or the setting of the test performed.[143]

132. *Id.*

133. *See id.*

134. Furlong, *supra* note 77.

135. Kalokairinou et al., *supra* note 17, at 126.

136. *Id.* at 124.

137. *Id.* at 129–30.

138. *See id.*

139. *Id.* at 126.

140. *Id.*

141. Kalokairinou et al., *supra* note 17, at 126.

142. *Id.*

143. *See id.* at 125.

In Spain, written consent for testing is only required when performed in a healthcare setting, thereby not including the direct-to-consumer option.[144] In Norway, genetic counselling is compulsory when it comes to pre-symptomatic, predictive, and carrier tests.[145] In Spain, counseling must be provided for any health-related genetic testing.[146] Further, in Spain, during genetic counseling, an individual must be provided with adequate information regarding the consequences of genetic diagnoses and possible alternatives available to the patient.[147]

Sweden is unique in that the requirements for genetic testing stipulate that genetic testing must be accompanied by genetic counselling and informed consent from the patient.[148] Further, professionals providing genetic counselling must have specific training.[149] Training certification, however, does not appear difficult to obtain because, at present, there is neither university-level education in genetic counselling nor a requirement for professional licensing or registration to be become a counselor.[150] The penalties do not appear to have been strictly enforced, but offer a unique hand-holding approach to genetic testing that could alter some people's perception or understanding of the process before they begin.[151] This requirement is much like the requirement of pre-bankruptcy credit counseling in the United States for consumer bankruptcy filers.[152] The counselor, or process, has the potential to impact how an individual approaches the process whether it be bankruptcy or genetic testing.[153]

The Czech Republic acted in early 2017 by passing additional genetics testing protocols.[154] Specifically, the protocols established guidelines for the quality of genetic services, prior information and consent, and genetic counselling.[155] The protocols established a general rule on the conduct of genetic

144. *Id.* at 125.

145. *Id.* at 122.

146. *Id.*

147. Kalokairinou et al., *supra* note 17, at 122.

148. Rebecka Pestoff et al., *Genetic Counsellors in Sweden: Their Role and Added Value in the Clinical Setting*, 24 EUR. J. OF HUM. GENETICS, 350, at 350 (2016).

149. *Id.*

150. *Id.*

151. *See id.*

152. 11 U.S.C. § 109(h).

153. *See id.*

154. *Czech Republic Signs the Additional Protocol on Genetic Testing*, COUNCIL OF EUR. (Oct. 26, 2017), https://www.coe.int/en/web/bioethics/-/genetic-protocol-signature [https://perma.cc/A84Y-HN4P].

155. *Id.*

tests, and was forward looking for the first time at the international level.[156] It delt with directly accessible genetic tests for which commercial offers could develop (and obviously did within the next five years).[157] Also, notably the protocols established procedures for tests that could be carried out by people who are unable to provide consent.[158] Lastly, it dictated the protection of and right to the information derived from the genetic testing.[159]

At the other end of the spectrum, numerous countries have no regulations for genetic testing, let alone direct-to-consumer testing.[160] Countries without regulations include Luxembourg, Poland, and Romania.[161] While the regulations implemented by the countries discussed above may look to provide some limitations, in actuality they may sit idle because direct-to-consumer genetic testing companies are based around the world and are not subject to the regulations.[162] As a result, even if a test is sent to a specific European country, the regulation of this service may (or may not) fall outside the national jurisdiction.[163] Not to mention, the simple definition of what is in the 'practice of medicine' varies by country, which furthers the non-uniformity of regulations across European nations.[164]

The varying actions of numerous European countries have created a patchwork of regulatory actions much like the patchwork present in the United States.[165] These regulations provide differing sets of rules that must be followed even as data, companies, and individuals increasingly travel across country and state borders.[166]

D. United States Federal Proposed Regulations

Not all proposals have sought to increase genetic regulation at the federal level in the United States.[167] In 2017, a House resolution was introduced that would have let employers demand access to their workers' genetic test results.[168] This resolution did not pass, but it reflects the uncertain nature of

156. *Id.*

157. *Id.*

158. *Id.*

159. *Id.*

160. Kalokairinou et al., *supra* note 17, at 126.

161. *Id.*

162. *Id.* at 127.

163. *Id.*

164. *Id.*

165. *See* Kalokairinou et al., *supra* note 17, at 127.

166. *See id.*

167. *See* H.R. 1313 Rep. No. 115–459 (2017).

168. *See id.*

changes to regulations in the genetics field and some of the possible push back against regulations.[169] Additionally, some free market tendencies may seek to influence and chip away at the regulations in the future as well.[170]

In 2019, a House resolution was proposed for the enactment of the Genetic Information Privacy Act (GIPA).[171] The resolution, if passed, would have required commercial testing companies housing customers' genetic data to have express consent from consumers before the data could be used by third parties.[172] This Act would have given the Federal Trade Commission (FTC) oversight of genetic data companies.[173] Further, the Act would have required that separate consent be provided for additional services and internal testing.[174] The resolution stalled and never made it out of the House.[175] Regulation of direct-to-consumer genetics testing companies, however, could occur in the form of rulemaking from the FTC, the Centers for Medicare and Medicaid Services, or the Food and Drug Administration.[176]

E. Proposed Regulations in the United Kingdom

The United Kingdom (U.K.) does not follow the EU's regulatory regime.[177] Similar to other European countries, U.K.'s Parliament is now considering whether and what kind of regulation action is needed regarding personal genetic information and privacy.[178] Perhaps a positive sign is the balancing of interests, both personal and business, being shown by Parliamentary members as possible advancements in science are weighed against personal protections.[179] New rules being considered seek to add some teeth, given that the current set of regulations lack any consequences for individu-

169. *See* Ricki Lewis, *Saving GINA: Is Genetic Privacy Imperiled?*, PLOS BLOG (Mar. 9, 2017), https://dnascience.plos.org/2017/03/09/saving-gina-is-genetic-privacy-imperiled/ [https://perma.cc/M522-XYRU].

170. *Id.*

171. Genetic Information Privacy Act of 2019, H.R. 2155, 116th Cong. §1 (2019).

172. *Id.* at § 2(a)(1)(a).

173. *Id.* at § 3(a)(2).

174. *Id.* at § 2(a)(2).

175. *Id.*

176. CONTRERAS & DESHMUKH, *supra* note 22, ch. 13 at 12.

177. *See MPs Urge Government to Review Regulations for Direct-to-Consumer Genetic Testing*, UK PARLIAMENT (Jun. 22, 2021), https://committees.parliament.uk/committee/135/science-and-technology-committee/news/156039/mps-urge-government-to-review-regulations-for-directtoconsumer-genetic-testing/ [https://perma.cc/Q544-CUMR] [hereinafter *MPs Urge Government*]; SCI. & TECH. COMMITTEE, REPORT, 2021-2, HC 94, ¶ 13 (UK).

178. *See MPs Urge Government*, *supra* note 177.

179. *See id.* 77.

als and businesses breaking genetic testing regulations.[180] This will likely layer on current regulations in the U.K. that are modeled after regulations of other European countries and distinguish between medical providers and direct-to-consumer options.[181] Currently, U.K. regulations do not prohibit the sale or use of direct-to-consumer offerings.[182]

F. U.S. State Proposed Regulations

Interestingly, the state of California proposed genetic privacy legislation that passed in 2021, mentioned earlier in the comment, was earlier vetoed by Governor Newsom in 2020.[183] The regulations, called the Genetic Information Privacy Act, require informed consent before disclosing data to third parties.[184] While the California bill was pending, Governor Newsom vetoed the bill because he thought it would hurt the response to the COVID-19 pandemic.[185] In response to California's proposed regulation, other states, such as Arizona, considered whether to should pass more restrictive legislation.[186] More U.S. citizens have been using direct-to-consumer options—in fact, in 2021, 20% of the United States population were estimated to have used an at home genetic test.[187] As a growing population uses these options, it stands to reason that more states will consider adding regulations because many of the efforts in Congress have stalled.[188]

IV. THE IMPLICATIONS OF CURRENT & PROPOSED REGULATION

Currently, the United States federal regulations create a minimum standard for regulatory action in the genetics space, but state action has the opportunity to go further.[189] Though limited to health insurance and

180. Furlong, *supra* note 77.

181. Kalokairinou et al., *supra* note 17, at 127.

182. *Id.*

183. Alyssa M. Sones, *California Governor Pulls the Plug on Genetic Information Privacy Act*, X 294 NAT'L L. REV., Oct. 20, 2020, at 1, https://www.natlawreview.com/article/california-governor-pulls-plug-genetic-information-privacy-act [https://perma.cc/XT8X-KCDE].

184. *Id.*

185. *Id.*

186. Emily Mullin, *States Are Toughening Up Privacy Laws for At-Home DNA Tests*, WIRED, (Oct. 21, 2021, 9:00 AM), https://www.wired.com/story/states-are-toughening-up-privacy-laws-for-at-home-dna-tests/ [https://perma.cc/5PDY-QU2K].

187. *Id.*

188. *See id.*

189. *See* GINA, *supra* note 75, at 1.

employment scenarios, the GINA regulations of 2008 provide the current basis for nation-wide regulatory activity in the United States.[190] The patchwork of regulations by states provide a view into the possible regulations that could be implemented nation-wide as well as the impact that specific regulation has on privacy in the genetics industry.[191] This contrasts the regulatory regime in Europe, which mostly focuses on regulating the framework within which the genetic tests are provided but then leaves issues related to appropriate medical supervision, genetic counselling, and adequate informed consent processes unregulated.[192]

Overall, consumers and companies in the genetic testing space face numerous potential privacy issues. Given the traditional informed consent requirement of contract law, most companies have indemnity provisions in their contracts that waive all consumer rights to later bring suit for invasion of privacy or other claims.[193] On its face, the numerous iterations of regulations that contemplate mandatory disclosure requirements would limit the ability of companies to use this method to avoid liability and allow for genetic data use.[194] Mandatory disclosure for gene testing has been passed in Illinois and proposed at the federal level and in other states.[195] However, there is limited applicability to some of the regulations for the full-array of uses for genetic information.[196]

The 2008 federal regulation GINA limited the use of genetic information in employment and health insurance situations.[197] The Act was structured to increase public confidence in the Human Genome Project as well as the increase in genetic research in the healthcare arena.[198] When GINA was passed, many regulators anticipated that the patchwork of state regulations would be eliminated by the introduction of a consistent federal regulatory structure.[199] Now thirteen years later, the patchwork of state regulations for genetic information has remained, and numerous states have added more reg-

190. *Id.*

191. *See id.*

192. Kalokairinou et al., *supra* note 17, at 119.

193. *See* Entrikin, *supra* note 13, at 863.

194. *E.g.*, 410 ILL. COMP. STAT. 513/15 (1997).

195. *Id.*

196. Valetk, *supra* note 100; *See* FLA. STAT. § 627.4301 (2020).

197. GINA, *supra* note 75, at 1.

198. *Id.*

199. Stephen E. Trimboli & Marissa B. Ruggiero, *Navigating the Genetic Information Nondiscrimination Act of 2008*, 58 FEDR. LAW. 24, 26 (Nov./Dec. 2011) ("Prior to enactment of GINA, 34 states and the District of Columbia had promulgated their own genetic discrimination laws").

ulations to the minimum requirements created by GINA.[200] Genetic information can now theoretically be useful in a number of other closely related insurance businesses, as discussed above, and in medical development.[201]

Use of genetic information has advanced well beyond simple genetic testing to new uses that threaten one's personal privacy.[202] Genetics data allows police and detectives to match or partially match DNA to cold cases using DNA from even distant biologic relatives, which, in turn, threatens personal privacy.[203] Commercial entities have long had incentives to get access to data but now so does law enforcement.[204] Multiple consumer genetics testing companies claim to take privacy seriously, yet their contracts contain clauses allowing disclosure of information to the government or other third parties as they see fit.[205]

There is also a concern for hacking, or the stealing of, genetic data that is similar to concerns with personal health or credit card information.[206] States that have enacted regulations around the proper storage of personal information are at the forefront of alleviating some of the concerns.[207] However, genetic information is sometimes forgotten by consumers and not tracked as rigorously as credit reports.[208] Regulation for proper storage of genetic information can also add a burden to businesses.[209] No efforts are perfect, but with the rise in data breaches, many states seem to be looking at ramping up standards in an effort to make these data breach events less severe and less frequent.[210]

The concern of law enforcement access to genetic data is separate from concerns of private companies selling or providing genetic data for research

200. *See* Valetk, *supra* note 100.

201. *Id.*

202. Entrikin, *supra* note 13, at 781; *See* Stein, *supra* note 15.

203. *See* Stein, *supra* note 15, (referencing quote by Yaniv Erlich: "It is kind of like each person in this database is a beacon that illuminates hundreds of distant relatives").

204. Entrikin, *supra* note 13, at 784–85.

205. *See* Rosenbaum, *supra* note 8.

206. *Id.*

207. *Id.*

208. *See id.*

209. *See* UTAH CODE ANN. § 13-60-201 (2021); *see* Kadish, *supra* note 99.

210. *See* Consumer Bob & Nicholas Kjeldgaard, *Data Breaches Could Reach All-Time High by End of 2021: ITRC*, NBC SAN DIEGO (July 15, 2021, 7:52 PM), https://www.nbcsandiego.com/news/investigations/nbc-7-responds/data-breaches-could-reach-all-time-high-by-end-of-2021/2655793/ [https://perma.cc/UW6J-S6BZ].

or other purposes.[211] While some companies clearly obtain an individual's consent to be included in third party research, other companies allow their contracts to establish the right to freely distribute collected data to other parties as they see fit.[212] There is the additional question of what constitutes a company asset in the event of a company being acquired at a later date.[213] Various outcomes present regulators and the public with the question of whether there should be a leash on personal genetic data, and if so, then what action is best. The current regulations, or proposed regulations, seem to mostly limit uses in a discriminatory sense and place barriers to mandatory disclosure requirements.[214]

For biologic relations, there has been little attention paid by regulators outside of law enforcement access to familial DNA.[215] Compared to individuals that provide the DNA sample, even with mandatory disclosure requirements, there is little oversight or control on how that information is used regarding biological relatives.[216] Furthermore, one may not be aware that a biological relative provided a genetic sample to a company, which may then use the information.[217] An individual's privacy could be compromised based on the disclosure of a relative to any direct-to-consumer testing company.[218] Mandatory disclosure requirements of any data use does limit how easily data can be disseminated, but genetics forms an unique problem because the information cannot be "put back in the bottle" after the data has left the original testing company.[219] Unlike changing a number or password to protect your identity or credit card, genes can never be changed, and they may be unretrievable once released.[220] Even if it was required to notify someone of usage or testing, there is no easy way to regulate, track, or ensure these steps have been followed.[221] Biologic relations have the same concerns about

211. Eric Rosenbaum, *Genetic Testing Company 23andMe Rises in First Trade After Richard Branson SPAC Merger*, CNBC (June 17, 2021, 12:47 PM), https://www.cnbc.com/2021/06/17/gene-testing-firm-23andme-trades-higher-after-branson-spac-merger-.html [https://perma.cc/QB5L-B4EJ].

212. *See id.*; Stephen Gandel, *Private Equity Wants to Own Your DNA*, CBS NEWS (Aug. 7, 2020, 4:52 PM), https://www.cbsnews.com/news/blackstone-private-equity-ancestry-com-dna/ [https://perma.cc/7APH-5MQG].

213. *See* Gandel, *supra* note 212 (providing an example of information provided by DNA tests being part of a company's assets).

214. *E.g.*, UTAH CODE ANN. § 13-58-201 (2021).

215. *See* Stein, *supra* note 15.

216. *See id.*

217. *Id.*

218. *Id.*

219. *Id.*

220. *See id.*

221. *See* Entrikin, *supra* note 13, at 857; *see* Stein, *supra* note 15.

security as the individual who provided their genetic data to direct-to-consumer entity.[222] As a bystander to any transaction, currently regulations do not considered the effect on biologic relations. As such, companies are, in a sense, morally trusted to preserve the rights of consumers without any regulatory guidance of their actions.

V. PROPER REGULATORY ACTION GIVEN THE IMPACT OF REGULATIONS

The varying impact of regulatory standards strains the relationship between individual privacy rights, data rights, and potential medical progress.[223] A data sharing model or framework could potentially offer a middle ground that would prevent individual countries from bogging down the sharing of data, while also protecting the public from unscrupulous data sharing or selling.[224] Proposals out of Europe discuss a code of conduct that would allow for better international transfers of data between countries that use similar models by providing a common standard to follow and allow for countries to simply add themselves to the network in the future.[225] Europe has slowly implemented uniform standards for certain aspects of medical services or products.[226] One example is the implementation of the 2017 Regulation on in vitro diagnostic (IVD) medical devices, which created a blanket limitation on tests using these medical devices.[227] Because of the limitations placed on IVDs used for medical services in clinical settings, there were critics who felt this was an intrusion on medical providers in certain countries.[228] In regard to direct-to-consumer genetic test offerings, however, critics of the limitation can be subdued with the knowledge that only the testing companies, and not clinical providers, would be subject to the new regulations.[229]

Regulations should be as clear as possible because interpretive questions tend to create more problems than solutions and should be avoided especially when millions of dollars in fines are possible.[230] From a business perspective, regulations that can eliminate uncertainty, while maintaining the integrity of the standards, are best. The most obvious way to address this within the ex-

222. Entrikin, *supra* note 13, at 857.

223. *See* Kalokairinou et al., *supra* note 17, at 128.

224. *See* Entrikin, *supra* note 13, at 895.

225. *See* Kalokairinou et al., *supra* note 17, at 120.

226. *See id.*

227. *Id.*

228. *Id.*

229. *See id.* at 129.

230. *See European Society of Human Genetics Critiques EU's GDPR*, Sci. Advisory Bd. (Aug.30, 2021), https://www.scienceboard.net/index.aspx?sec=Srr&sub=def&pag=dis&ItemID=3211 [https://perma.cc/D5UT-7K4A] [hereinafter *Critiques*].

isting "ecosystems" of Europe or the United States is through collaboration between member countries or states to facilitate uniform partnerships and enforcement of the rules rather than a patchwork of regulations.[231] This will allow for the sharing of information, and when there is a more uniform basis from which to operate, for businesses to succeed.[232]

The use of genetic data by third parties can cause issues, but the key choice regulators can make is a distinction between using the data with or without personal identifiers.[233] As was previously noted, privacy concerns exist regarding government and businesses access to consumer's personal data.[234] When the ability to separate personal identifiers from the data becomes available, a compromise between data privacy and scientific advancement can be reached by protecting consumers through hiding their personal identification, while simultaneously allowing for commercial and medical advancement through data sharing.[235] This will balance the ability of gains possible from the data without the issues of personal connection to the samples provided by consumers.[236] Another potential benefit of separating personal information from genetic data is that after the first consented use, law enforcement or government requests to use the data can be limited due to the fact that personal identifiers have been eliminated and cannot be readily given to the government.[237] Thus, the traditional channels of an individual's consent or a court order would be the only ways for law enforcement to acquire genetic data.

Finally, the biggest issue regarding personally identified genetic data is that it cannot be altered.[238] Use of genetic data against an individual creates a policy issue of potential fairness.[239] Some states have outlawed the usage of genetic data for employment or certain insurance coverage, but the laws are nowhere near uniform.[240] The use of genetic data, when linked to one's identity, should require consent and should not be allowed for any additional use later on without additional consent by the individual who provided the genetic data. The new California regulation that requires that a direct-to-consumer company destroy the data sample within thirty days after receiving a notification of revoked consent by the sample provider is an interesting way

231. *See id.*; Trimboli & Ruggiero, *supra* note 199, at 26.

232. *See Citiques*, *supra* note 230; *see* Trimboli & Ruggiero, *supra* note 199, at 26.

233. Entrikin, *supra* note 13, at 857.

234. Auxier & Rainie, *supra* note 12.

235. *See* Entrikin, *supra* note 13, at 892, 896.

236. *See id.*

237. *See id.* at 785 n.5.

238. *See id.* at 892.

239. *E.g.*, Stein, *supra* note 15.

240. *See* Valetk, *supra* note 100.

to keep control of personal data.[241] This is a great way for consumers to potentially reel in their past decision to participate in a testing service.[242] The goal is balance, allowing for innovation and protecting the public from the risk of being taken advantage of by a testing service.[243] Another path to achieve this balance would be to require genetic test providers to gain consent for all their uses of the data through contracts with individuals.[244]

From an enforcement perspective, penalties that include a civil penalty, class actions, or the loss of the right to practice could be a solid basis for enforcement. There is also a potential for disgorgement or, like the EU, for allowing damages as high as 4% of revenue.[245] All of this can be implemented to deter companies from breaking the law.

Solutions do not exist only in the regulatory or political sphere. From a business perspective, businesses need to evaluate potential regulations and the varied regulations that exist around the world.[246] Businesses have a chance to direct and implement processes that guide the regulations of the future.[247] All direct-to-consumer options have a brand as wells as an image that is earned over time through the businesses' processes and actions.[248] From a brand perspective, businesses can identify different legislative tools that may be useful in guiding direct-to-consumer genetic testing companies to act responsibly, and can give the public confidence in certain regulatory rules or standards.[249] Additionally, businesses have a chance to protect themselves from liability by not pushing the limits of what is acceptable, but instead keeping and meeting customer expectations for service, privacy, and data protection.[250] Depending on how they choose to do business, businesses can have a huge impact on hindering or assisting with the creation of regulations.[251]

Finally, to protect biologic relations, the regulatory options seem to emanate best from effective policies regarding individual genetic privacy. As noted, studies have found the availability of genetic testing data in the United States has made it so that one could potentially triangulate the identities of a

241. *See* Kadish & Schafer, *supra* note 103, at 2.

242. *See id.*

243. Entikin, *supra* note 13, at 860, 865.

244. *See* Kadish & Schafer, *supra* note 103, at 2.

245. *See* Wolford, *supra* note 118.

246. *See id.*

247. Entikin, *supra* note 13, at 866.

248. *See* Rosenbaum, *supra* note 8.

249. *See* Entikin, *supra* note 13, at 866.

250. *See* Rosenbaum, *supra* note 8.

251. *See* Kalokairinou et al., *supra* note 17, at 130.

majority of individuals in the United States in the next few years.[252] Clamping down on data from genetic tests means that fewer individuals who did not submit their genes for testing would be caught up in a close relative's personal data.[253] By limiting the dissemination of personal genetic information in general the privacy concerns for biological relatives decrease significantly.[254]

Overall, a uniform set of regulations has the most potential to limit the disparate impact that the current patchwork of regulations has on businesses. By preempting state rules, a federal set of laws could eliminate the thicket of rules while also allowing regulations to be more easily enforced. Should Europe achieve uniformity before the United States, its rules could offer a framework or model for the United States to emulate. Finally, when personal identifiers can be eliminated a middle ground could potentially allow for the use of genetic data for medical advancement without compromising concerns over privacy.

VI. CONCLUSION

The genetics industry and its impact on human life continue to grow. As such, the issues of privacy and protection of information that can be culled from individual genes or the human genome grow as well. The current federal regulation in the United States creates a nation-wide minimum standard, but variations in state requirements create a confusing patchwork of regulations. Additionally, there are concerns from a commercial and privacy aspect, as globally the world lacks a common approach. Numerous questions linger on how genetic data should, or can, be treated. Congress seems inclined not to preempt state laws on privacy and genetics. As such, the patchwork of state regulations seems here to stay. On a related note, there is uncertainty on how the genetic data is used after testing and whether companies may provide the data to third parties. Moreover, there is little to no thought on how genetic data voluntarily obtained by one individual can be used in regard to individuals who share a genetic relationship. Close biological relatives share a high percentage of the identical genes but may not have consented to provide genetic data. Europe offers another basis for ideas on how to regulate the direct-to-consumer genetics industry. They have a General Data Protection Regulation for the entire European Union, but individual countries have added regulation well beyond those provided by the European Union. Considering the impacts of genomics on closely related individuals ushers in new questions on how to properly regulate the genomics industry.

From a proposed regulatory regime perspective, it is best to try and preempt individual states or country regulations. First, though perhaps unattainable, this proposed uniformity in a regulatory regime would aid in the

252. Haag, *supra* note 34.

253. *See* Entrikin, *supra* note 13, at 860.

254. *See id.*

enforcement of and the conformity to the rules, and, perhaps most importantly, aid in the ability for cross-border data sharing and medical advancements. Next, this proposed uniform regulatory regime would create the ability to consider a middle ground for data sharing when personal identification is made unavailable. This "faceless" data could be used for commercial and medical advancement without the worries associated with personal privacy. Finally, the ability of companies to use personally identified data should at a minimum mandate informed consent for additional use from the consumer, and consent should perhaps not be allowed at all given the potential of violations to personal privacy. Regulators have been mostly passive, but opportunities to harmonize the rules exist within the European Union and the United States to both further the advancement of science and data usage, while protecting individual privacy.