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23andPleaseDoNotDenyMe: The Insurance Coverage Backlash Consumers Suffer When Human Identity Becomes a Commodity

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23ANDPLEASEDONOTDENYME: THE INSURANCE COVERAGE BACKLASH CONSUMERS SUFFER WHEN HUMAN IDENTITY BECOMES A COMMODITY

Megan A. Rogers-Hasie[*]

I. INTRODUCTION

Today, consumers purchase at-home genetic tests for a myriad of reasons. Some people want to become more informed about their bodies and their health, some people are curious about the science behind why they sneeze when they look into a bright light, others might seek information about their global heritage in an increasingly connected world, still others may be looking for their biological families or unknown relatives. The more that consumers utilize direct-to-consumer ("DTC") genetic tests like the ones offered by 23andMe, the more genetic data becomes available to researchers and scientists.[1] This increase in information leads to discoveries both novel and life-saving.[2] But lurking under the surface of all this personal and scientific revelation is a dangerous undercurrent for the very consumers who quite literally offer themselves up for the betterment of society.[3]

This comment advocates for greater consumer protections in the area of genetic testing and the life and disability insurance marketplace. Part I provides a history of 23andMe, showing how the company has turned certain regulatory setbacks into strengths. Part II explores the background of the current laws surrounding life insurance discrimination, data mining, and DTC genetic testing research. Part III explains how consumers consent to 23andMe research, data exhaust and data mining, and the accumulation of data by 23andMe for their research. Part IV covers the growing problems with re-identifying consumers from de-identified data. Part V is a discussion on the Genetic Information Nondiscrimination Act which

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1. Katherine Drabiak, Article*: Caveat Emptor: How the Intersection of Big Data and Consumer Genomics Exponentially Increases Informational Privacy Risks*, 27 Health Matrix 143, 152-53 (2017).

2. 23andMe, https://www.23andme.com/ (last visited March 5, 2020).

3. Drabiak, *supra* note 1, at 156.

prohibits health insurance companies from discriminating against consumers for their genetics but does not extend that same protection to life insurance consumers. Part VI looks to the advances made by the study of genomics while Part VII suggests solutions to better protect consumers of DTC genetic testing.

I. A BRIEF HISTORY OF 23ANDME

23andMe offers in-home genetic testing to determine ancestry for as low as $99.00.[4] This testing tells the consumer which part of the world their ancestors came from and can help the consumer locate family members who have also used 23andMe's services.[5] For the more curious consumer, 23andMe offers a "Health Service" in conjunction with their ancestry service.[6] This testing, priced at either $199.00 or $499.00, depending on how much information you want, educates the consumer as to certain health predispositions, such as whether the consumer is positive for cancer-causing genes like BRCA1 and BRCA2.[7]

The process is quite simple, once a consumer has selected their product of choice, 23andMe sends out a testing kit which includes a tube for the consumer's saliva.[8] After the consumer has returned their DNA sample, 23andMe provides results within 3-5 weeks.[9] Consumers have access to their raw data, whatever analyses they've selected from 23andMe, and they can register their data through 23andMe's app.[10] Once the analysis is complete, consumers can participate in 23andMe research.[11] Per the company's website, "[t]he choice to opt into or out of research is always up to the participant."[12] The company states that on average, a participant's data is used in over 230 studies and over 80% of consumers opt-in to the research.[13]

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4. *Compare our DNA Tests*, 23andMe, https://www.23andme.com/compare-dna-tests/?vip=true (last visited Oct. 29, 2019).

5. *Id*.

6. *Id*.

7. *Id*.

8. *How it Works*, 23andMe, https://www.23andme.com/howitworks/?vip=true (last visited Oct. 29, 2019).

9. *Id*.

10. *Compare our DNA Tests*, *supra* note 4; *The 23andMe Mobile DNA Reports App*, 23andMe, https://customercare.23andme.com/hc/en-us/articles/212193898-The-23andMe-Mobile-DNA-Reports-App (last visited Oct. 29, 2019).

11. *Research – 23andMe*, 23andMe, https://www.23andme.com/research/?vip=true (last visited Oct. 30, 2019).

12. *Id*.

13. *Id.*; *About Us – 23andMe Media Center*, 23andMe, https://mediacenter.23andme.com/company/about-us/ (last visited Oct. 30, 2019).

Today, 23andMe boasts over 12,000,000 customers.[14] The company's path to success has not been without regulatory setbacks though. The United States Food and Drug Administration ("FDA") sent the company a warning letter in November of 2013 because 23andMe had violated the agency's Federal Food, Drug, and Cosmetic Act by selling its saliva kits and genome testing without first securing FDA approval.[15] The offending 23andMe product was the company's Personal Genome Service which assessed risk for breast cancer and Alzheimer's among other traits and conditions.[16] The FDA warned of misbranding due to false positives or false negatives in addition to concerns about 23andMe's lack of validation of the health claims made by the testing service.[17] As a result, the company ceased selling the Personal Genome Service in the United States but maintained sales of the ancestry service and continued selling the Personal Genome Service in the United Kingdom and Canada.[18] While the warning letter has since been removed from the FDA's website, a copy is still available through the Business Insider website.[19]

II. CURRENT LAWS AND REGULATORY FRAMEWORK

The consumer data stored by 23andMe doesn't just hold value in its scientific worth, the genetic profiles are a lucrative commodity attractive to pharmaceutical companies, insurance companies, and the data miners who track our every click, purchase, and location.[20] As long as data mining is legal, DTC genetic testing companies can sell data from their bank of genome profiles, and insurance companies can deny life insurance coverage based on the results.[21] Consumers often must self-report their genetic tests to life insurance companies and consumer data is available for purchase from data miners.[22] Consumers need protection so they aren't discriminated against because they took a genetic test.

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14. *About Us*, *supra* note 13.

15. Megan Rose Dickey, *The FDA Wants 23andMe to Stop Marketing its Genetic Testing Kits*, BUSINESS INSIDER (Nov. 25, 2013, 10:08 AM), https://www.businessinsider.com/fda-sends-warning-letter-to-23andme-2013-11.

16. Drabiak, *supra* note 1, at 149-51.

17. Dickey, *supra* note 15.

18. Drabiak, *supra* note 1, at 151.

19. Dickey, *supra* note 15.

20. Drabiak, *supra* note 1, at 157.

21. *Id*.

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

A. Genetic Information Nondiscrimination Act

The Genetic Information Nondiscrimination Act of 2008 ("GINA") prohibits health insurance companies from using a consumer's genetic information as a basis for providing or denying coverage.[23] The law, which took more than thirteen years to pass in Congress, was designed to promote "an age of genetic medicine" while providing necessary safeguards.[24] Genetic tests cannot be used in determining a consumer's premium, nor can the genetic information be considered a pre-existing condition.[25] GINA also prohibits employers with more than fifteen employers from hiring, firing, or otherwise discriminating against employees based on the employee's genetic information.[26] Prior to the Affordable Care Act ("ACA"), pre-existing conditions could be grounds for denying health insurance coverage.[27] For as long as the ACA is good law, pre-existing conditions cannot be the determinative factor of whether or not a health insurance company will insure an applicant.[28] However, the safeguards of GINA and the ACA do not extend to life or disability insurance providers.[29] Early versions of GINA included protections in life and disability insurance, not just health insurance.[30] However, these provisions were dropped after hard lobbying by life and disability insurance providers.[31] Because of the difficulties in getting GINA through both chambers of Congress, proponents of the bill compromised on the broadness of the bill's protections.[32] One advocate for GINA described focusing efforts on health insurance and employment discrimination, where the law's protections were most needed, since not everyone purchases a life insurance policy.[33] Currently, life and disability insurance companies can request a potential

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23. Genetic Information Nondiscrimination Act, Pub. L. No. 110-233, § 101(a)(3)(A), 122 Stat. 881, 883 (2008).

24. Andrew Pollack, *Congress Near Deal on Genetic Test Bias Bill*, NYTIMES (Apr. 23, 2008), https://www.nytimes.com/2008/04/23/business/23gene.html.

25. Genetic Information Nondiscrimination Act § 101(d)(1-2).

26. Sejin Ahn, *Whose Genome Is It Anyway?: Re-Identification and Privacy Protectionin [sic] Public and Participatory Genomics*, 52 SAN DIEGO L. REV. 751, 775-76 (2015).

27. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1101(d)(3), 124 Stat. 119 (2010).

28. *Id*.

29. Ahn, *supra* note 26, at 777.

30. Farr, *supra* note 22.

31. *Id*.

32. Sarah Zhang, *The Loopholes in the Law Prohibiting Genetic Discrimination*, THE ATLANTIC (Mar. 13, 2017), https://www.theatlantic.com/health/archive/2017/03/genetic-discrimination-law-gina/519216/.

33. *Id.*

client's genetic test results and deny coverage if the potential client is not forthcoming about having had a genetic test performed.[34] Life and disability insurance companies can also deny coverage if the potential client's genetic test indicates a predisposition for certain illnesses or diseases, even if that person never develops the illness or disease or takes preventative measures.[35] It is not only the shortcomings in GINA that leave DTC genetic testing consumers at risk. The Supreme Court's decision in *Sorrell v. IMS Health, Inc.* allows for the sale and data mining of consumer genetic data which presents a risk for consumer privacy and insurance coverage.

B. Sorrell v. IMS Health, Inc.

In June of 2011, the Supreme Court found constitutional support for selling consumer data in *Sorrell v. IMS Health, Inc*.[36] The case centered around the practice of pharmacies selling information about the prescribing practices of doctors to data miners – companies that take consumer data and repackage it as a commodity that can be sold to marketing and advertising firms, insurance companies, and even political campaigns.[37] The data mining at the heart of *Sorrell* converted a physician's prescription pad into data that was sold or leased to pharmaceutical companies.[38] Pharmaceutical companies then utilize this data to market new brand-name prescriptions to doctors they believe will be more likely to prescribe the drug.[39] To combat this practice, the state of Vermont enacted the Prescription Confidentiality Law, which (1) prohibited pharmacies from selling this data for the purpose of pharmaceutical marketing, (2) prohibited pharmacies from allowing prescriber data to be used for marketing, and (3) prohibited pharmaceutical manufacturers and marketers from using prescriber data for marketing.[40] The Court consolidated two suits, one brought by the data miners and one brought by an association of pharmaceutical manufacturers.[41] While the

34. Farr, *supra* note 22.

35. *Id.*

36. Sorrell v. IMS Health, Inc., 564 U.S. 552 (2011).

37. *Id*. at 558; Lois Beckett, *Everything We Know (So Far) About Obama's Big Data Tactics*, PROPUBLICA (Nov. 29, 2012, 10:45 AM), https://www.propublica.org/article/everything-we-know-so-far-about-obamas-big-data-operation; Matthew Rosenberg, Nicholas Confessore, & Carole Cadwalladr, *How Trump Consultants Exploited the Facebook Data of Millions*, NYTimes (Mar. 17, 2018), https://www.nytimes.com/2018/03/17/us/politics/cambridge-analytica-trump-campaign.html.

38. Sorrell v. IMS Health, Inc., 564 U.S. 552, 558 (2011).

39. *Id*.

40. *Id*. at 558-59.

41. *Id*. at 561.

United States District Court for the District of Vermont upheld the law, the Second Circuit reversed.[42] Due to a circuit split with the First Circuit upholding similar laws in Maine and New Hampshire, the Supreme Court granted certiorari and affirmed the Second Circuit's holding.[43]

The Supreme Court, like the Second Circuit, decided the case on First Amendment grounds.[44] Although the Vermont legislature made several findings relating to the practice of prescribing name brand medications, pharmaceutical sales, and data mining, the sole effect of the Prescription Confidentiality Law was to chill commercial speech in violation of the First Amendment.[45] The Court did note that even with the Prescription Confidentiality Law in place, pharmacies were free to disseminate prescriber data for "health care research."[46]

C. The Food and Drug Administration

Less than a decade after the Court's decision in *Sorrell*, the Food and Drug Administration (FDA) legalized the use of DTC Genetic Testing for the purpose of pharmacogenetics for the first time in October of 2018.[47] Per the FDA, "[p]harmacogenetics is the process of understanding what, if any, role genetics plays in a patient's reaction to drugs."[48] Specifically, the FDA authorized 23andMe, one of the largest companies in the field of DTC Genetic Testing, to market a test that informs consumers of whether their genetics prohibit the absorption of certain medications.[49] This FDA approval came in the wake of 23andMe's $300,000,000 partnership with pharmaceutical company, GlaxoSmithKline ("GSK") on July 25, 2018.[50] The partnership between 23andMe and GSK is intended to include only those 80% of 23andMe consumers that have opted in to the company's research while maintaining consumer confidentiality.[51] As Justice Kennedy speculated when writing the majority opinion for *Sorrell* in 2011,

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42. *Id*. at 561-62.
43. *Id*. at 562.
44. *Id*. at 557.
45. *Id*. at 560-61, 565.
46. *Id*. at 559.
47. Press Release, Food and Drug Administration, *FDA Authorizes First Direct-to-Consumer Test for Detecting Genetic Variants that may be Associated with Medication Metabolism* (Oct. 31, 2018) (on file with author).
48. *Id*.
49. *Id*.
50. Press Release, GlaxoSmithKline, *GSK and 23andMe sign agreement to leverage genetic insights for the development of novel medicines* (25 July 2018) (on file with author).
51. *Id*.

consumer data has been converted into a marketing tool for "health care research."[52]

D. And Thus, the Problem

There is now a clear relationship between DTC genetic testing, manufacturers of pharmaceutical drugs, and the availability of the data from that testing to health, life, and disability insurers. Without legislative intervention in the form of an amendment to GINA, consumers who have contributed their genetic makeup to scientific research or who have had genetic testing performed as an early preventative measure for serious diseases, can and will be denied life and disability insurance. These same consumers may find that they cannot get health insurance payments for certain medications because the available data shows that medication is not suitable for the consumer in terms of pharmacogenetics. While it is fair that a health insurance company would not want to pay for medication that won't help the consumer, genetic testing is rife with false positives and inaccurate results. The medicine that data suggests will not help the consumer may actually be a life-saving treatment. The appeal of databases like 23andMe's is the mass amount of genetic information coupled with self-reported health issues and individual characteristics. But the risk of rejection of life and disability insurance or denial of health insurance claims will discourage consumers from partaking in DTC genetic testing. This will hinder scientific progress and possibly cause otherwise preventable or treatable diseases to run rampant. Improved approaches by regulatory bodies like the FDA and updated legislation by Congress is needed to preserve consumer protections and advance the future of medical studies.

III. DEEP DIVE INTO THE DATA POOL

Between GINA, the *Sorrell* decision, and the FDA's approval of using consumer data for the research of pharmacogenetics, there is now a gap in protection for consumers who may later seek life or disability insurance coverage. The problem begins with data miners who sell prescriber information to willing buyers such as pharmaceutical manufacturers and insurance companies.[53] Data miners also track and sell other data, online data such as social media likes and comments, websites visited, purchases made; physical data like our location, age, profession, and sexual orientation; and now with the boom in DTC genetic testing and pharmacogenetic studies, data miners can sell a consumer's very DNA.[54]

52. *Sorrell*, 564 U.S. at 559.
53. *Id.* at 558.
54. Drabiak, *supra* note 1, at 146-47.

As worrisome as it is that all this data is available to data miners, consumers have already self-reported this information to 23andMe directly.[55] While 23andMe promises to de-identify consumers' data during the research process,[56] re-identification is not only possible but has been achieved through multiple studies.[57] Re-identification is discussed in detail below. All of this information is widely available, legally so, allowing life insurance companies to make determinations about coverage without truly considering the applicant as a human.[58] To their detriment, consumers become reduced to statistical projections.[59]

A. Changing Notions of Informed Consent

The FDA's 2013 reprimand caused 23andMe to shut down its most lucrative and scientifically advanced department.[60] Not to be deterred, 23andMe then began to grow its database of genetic profiles by marketing the ancestry component of its business and providing consumers with their raw genetic data.[61] The company's long-term goal is now to amass its database of genetic profiles and to sell access to that database.[62] It is the volume of this database that attracts research partners and contracts with pharmaceutical companies.

Although 23andMe has partnered with other companies in the past,[63] the partnership with GSK is the first study that has been FDA-sanctioned.[64] 23andMe has turned an FDA rebuke into FDA success to the tune of $300,000,000. With this partnership comes questions concerning those who have submitted their DNA to 23andMe and have consented to the company's research. One needs only to think of Henrietta Lacks to realize the pitfalls that come with uninformed human research subjects.[65]

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55. *Id.* at 157-58.
56. *Id.* at 158.
57. Ahn, *supra* note 26, at 767-70.
58. *Id.* at 764-66.
59. *Id.* at 770-71.
60. Drabiak, *supra* note 1, at 149-51.
61. *Id.* at 151-52.
62. *Id.* at 152-53.
63. *Id.* at 151, 154.
64. Food and Drug Administration, *supra* note 47; GlaxoSmithKline, *supra* note 50.
65. Henrietta Lacks, the woman who became the source of the HeLa cell line, was an unwitting human research subject – both in life and in death. The biopsy of her cancer cells was used for research without Henrietta's consent or knowledge, and her family has never been compensated for the discoveries that have resulted from Henrietta's cell line. Kayte Spector-Bagdady & Elizabeth Pike, Article: *Consuming*

The Common Rule, which is a federal regulation for studies involving human research subjects, only applies to federally funded research.[66] Because the 23andMe and GSK project is between two private companies, the Common Rule is not applicable. Even still, the Common Rule is useful in considering the effectiveness of 23andMe's consumer consent process. Under the Common Rule, informed consent consists of describing the research procedure, explaining risks and benefits, offering the right to withdraw from the study, and a degree of confidentiality.[67] 23andMe encourages consumers to join the company's research efforts and provides consumers with a Research Consent.[68] The Research Consent informs consumers that the company's goal is "to make and support meaningful scientific discoveries."[69] The Research Consent covers research done by 23andMe, research done with partner companies, the publication of research in peer-reviewed journals, and research funded by the National Institutes for Health and other federal government grants.[70] Signing the Research Consent is mandatory to partake in 23andMe research and the company informs consumers that the consent is comparable with consent documents required by the Common Rule.[71]

But questions linger that this consent is not enough given the rapidly advancing nature of genome research and the number of studies a consumer's data will be involved in. In its Research Consent, 23andMe informs consumers of the lengths the company goes to protect consumer data physically, technically, and administratively.[72] However, the company does not commit to whether it will require its third-party partners to protect a consumer's confidentiality.[73] The company references GINA on its website but is not forthcoming in regards to the limits of the protection that legislation offers.[74] The Research Consent does inform consumers that re-identified data may be made available to insurance companies which could have a negative impact on the consumer's ability to obtain insurance coverage.[75] As a safeguard for itself, 23andMe denies any liability for risks

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Genomics: Regulating Direct-to-Consumer Genetic and Genomic Information, 92 NEB. L. REV. 677, 681-82 (2014).

66. Ahn, *supra* note 26, at 778-79.

67. *Id.* at 778.

68. Drabiak, *supra* note 1, at 155-56.

69. *Id.* at 155.

70. *Id.*

71. Angela L. Morrison, *Note, A Research Revolution: Genetic Testing Consumers Become Research (and Privacy) Guinea Pigs*, 9 J. on Telecomm. & High Tech. L. 573 (2011).

72. Drabiak, *supra* note 1, at 156-57.

73. Morrison, *supra* note 71. at 586.

74. *Id.*

75. Drabiak, *supra* note 1, at 157.

experienced by consumers as a result of their purchase of 23andMe products.[76] In short, consumers may be topically aware of the consequences of genetic testing but there are sizeable gaps in both the information provided and how that information is provided. Such gaps suggest the consent is not informed, or at least not as informed as it should or ought to be given the risks to the consumer.

B. Data: Our Digital Footprint

As evidenced in *Sorrell*, data is valuable to pharmaceutical manufacturers.[77] But prescription data is a small fraction of the available data about a consumer that has value. "Data exhaust," data about what we look at, where we have been, and what we have bought, includes social media likes, interests, and photos.[78] Commercial databases track our purchases while fitness bands monitor exercise, heart rate, location, and sleeping habits.[79] Smart watches also track our location, our purchases, and our communications in conjunction with our mobile phones.[80]

A person's entire internet presence is tracked through technology called cookies, action tags, and web bugs.[81] Cookies, action tags, and web bugs are embedded in nearly every website we visit.[82] This technology is useful for recording limited categories of information like passwords and browser history.[83] Cookies make functions like "autofill" possible.[84] Cookies like Google's DoubleClick provide targeted ads to users based on the information gathered by the cookie.[85] Google's DoubleClick accumulates a large quantity of data from consumers because it tracks each website the consumer visits which is how it is able to offer a targeted ad on Facebook based on a consumer's visit to the 23andMe website.[86] Action tags, or web bugs as they may be known, record mouse movements and keystrokes that were not submitted to the webpage.[87] This data gets written into the consumer's cookie.[88] Within thirty minutes of web searching,

76. *Id.*
77. *Sorrell*, 564 U.S. at 552.
78. Jane Yakowitz Bambauer, Article: *The New Intrusion*, 88 NOTRE DAME L. REV. 205, 207-08 (2012); Drabiak, *supra* note 1, at 146.
79. Drabiak, *supra* note 1, at 146-47.
80. Bambauer, *supra* note 78, at 239-42.
81. *Id.*
82. *Id*. at 239-40.
83. *Id*. at 240.
84. *Id*. at 240-41.
85. *Id*.
86. *Id*. at 240.
87. *Id*. at 241.
88. *Id*. at 241-42.

cookies can acquire data relating to a consumer's social media, age, location, employment, and sexual orientation, just to name a few identifiers. Although industry standards require that cookies must be encrypted and cannot contain malicious code or be visible to others,[89] this is still a lot of personal information in the hands of corporate bodies who can turn around and sell aggregated data.

C. 23andMe Houses All This Data

As has been demonstrated, 23andMe has a massive database of consumer data. When it comes to the individual consumer, the company has raw genetic data, self-reported health histories, and family histories, name, race, sexual orientation, and age.[90] The company's privacy statement informs consumers that in addition to research purposes, the company can use consumer data for other purposes, such as targeted marketing and advertising.[91] 23andMe achieves this goal through the use of cookies and web bugs which track IP addresses and clickstream data.[92] Through web tracking, the company also has consumer social media information, employer information, photos, a record of websites visited, and real-time geo-tracking.[93] 23andMe gains this information in part through self-reported consumer information as part of the testing process. But the company also encourages consumers to share their purchase and results of 23andMe genome testing on social media websites like Facebook and LinkedIn. Consumers that do so grant 23andMe access to their photos, network, gender, age, and list of friends.[94] This data may be retained by 23andMe and shared with third parties without consumer consent if the data has been de-identified.[95]

IV. THE INEVITABILITY OF RE-IDENTIFICATION

True de-identification of consumer DNA is arguably impossible and re-identification is all but unavoidable. After all, DNA is specific to the consumer, differentiating that consumer from every other human on the planet. Human beings share close to 99% of the same DNA, it is the 1% of

89. *Id*.
90. Drabiak, *supra* note 1, at 156.
91. *Privacy Highlights § (2)(c),* 23andMe, https://www.23andme.com/about/privacy/ (last updated Jan. 1, 2020) [hereinafter Privacy Highlights].
92. *Id.* at § (2)(a)(v).
93. Drabiak, *supra* note 1, at 159.
94. *Id.* at 157-159.
95. *Id.* at 158-59.

variation in conjunction with environmental factors that leads to distinctions in hair and eye color, health conditions, and personality traits.[96] It is these variations in DNA that interest data scientists.[97] Having a large genomic database is essential to understanding variations from consumer to consumer.[98] During consumer intake, 23andMe obtains three kinds of information about the consumer.[99] The company gets Registration Information which includes name, email address, and credit card information.[100] Genetic Information consists of the consumer's DNA sample and the data generated by it.[101] Self-Reported Information includes the consumer's survey responses telling 23andMe about diagnoses, medical history, and family history.[102] For data profiles that enter the research arena, the genetic and self-reported information is aggregated and stripped of registration identifiers.[103]

23andMe's Research Consent informs consumers that their genomic data and self-reported health histories will be used for research conducted by both 23andMe and 23andMe's research partners.[104] The self-reported consumer data includes family history, current health status, personal traits, age, racial origin, sexual orientation, and ethnicity.[105] 23andMe's Privacy Statement says consumer data is combined with data from other users to minimize the risk of re-identification but as studies have shown, re-identification is probable.[106] And despite this assurance, 23andMe retains enough consumer information, highly personal and individualistic information at that, that re-identification is entirely possible.[107] De-identified data can be cross-referenced with social media, self-reported health information, and publicly accessible ancestry websites such as GEDmatch to re-identify the specific consumer.[108] For instance, a teenager was able to re-identify his anonymous sperm donor father through genotyping and searching the internet.[109] Data scientists have successfully re-identified consumers whose DNA was available on public genome

96. Spector-Bagdady, *supra* note 65, at 685.
97. Ahn, *supra* note 26, at 761-62.
98. *Id*. at 764.
99. Morrison, *supra* note 71, at 585.
100. *Id.*
101. *Id.*
102. *Id.*
103. *Id.*
104. Drabiak, *supra* note 1, at 158.
105. *Id.* at 156.
106. Morrison, *supra* note 71, at 585, 590-91.
107. *Id.* at 592.
108. Drabiak, *supra* note 1, at 167.
109. Ahn, *supra* note 26, at 755 n.10, 769.

databases.[110] Re-identification is not only concerning for safety and privacy reasons, re-identification can cause stigma, shame, discrimination, and even criminal accusations for the individual consumer and their relatives.[111]

Anytime a consumer shares their genetic data, the possibility arises that someone will reconstruct the data to identify the individual behind it.[112] A Massachusetts governor was identified in a database of publicly available de-identified patient records.[113] Using birth date, sex, zip code, and a widely reported hospitalization, a researcher was able to pair anonymous data with a very real human – the governor.[114] Similar studies prompted the National Institutes of Health to remove genetic data from public websites out of concern for consumer privacy.[115] DTC genetic testing generally involves examination of up to a million genetic variations, but a 2004 study found only thirty are needed to differentiate one data set from another.[116]

Aggregate data held by 23andMe and their partners may be made public through research findings or released to insurance companies.[117] 23andMe does advise consumers in their Research Consent that information given to insurance companies may affect a consumer's ability to obtain insurance coverage.[118] The company retains the rights to use all consumer data for non-research purposes as allowed by law, and for targeted marketing and advertising.[119]

Thus, the risks of re-identification extend to the 20% of 23andMe consumers who do not opt into research as well as the 80% of consumers who do.

For consumers who seek to revoke their consent to research, 23andMe will cease use of that individual's data in the future, but the data will remain part of past and on-going research.[120] In the event a consumer wants to withdraw their consent from 23andMe research, they can do so through the company's webpage or app but it will take up to 30 days to

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110. *Id.* at 767-68.

111. *Id.* at 774; Michael R. Dohn, *Article: Personal Genomics and Genetic Discrimination: Is Increased Access a Good Thing?*, 45 W. ST. L. REV. 107, 107-08 (2018).

112. Morrison, *supra* note 71, at 591-92.

113. *Id.* at 590-91.

114. *Id.*

115. *Id.* at 591.

116. *Id.*

117. *Id.* at 585.

118. *Id.* at 586.

119. Drabiak, *supra* note 1, at 157-58.

120. *Id.* at 158-59.

remove that consumer from the research database.[121] Withdrawing consent does not remove a consumer's data from ongoing research or from data pools submitted to third-party research partners, like GSK.[122] Nor does withdrawing consent remove a consumer's data from published research.[123] Whether or not a person has enrolled in 23andMe research, their genetic data exists in the company's database indefinitely.[124] Requests for entire removal of data from 23andMe's database does not guarantee the company will not use the data for sequencing in the future or deny a third-party to retain consumer genomic information or a backup copy of it.[125] The data retention includes the full genomic sequence, the self-reported health information which is highly personal and identifiable, and the fact that the consumer underwent 23andMe genome testing.[126] Once a consumer sends their tube of saliva to 23andMe, their data is liable to become part of the ether for the rest of time.

The mass amount of data 23andMe holds for each consumer multiplied by over 10,000,000 customers makes the company a desirable target for cyber-attacks.[127] Despite the company's best efforts at privacy, an internet hacker could access the consumer database and sell the data to the highest bidder or post it freely on the web. This was almost a reality for a 23andMe rival company, Ancestry, in 2014.[128] Further, one study concluded that synthetic DNA submitted by a consumer under false pretenses could possibly be encoded with malware to infiltrate DNA processing programs.[129] These are yet additional reasons for updated legislation that protects consumers from discrimination in the event that their data becomes publicly available.

V. THE INSURANCE COMPANY LOOPHOLE

GINA's protections extend only to workplace and health insurance discrimination.[130] This loophole allows life, disability, and long-term care insurance companies to utilize genetic testing results to deny applicants.[131] 23andMe's privacy statement informs consumers their data may be used by

121. *Privacy Highlights*, *supra* note 91, at §§ (3)(d), (5)(d)(i).
122. *Id.* at § (5)(d)(ii).
123. *Id.* at § (3)(d).
124. Drabiak, *supra* note 1, at 158-59.
125. *Id.*
126. *Id.*
127. Dohn, *supra* note 111, at 113.
128. *Id.* at 118.
129. *Id.* at 118-19.
130. Ahn, *supra* note 26, at 777.
131. *Id.*

the company as the company deems acceptable by current laws and regulations.[132] This can certainly include releasing aggregate data to insurance companies who may then initiate a re-identification process of their own. Similarly, aggregate data may be sold or leased to data miners who may seek to re-identify the numbers of consumers compiled in that aggregate data for purposes of making life or disability insurance coverage determinations.

Fears of re-identification and discrimination may seem fantastical, but life insurance denial based on genetic testing is already a reality. In 2016, a report surfaced of a thirty-six year old, healthy woman who'd been denied life insurance coverage because of a positive BRCA 1 gene.[133] A positive BRCA 1 or 2 gene does not definitively indicate a person will develop breast or ovarian cancer but it does raise the person's risk from about twelve percent to fifty-five or sixty-five percent that the cancer will develop.[134] Knowing about a positive BRCA gene early gives patients an advantage in decreasing the risk they will get sick.[135] Angelina Jolie famously penned an op-ed in 2013 about her positive BRCA gene and choice to undergo a double mastectomy to minimize any risk of developing breast cancer.[136] Many consumers, like Angelina Jolie, when faced with the news of a potential health risk, use the opportunity to take preventative measures and improve their overall health.[137]

The gap in GINA protections leave consumers stuck between a rock and a hard place. If a person wants to get an idea of future health complications, they do so at the risk of losing or not being able to obtain life or disability insurance.[138] Northwestern Mutual, a life insurance company, for instance, doesn't require that applicants submit to genetic testing, but will deny an applicant if they are not forthcoming about past genetic testing.[139] The reasoning behind GINA was that the legislation allows for scientific advancements while protecting consumers.[140]

Life and disability insurance companies employ actuaries to determine whether an applicant is a safe choice to insure.[141] With the amount of genetic data available with the Human Genome Project,

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132. *Privacy Highlights*, *supra* note 91, at § (4)(e).

133. Farr, *supra* note 22.

134. *Id.*

135. *Id.*

136. Angelina Jolie, *My Medical Choice,* N.Y. TIMES (May 14, 2013), https://www.nytimes.com/2013/05/14/opinion/my-medical-choice.html.

137. Spector-Bagdady, *supra* note at 65, at 692.

138. Farr, *supra* note 22.

139. *Id.*

140. *Id.*

141. *Id.*

GEDmatch, and others, insurance companies can easily employ data hackers to match available data exhaust to an applicant's file to determine genetic predispositions not otherwise available to the company.[142] The biggest danger of the GINA gap and the probability of re-identification and data hacking is that many consumers don't know their genetic tests could prevent them from getting insured when they purchase products from 23andMe.[143] With pharmaceutical companies like GSK now having access to 23andMe's genetic database, the available privacy to consumers is dwindling.

VI. BENEFITS OF GENOME TESTING

Part of 23andMe's marketing strategy is encouraging consumers to become their own best medical advocates.[144] The idea is that once a person knows of a risk or predisposition, they will take steps to reduce or eliminate the threat of poor health. This is in fact one of the upsides to the partnership between 23andMe and GSK, future consumers will be able to better treat their illnesses using pharmaceuticals most suitable to their DNA.[145] This thinking is not without reason, studies have shown that consumers generally take steps to improve their health upon receiving their genome results from 23andMe and other DNA testing companies.[146] If consumers use their genetic testing to improve their health, there is reduced concern for life and disability insurance companies that their applicants are bad bets.

A. Advancements in Genetic Testing Require a Vast Data Pool

DNA testing has made invaluable advancements and improvements in a span of just a few years. Undoubtedly, the study of pharmacogenetics will improve health outcomes. 23andMe's genome research has led to major discoveries and two clinical research communities for Parkinson's disease and sarcoma.[147] As the technology develops, researchers have greater demand for access and easier sharing of all kinds of data.[148] Genetic research functions best when data scientists have access to self-reported data.[149] Self-reported data helps scientists distinguish genes across a vast

142. Ahn, *supra* note 26, at 756-57.
143. Farr, *supra* note 22.
144. John Meyer, *Consumers Left Up A Genetic Date Creek Without A Paddle*, 27 Annals Health L. Advance Directive 37, 42 (2018).
145. *Id.*
146. Spector-Bagdady, *supra* note 65, at 692.
147. Morrison, *supra* note 71, at 580-81.
148. *Id.* at 593.
149. *Id.*

database.[150] One scholar explains this as, if researchers know a group of study participants have Alzheimer's, they know which genes to study and which to exclude.[151] Combining genetic data with personal information like medical history, diet, and exercise shows the correlation between genetic and environmental factors on overall health.[152] Likewise, observing a study participant over a long period of time and having continual access to self-reported health updates demonstrates how data and conditions change over time.[153] When researchers and scientists have access to complete and reliable information, their studies are more conclusive and can do more to advance the study of genomics.[154]

B. The Future of Genomics

In January of 2020, 23andMe announced it had sold the rights to a drug that treats inflammatory diseases.[155] The drug was developed using the company's consumer database.[156] In announcing this new development, the company is celebrating going "from database to discovery to developing a drug."[157] Critics are fair to point out that there is ethical ambiguity in the company using data they were paid to process as the basis for new drug discoveries from which they will invariably further profit.[158] But even with the criticism, the creation of a drug that was manufactured using the human genome is an incredible scientific and medical advancement.[159]

The next phase of genome testing has been in the works for some years now, with advances in the research of polygenic diseases.[160] Large-scale genetic testing as it is known, looks for the relationship between varied genes to determine the cause of complex diseases.[161] Research of this level requires a large database and information about environmental

150. *Id.* at 593-94.
151. *Id.* at 593.
152. *Id.* at 594.
153. *Id.* at 593.
154. *Id.* at 593-94.
155. Jessica Hamzelou, *23andMe Has Sold the Rights to Develop a Drug Based on its Users' DNA*, NEWSCIENTIST (Jan. 10, 2020), https://www.newscientist.com/article/2229828-23andme-has-sold-the-rights-to-develop-a-drug-based-on-its-users-dna/.
156. *Id.*
157. *Id.*
158. *Id.*
159. *Id.*
160. Spector-Bagdady, *supra* note 65, at 687.
161. *Id.*

causes.[162] The ENCODE program, whose goal it is to identify functional elements of the human genome sequence, recently determined that "many human genomic regions previously assumed to be nonfunctional have recently been found to be teeming with biochemical activity."[163] Genome research is the new frontier. It is important work that, while coming with significant risks, should be supported and given room to explore new technologies and findings.

VII. SOLUTIONS

Consumers seek to control the publicly available data about themselves to mitigate judgment, ridicule, and stereotyping.[164] As a nation though, Americans value the free flow of information and scientific development.[165] The growth of genome testing necessitates updated regulation and legislation, but any steps taken by the government need to balance the individual's right to privacy with the societal benefit of medical advances. One scholar goes so far as to posit that the societal benefit of genome testing is greater than any privacy loss.[166] While certainly not all share this belief, it does stress the importance of finding privacy solutions that will encourage this important research.

A. Proposals for Informed Consent in the Internet Age

One proposition for a more-informed consent process is an offline approach. Consumers consent to 23andMe's entire product line through the web which can create a false sense of casual exchange.[167] Paying a company to take a permanent record of your DNA and consenting to join their research takes a few clicks, it is as easy as composing a tweet but can have much more serious ramifications.[168] The choice to submit to genetic testing and genome research is a serious decision that has implications for the individual consumer and their family members.[169] Consider the Golden State Killer who was caught when detectives compared DNA from a crime scene with publicly available DNA samples on GEDmatch.[170] A relative

162. *Id.*
163. Dohn, *supra* note 111, at 121.
164. Bambauer, *supra* note 78, at 213.
165. *Id.* at 218.
166. *Id.* at 227-28.
167. Morrison, *supra* note 71, at 592.
168. *Id.*
169. *Id.*
170. Gina Kolata & Heather Murphy, *The Golden State Killer is Tracked Through A Thicket of DNA, and Experts Shudder*, N.Y. TIMES (Apr. 27, 2018),

of the defendant uploaded raw genetic data to the GEDmatch website. Accessing such databases has become a tool for law enforcement and this enabled the arrest of a serial rapist and murderer whose cases had gone cold decades ago.[171] Although genome profiles submitted to 23andMe are not publicly available, the company's privacy statement does warn consumers that the company will, when required by law, comply with valid court orders, subpoenas, or search warrants.[172]

To get truly informed consent, 23andMe should enhance its informed consent process, and there are many options. For instance, consumers could be required to go through a phone interview with a staff genetic counselor or research aide.[173] The genetic counselor or aide would be available from the client intake through the delivery of test results. This option remedies complaints against the sterility of the current DTC genetic testing process. For many people, receiving news about their genetic profile through an email or letter is cold and alienating. Because of the propensity to receive life-altering news, such as a bad health outcome, news of parental infidelity, or reminders of the horrors inflicted on people of African descent during the Trans-Atlantic slave trade, providing phone calls with a genetic counselor could lend a great deal of comfort.[174] Another option would be requiring consumers to re-type a provided sentence that explains the privacy and discrimination risks of re-identification.[175] A third option is an interactive multiple choice quiz which must be perfected before enrollment is complete.[176] Lastly, 23andMe could seek updated consent when future developments and uses for genetic testing become available.[177] This last option is perhaps a bit clunky,[178] but because 23andMe offers consumers the opportunity to engage in research through an app, the company could obtain updated consent fairly easily.

The rapid development of new technologies and discoveries and the dearth of regulations keeping tabs make the study and use of genetic

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https://www.nytimes.com/2018/04/27/health/dna-privacy-golden-state-killer-genealogy.html.

171. *Id.*

172. *Privacy Highlights* § (4)(e), *supra* note 91, at § (4)(e).

173. Morrison, *supra* note 71, at 604.

174. Dorothy Pomerantz, *23andMe Had Devastating News About My Health. I Wish A Person Had Delivered It*, STAT NEWS (Aug. 8, 2019), https://www.statnews.com/2019/08/08/23andme-genetic-test-revealed-high-cancer-risk/; Dani Shapiro, *How a DNA Testing Kit Revealed a Family Secret Hidden for 54 Years*, TIME (Jan. 3, 2019), https://time.com/5492642/dna-test-results-family-secret-biological-father/; Dohn, *supra* note 111, at 114.

175. Morrison, *supra* note 71, at 604.

176. *Id.* at 605.

177. Ahn, *supra* note 26, at 795.

178. *Id.* at 796.

information feel like the Wild West. In a culture where consumers risk so much by participating in the study of the human genome, gaining informed consent is the first step in consumer protection.

B. Food and Drug Administration

The FDA has demonstrated through their 2013 warning letter and 2018 approval of the study for pharmacogenetics that they are willing to regulate DTC genetic testing.[179] The federal agency informed 23andMe that its personal genome service would be considered a Class III device.[180] Class III devices are of "substantial importance in preventing impairment of human life."[181] From 2003 up until the warning letter, the FDA had cleared genetic tests as Class II devices that are designed to perform without injury or harm to the user.[182] The concern the FDA has regarding 23andMe and other DTC genetic testing companies is false negatives and false positives.[183] Because users tend to take their genetic test results and apply health changes, often without consulting a doctor, there is an emphasis on reliable test results.[184]

C. Congressional Action

For all the benefits it provides, GINA has several shortcomings. Once deemed "the first civil rights bill of the new century," GINA leaves consumers exposed to discrimination in life and disability insurance, in financial transactions, and the public sphere.[185] GINA does not protect Americans from discrimination based on the actual manifestation of disease.[186] Nor does GINA extend to all health insurance decision making.[187] The Act allows health insurers to obtain genome testing

179. Spector-Bagdady, *supra* note 65, at 717; Press Release, Food and Drug Administration, FDA Authorizes First Direct-to-Consumer Test for Detecting Genetic Variants that may be Associated with Medication Metabolism (Oct. 31, 2018) (on file with author).

180. Spector-Bagdady, *supra* note 65, at 717.

181. *Id.* at 699-700.

182. *Id.* at 699, 701.

183. *Id.* at 710.

184. *Id.* at 690-92; Meyer, *supra* note 154, at 152-53.

185. Dohn, *supra* note 111, at 122-24.

186. Morrison, *supra* note 71, at 584.

187. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 101(c)(3)(A), 122 Stat. 881 (2008).

information about applicants and consumers through incidental means.[188] GINA does not extend to data on the internet, such as DNA that has been shared on GEDmatch or re-identified and posted online.[189]

The original version of GINA applied to all forms of insurance.[190] One advocate of this early form of the bill pointed out that the bill would not have passed as it was,[191] but now, twelve years later and with all the advancements that have been made in genetic testing, it's time for an update. Some critics of this idea claim that there's no evidence of genetic discrimination in life insurance underwriting, so there's no need to change the bill.[192] Our understanding of the human genome is changing rapidly, and with that, we have more insight into a person's health outcomes and life expectancy.[193] Without protections, consumers will face backlash in the life and disability market. Even if a consumer's genetic profile is not stored in their medical records, the data exhaust ensures the availability of a consumer's genome for insurance companies that want to find it.[194]

In addition to regulation on the DTC genetic testing companies themselves and amending GINA, Congress needs to pass a comprehensive ban on malicious re-identification of consumer genetic material. Observing others around us, and particularly those we encounter online, is a natural facet of life.[195] But deliberate observation, observation that is intended to invade a person's sense of seclusion or cause harm, is offensive and should be subject to civil liability.[196] Malicious re-identification laws would grant a remedy to consumers whose data was accessed in a cyber-attack, such as in the 2014 cyber-attack on Ancestry.[197] Not all deliberate or malicious observation is done by humans in the 21st Century.[198] Algorithms and automated processes can infringe a sense of privacy.[199] Even when a consumer is unaware that that a deliberate observation has occurred, it is in the public's best interest to quash that sort of behavior.[200] Malicious re-identification is one such deliberate observation.

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188. *Id.* at § 101(d)(3).
189. Morrison, *supra* note 71, at 584.
190. Farr, *supra* note 22.
191. *Id.*
192. Dohn, *supra* note 111, at 127.
193. *Id.*
194. *Id.* at 128.
195. Bambauer, *supra* note 78, at 231.
196. *Id.*
197. Dohn, *supra* note 108, at 118-19.
198. Bambauer, *supra* note 78, at 207.
199. *Id.* at 245.
200. *Id.* at 232.

VIII. CONCLUSION

23andMe is one of the largest DTC genetic testing companies in the world. The company has over 10,000,000 consumer profiles in their database which garners them funding by the National Institutes of Health and partnerships with pharmaceutical companies like GlaxoSmithKline. However, this accumulation of consumer data leads to concerns about data hacking and cyber-attacks. Data hacking, which the Supreme Court has held is legal, allows life insurance companies to discriminate against applicants based on their genetic profile. 23andMe should update its method of obtaining informed consent so consumers are fully aware of the risks of discrimination based on genetic testing. Consumer protections like GINA need to be amended to cover life and disability insurance companies. Further, Congress should pass a law outlawing malicious re-identification. The benefits of genetic testing are worth pursuing but consumer privacy needs to be ensured in the process.