

**PHYSICIAN PARTICIPATION IN DIRECT-TO-CONSUMER  
GENETIC TESTING: PRAGMATISM OR PATERNALISM?**

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## I. INTRODUCTION

DNA has gone mainstream.<sup>1</sup> In the sixty-plus years since Watson and Crick first opened the world's eyes to the double helix,<sup>2</sup> genetics — as a construct — has morphed into a cultural juggernaut.<sup>3</sup> From forensic crime dramas<sup>4</sup> to the ubiquitous soap opera paternity test,<sup>5</sup> DNA is everywhere, and not just in the literal sense. In our new “Genomic Era,”<sup>6</sup> concepts once limited to the laboratory have made their way into men's<sup>7</sup> and women's<sup>8</sup> magazines, cartoon sitcoms,<sup>9</sup> and, er-

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1. See generally DOROTHY NELKIN & M. SUSAN LINDEE, *THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON* (2004); Anne Machalinski, *DNA Meets Pop Culture at “Spit Party”*, *NEWSDAY* (Sept. 14, 2008), <http://www.newsday.com/entertainment/pop-cult-1.811972/dna-meets-pop-culture-at-spit-party-1.832583>; *You Know DNA Testing Has Gone Mainstream When It's Offered on TIPPR*, *UPFRONT WITH NGS* (May 22, 2012), <http://upfront.ngsgenealogy.org/2012/05/you-know-dna-testing-has-gone.html>.

2. See J.D. Watson & F.H.C. Crick, *Molecular Structure of Nucleic Acids — A Structure for Deoxyribose Nucleic Acid*, 171 *NATURE* 737, 737–38 (1953).

3. See NELKIN & LINDEE, *supra* note 1, at xii.

4. See, e.g., N.J. Schweitzer & Michael J. Saks, *The CSI Effect: Popular Fiction About Forensic Science Affects the Public's Expectations About Real Forensic Science*, 47 *JURIMETRICS J.* 357, 357–58 (2007), available at <http://lsprg.asu.edu/archive/csieffect.pdf>; Jim McKay, *Forensic Evidence Demands Rise as TV Crime Dramas Influence Juries*, *GOV'T TECH.* (Feb. 7, 2008), <http://www.govtech.com/public-safety/Forensic-Evidence-Demands-Rise-as-TV.html>.

5. See NELKIN & LINDEE, *supra* note 1, at xxi. In fact, paternity tests are so ubiquitous that they are now available at local pharmacy chains. See *Identigene DNA Paternity Test Collection Kit*, *WALGREENS*, <http://www.walgreens.com/store/c/identigene-dna-paternity-test-collection-kit/ID=prod4202920-product> (last visited Apr. 11, 2013).

6. Alan E. Guttmacher & Francis S. Collins, *Welcome to the Genomic Era*, 349 *NEW ENG. J. MED.* 996, 996 (2003). In fact, many scientists would clarify that we are now living in the “post-genomic era” — referring to the fact that the genomes of many important research organisms, including humans, have already been sequenced. See Andrew Moore, *Proteomics: Biology in the Post-Genomic Era*, 2 *EUR. MOLECULAR BIOLOGY ORG. REP.* 558, 558 (2001).

7. See generally Richard Powers, *The Book of Me*, *GQ* (Oct. 2008), <http://www.gq.com/news-politics/big-issues/200810/richard-powers-genome-sequence>.

8. See generally Margaret Renkl, *Tough Choices*, *LADIES' HOME J.* (Oct. 2010), <http://www.lhj.com/health/conditions/cancer/tough-choices>.

9. *Family Guy*, *FAMILY GUY WIKI*, [http://familyguy.wikia.com/wiki/Family\\_Guy](http://familyguy.wikia.com/wiki/Family_Guy) (last visited Apr. 11, 2013) (explaining the plot of an episode of “Family Guy,” originally airing on March 8, 2009, in which protagonist Peter Griffin, who volunteers as a subject for medi-

go, daily conversation. This increasing public awareness of DNA science — intensified by completion of the thirteen-year-long<sup>10</sup> and nearly four billion dollar<sup>11</sup> Human Genome Project (“HGP”) in 2003<sup>12</sup> — has created a new market for personal genetic information.<sup>13</sup> “Americans want to know the details of their genetic codes.”<sup>14</sup> As the cost of DNA technology has plummeted,<sup>15</sup> the direct-to-consumer (“DTC”) genetics industry has emerged to meet this demand.<sup>16</sup> Today, people curious about the contents of their genomes can simply select a DTC provider,<sup>17</sup> order a test kit online, mail back a saliva sample, and wait.<sup>18</sup> Once a laboratory has analyzed their DNA for hundreds of genetically correlated traits, disease risks, carrier statuses, and drug responses,<sup>19</sup> customers simply log in to a secure, online portal to view their results.<sup>20</sup> No doctor required.<sup>21</sup>

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cal testing, is injected with several fictional genes and endures scientifically improbable results). For a much earlier example of genetics on television, see *Lisa the Simpson*, SIMPSONS WIKI, [http://simpsons.wikia.com/wiki/Lisa\\_the\\_Simpson](http://simpsons.wikia.com/wiki/Lisa_the_Simpson) (last visited Apr. 11, 2013) (explaining the plot of an episode of *The Simpsons*, originally airing on March 8, 1998, in which daughter Lisa is relieved to learn that she could not have inherited the “Simpson Gene” because the gene is located on the Y chromosome, which is inherited only by male offspring).

10. *Human Genome Project Information*, GENOMICS.ENERGY.GOV, [http://www.ornl.gov/sci/techresources/Human\\_Genome/home.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml) (last modified July 31, 2012).

11. Nadia Drake, *What Is the Human Genome Worth?*, NATURE (May 11, 2011), <http://www.nature.com/news/2011/110511/full/news.2011.281.html>.

12. *Human Genome Project Information*, *supra* note 10.

13. *See DTC Efforts and Regulation Spur Growth in Genetic Testing Market*, PR WEB (May 29, 2003), <http://www.prweb.com/releases/2003/05/prweb67334.htm>; Claudia Kalb, *New Research Has Found That a Majority of Americans Want to Know the Details of Their Genetic Codes*, DAILY BEAST (June 9, 2010), <http://www.thedailybeast.com/newsweek/2010/06/09/inside-information.html>.

14. *See* Kalb, *supra* note 13.

15. Kris Wetterstrand, *DNA Sequencing Costs*, NAT’L HUM. GENOME RESEARCH INST., <http://www.genome.gov/sequencingcosts> (last modified Feb. 11, 2013).

16. Amy Harmon, *My Genome, Myself: Seeking Clues in DNA*, N.Y. TIMES, Nov. 17, 2007, at A1, available at <http://www.nytimes.com/2007/11/17/us/17dna.html>.

17. For available providers as of 2011, see R. Dvoskin and D. Kaufman, *Tables of Direct-to-Consumer Genetic Testing Companies and Conditions Tested*, GENETICS & PUB. POLICY CENTER (Aug. 2011), [http://www.dnapolicy.org/pub.reports.php?action=detail&report\\_id=28](http://www.dnapolicy.org/pub.reports.php?action=detail&report_id=28).

18. *How It Works*, 23ANDME, <https://www.23andme.com/howitworks> (last visited Apr. 11, 2013).

19. *See, e.g., Health Reports: Complete List*, 23ANDME, <https://www.23andme.com/health/all> (last visited Apr. 11, 2013) [hereinafter *Conditions Tested*].

20. *See, e.g., How It Works*, *supra* note 18; *When and How Do I Get My Data?*, 23ANDME CUSTOMER CARE (Apr. 10, 2012), <https://23andme.zendesk.com/entries/21251953-When-and-how-do-i-get-my-data->.

21. *What Is Direct-to-Consumer Genetic Testing?*, GENETICS HOME REFERENCE (Feb. 25, 2013), <http://ghr.nlm.nih.gov/handbook/testing/directtoconsumer> [hereinafter *Direct-to-Consumer Genetic Testing*].

While DTC providers, and many customers, promote the lack of physician involvement as a form of “patient empowerment,”<sup>22</sup> critics of the process are concerned about the public’s ability to understand the meaning and limits of genetic testing without a doctor’s guidance.<sup>23</sup> Accordingly, some scholars have argued for increased regulation that would require physician participation — not only to help consumers interpret results, but also to help them decide whether to get tested in the first place.<sup>24</sup> This Note argues against such requirements and in favor of the true DTC model. Part II explains the details of the DTC process. Part III summarizes the regulatory landscape affecting the DTC industry, with an emphasis on federal and state authorities that currently mandate doctor involvement, or that might do so in the future. Part IV addresses the rationales for mandating physician participation — arguing that (1) fears of customer harm are exaggerated, (2) leading DTC providers adequately explain testing risks, (3) most doctors are ill-equipped to advise their patients about genetic testing, (4) physician involvement would implicate privacy concerns, and (5) advertising regulation via the Federal Trade Commission (“FTC”) would better serve consumers. Part V concludes.

## II. WHAT IS DTC GENETIC TESTING, AND HOW DOES IT WORK?

Traditional genetic testing is accessed via a healthcare provider.<sup>25</sup> A patient who wants to be tested must seek out a doctor, who will

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22. Eric T. Juengst et al., *Personalized Genomic Medicine and the Rhetoric of Empowerment*, MEDSCAPE (2012), [http://www.medscape.com/viewarticle/771362\\_2](http://www.medscape.com/viewarticle/771362_2); see also Michelle L. McGowan et al., *Personal Genomics and Individual Identities: Motivations and Moral Imperatives of Early Users*, 29 NEW GENETICS & SOC’Y 261, 264, 269–70 (2010) (highlighting the individualized medicine rhetoric used by genomic companies); Thomas Goetz, *Attention, California Health Dept.: My DNA Is My Data*, WIRED (June 17, 2008), <http://www.wired.com/wiredscience/2008/06/attention-calif> [hereinafter Goetz, *Attention, California*] (arguing that results of genetic testing are an inherently personal matter).

23. See Christopher Freet, *Direct-to-Consumer Genetic Testing: Evolving Challenges*, 19 ANNALS HEALTH L. ADVANCE DIRECTIVE 191, 192 (2010); Jessica D. Gabel, *Redeeming the Genetic Groupon: Efficacy, Ethics, and Exploitation in Marketing DNA to the Masses*, 81 MISS. L.J. 363, 365–67 (2012); Laurie Udesky, *The Ethics of Direct-to-Consumer Genetic Testing*, 376 LANCET 1377, 1377 (2010); Deepthy Kishore, Comment, *Test at Your Own Risk: Your Genetic Report Card and the Direct-to-Consumer Duty To Secure Informed Consent*, 59 EMORY L.J. 1553, 1553–54 (2010); Molly C. Novy, Note, *Privacy at a Price: Direct-to-Consumer Genetic Testing & the Need for Regulation*, 2010 U. ILL. J.L. TECH. & POL’Y 157, 157–58 (2010).

24. See Gaia Bernstein, *Direct-to-Consumer Genetic Testing: Gatekeeping the Production of Genetic Information*, 79 UMKC L. REV. 283, 288 (2010).

25. *Direct-to-Consumer Genetic Testing*, *supra* note 21.

determine whether or not the test is appropriate.<sup>26</sup> This may require referral to a specialist.<sup>27</sup> The doctor then decides which tests to order, collects the patient's samples, and sends them to a laboratory.<sup>28</sup> The laboratory returns the results to the doctor, who interprets them for his patient.<sup>29</sup> In stark contrast, "pure"<sup>30</sup> DTC genetic testing removes the doctor from the equation:<sup>31</sup> customers decide whether and when to get tested, send their own samples to the laboratory, and receive their results — all from the comfort of the home.<sup>32</sup> The typical process is outlined below.

#### A. Select a Provider and Purchase a Kit

In 2011, the Genetics and Public Policy Center counted twenty-seven online, commercial testing providers (twenty offering pure DTC testing<sup>33</sup> and seven requiring that a physician at least order the test) together covering nearly 400 different conditions.<sup>34</sup> While the companies varied widely in scope and quality, a few emerged as industry

26. GENETIC ALLIANCE, UNDERSTANDING GENETICS: A NEW YORK, MID-ATLANTIC GUIDE FOR PATIENTS AND HEALTH PROFESSIONALS 29–31 (2009), available at <http://www.ncbi.nlm.nih.gov/books/NBK115563/pdf/TOC.pdf>.

27. *Id.*

28. *Id.* at 49.

29. *Direct-to-Consumer Genetic Testing*, *supra* note 21.

30. Throughout this Note, the term "pure" DTC testing is used to emphasize the distinction between models where no doctors are involved and models where physicians order the tests but patients may access their results. The distinction is necessary because some formerly "DTC" providers — such as Pathway Genomics — began requiring consumers to order and receive results through a doctor after FDA threatened regulatory action. See, e.g., Dan Vorhaus et al., *DTC Genetic Testing and the FDA: Is There an End in Sight to the Regulatory Uncertainty?*, GENOMES UNZIPPED (June 16, 2011), <http://www.genomesunzipped.org/2011/06/dtc-genetic-testing-and-the-fda-is-there-an-end-in-sight-to-the-regulatory-uncertainty.php#more-3681> ("Pathway Genomics responded to [the threat of regulatory action] by promptly eliminating the ability of consumers to purchase its product without physician involvement."). Nonetheless, Pathway is often still listed under the DTC umbrella because — with the doctor's permission — Pathway still provides patients direct access to their results via a web portal. *Frequently Asked Questions*, PATHWAY GENOMICS, <http://www.pathway.com/about-us> (last visited Apr. 11, 2013); see Heidi Carmen Howard & Pascal Borry, *Is There a Doctor in the House? The Presence of Physicians in the Direct-to-Consumer Genetic Testing Context*, 3 J. CMTY. GENETICS 105, 106 (2012).

31. *Direct-to-Consumer Genetic Testing*, *supra* note 21 ("This form of testing . . . provides access to a person's genetic information without necessarily involving a doctor or insurance company in the process.")

32. *How It Works*, *supra* note 18.

33. For an explanation of pure DTC testing, see *supra* note 30.

34. Dvoskin & Kaufman, *supra* note 17. The conditions covered by the industry include forty-four cancer risk markers (e.g., breast cancer and basal cell carcinoma), twenty-six cardiovascular markers (e.g., arterial fibrillation and hypertension), forty-seven metabolic markers (e.g., caffeine metabolism and gout), twelve reproductive markers (e.g., endometriosis and placental abruption), and thirty-three pharmacogenomic markers (e.g., warfarin sensitivity and beta blocker response). *Id.*

leaders: deCODEme, Navigenics, Pathway Genomics, and 23andMe.<sup>35</sup> Of these four brands, only deCODEme and 23andMe offered pure DTC services — both Pathway Genomics and Navigenics began requiring customers to order tests through physicians after the Food and Drug Administration (“FDA”) threatened regulatory action.<sup>36</sup> In 2012, the industry experienced quite a shake-up: both deCODEme and Navigenics dropped out of the DTC market due to acquisition by Amgen<sup>37</sup> and Life Technologies,<sup>38</sup> respectively. These changes have left 23andMe, whose product was hailed in 2008 by Time Magazine as the Invention of the Year,<sup>39</sup> as the undisputed market leader in the DTC arena.<sup>40</sup> For ninety-nine dollars, 23andMe offers testing for “a growing list of 247 diseases and conditions.”<sup>41</sup> The rest of the DTC process is explained according to 23andMe’s model.

### B. Spit!

The 23andMe test kit arrives with step-by-step instructions.<sup>42</sup> Essentially, customers spit roughly two milliliters of saliva into a collec-

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35. Jeanne Erdmann, *Home Genetics Tests Are Called Unreliable*, ST. LOUIS POST DISPATCH (Mar. 23, 2011), [http://www.stltoday.com/lifestyles/health-med-fit/medical/home-genetics-tests-are-called-unreliable/article\\_cee6a092-0dc7-565e-b159-b53215f42ba1.html](http://www.stltoday.com/lifestyles/health-med-fit/medical/home-genetics-tests-are-called-unreliable/article_cee6a092-0dc7-565e-b159-b53215f42ba1.html) (“The biggest companies in home genetic tests are 23andMe, Navigenics, deCODEme, and Pathway Genomics.”).

36. Turna Ray, *With Navigenics Purchase, LifeTech Speeds Entry into Molecular Diagnostics Space*, PHARMACOGENOMICS REP. (July 18, 2012), <http://www.genomeweb.com/mdx/navigenics-purchase-lifetech-speeds-entry-molecular-diagnostics-space> [hereinafter Ray, *LifeTech Speeds*] (“[A]fter the nascent consumer genomics field faced pushback from the US Food and Drug Administration . . . Navigenics abandoned the DTC strategy, choosing to market its genome-wide testing services through doctors’ practices . . . .”); Vorhaus et al., *supra* note 30. As explained in *supra* note 31, Pathway Genomics is still considered part of the DTC sphere because — with a doctor’s permission — it continues to provide patients with direct access to their results via a web portal.

37. Turna Ray, *With Decode Purchase, Amgen Gains Genetics Expertise, Consumers Lose DTC Testing Option*, PHARMACOGENOMICS REP. (Dec. 12, 2012), <http://www.genomeweb.com/clinical-genomics/decode-purchase-amgen-gains-genetics-expertise-consumers-lose-dtc-testing-option> [hereinafter Ray, *Decode Purchase*] (explaining that Amgen’s purchase of Decode will remove deCODEme from the DTC market); *Your Questions Answered*, NAVIGENICS, [http://www.navigenics.com/visitor/about\\_us/acquisition\\_faqs](http://www.navigenics.com/visitor/about_us/acquisition_faqs) (last visited Apr. 11, 2013) (“As of August 3, 2012, we will not be accepting new orders going forward.”).

38. Ray, *LifeTech Speeds*, *supra* note 36.

39. Anita Hamilton, *Best Inventions of 2008*, TIME (Oct. 29, 2008), [http://www.time.com/time/specials/packages/article/0,28804,1852747\\_1854493\\_1854113,00.htm](http://www.time.com/time/specials/packages/article/0,28804,1852747_1854493_1854113,00.htm).

40. Dan Vorhaus, *DNA DTC: The Return of Direct to Consumer Whole Genome Sequencing*, GENOMICS L. REP. (Nov. 29, 2012), <http://www.genomicslawreport.com/index.php/2012/11/29/dna-dtc-the-return-of-direct-to-consumer-whole-genome-sequencing> (calling 23andMe “the acknowledged market leader in DTC genetic testing”).

41. *Health*, 23ANDME, <https://www.23andme.com/health> (last visited Feb. 28, 2013).

42. *How Do I Collect Saliva Samples?*, 23ANDME CUSTOMER CARE (Apr. 10, 2012), <https://23andme.zendesk.com/entries/21252223-How-do-I-collect-saliva-samples->

tion tube via an attached funnel.<sup>43</sup> Shutting the lid of the funnel causes a chemical buffer to mix with the sample and stabilize it for shipment.<sup>44</sup> After closing the tube, customers pack up their sample and drop the pre-paid, pre-addressed box into the U.S. mail.<sup>45</sup>

### C. Wait

23andMe results are typically available four to six weeks after a customer's kit arrives at the laboratory.<sup>46</sup> During this time, 23andMe analyzes each DNA sample by genotyping<sup>47</sup> over one million locations.<sup>48</sup> In the context of genomic analysis, it is important to distinguish genotyping services from sequencing services.<sup>49</sup>

Full genome sequencing entails determining the precise sequence of the roughly three billion base pairs<sup>50</sup> in the human genome.<sup>51</sup> In contrast, 23andMe's genotyping service only examines predetermined locations on the genome where small variations — called single nucleotide polymorphisms (“SNPs”)<sup>52</sup> — are associated with a particular trait.<sup>53</sup> Genotyping has enormous cost savings over sequencing<sup>54</sup> but

43. *Id.*

44. *Id.*

45. *Id.*

46. *When Will My Results Be Ready?*, 23ANDME CUSTOMER CARE (Jan. 5, 2013), <https://23andme.zendesk.com/entries/22872486-When-will-my-results-be-ready->.

47. A genotype “refers to a person's genetic composition.” *What Is the Difference Between Genotype and Phenotype?*, 23ANDME CUSTOMER CARE (Apr. 10, 2012), <https://customercare.23andme.com/entries/21259107-What-is-the-difference-between-genotype-and-phenotype-> (offering the following example: “Your genotype at the [location] that determines earwax type is TT.”). The term genotype is often used in contrast to the term phenotype, which “refers to the physical and behavioral characteristics of an individual, such as height [or] hair color.” *Id.* The act of genotyping “refers to the process of determining which versions of . . . genes an individual possesses.” *Id.*

48. *Genotyping Technology*, 23ANDME, <https://www.23andme.com/more/genotyping> (last visited Apr. 11, 2013).

49. *What Is the Difference Between Genotyping and Sequencing?*, 23ANDME CUSTOMER CARE (Apr. 10, 2012), <https://23andme.zendesk.com/entries/21262606-What-is-the-difference-between-genotyping-and-sequencing-> [hereinafter *Genotyping vs. Sequencing*].

50. *The Human Genome Project Completion: Frequently Asked Questions*, NAT'L HUM. GENOME RESEARCH INST., <http://www.genome.gov/11006943> (last modified Oct. 30, 2010).

51. *See Genotyping vs. Sequencing*, *supra* note 49.

52. *What Is a SNP?*, 23ANDME CUSTOMER CARE (Apr. 10, 2012), <https://23andme.zendesk.com/entries/21263578-What-is-a-SNP->.

53. *Genotyping vs. Sequencing*, *supra* note 49. Most genotyping processes take advantage of the sticky nature of complementary DNA strands. *See Affymetrix, How Affymetrix GeneChip® DNA MicroArrays Work*, <http://public.tgen.org/tgen.org/downloads/autism/Genotypingessentials.pdf> (last visited Apr. 11, 2013) [hereinafter *Affymetrix*]. DNA is made up of a chain of four nucleotides — adenine (“A”), thymine (“T”), cytosine (“C”), and guanine (“G”). *DNA Is a Structure That Encodes Biological Information*, SCITABLE, <http://www.nature.com/scitable/topicpage/dna-is-a-structure-that-encodes-biological-6493050> (last visited Apr. 11, 2013). DNA normally exists as a double-stranded molecule. *See id.* The two strands of DNA are attached together (via hydrogen bonds), but they do not pair up randomly. *Id.* Where one strand has an A, the other strand will have a T. *Id.* Accord-

does suffer from several disadvantages.<sup>55</sup> First and foremost, genotyping “miss[es] a lot of data” because not all genetic variation takes the form of SNPs.<sup>56</sup> Every individual’s genome contains hundreds of thousands of small-scale insertions or deletions of genetic material, and thousands of large-scale ones, but genotyping does not catch these differences.<sup>57</sup> At least one company currently offers a DTC sequencing product — for the hefty price of \$6,995<sup>58</sup> — but provides custom-

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ingly, we say that A and T (or C and G) are “complementary” bases. *See id.* When two single-stranded DNA molecules with complementary sequences come across each other, the two strands will stick together. Affymetrix, *supra*. Now, imagine the following hypothetical. Suppose that a particular location within the human genome affects whether an individual is likely to suffer from a given disease. Suppose that, at this location, most individuals’ DNA reads (on one strand) “ACCTGC.” Suppose further that people whose DNA instead reads “ACCTGG” are ten times more likely to develop the disease. By determining which of these variants — or genotypes — a customer’s DNA contains, 23andMe can offer a prediction about how likely that customer is to develop the disease. To figure out the customer’s genotype, 23andMe uses a “chip,” or small glass slide, with tiny DNA probes attached to it. *See Genotyping Technology, supra* note 48. The chip contains a DNA probe that corresponds to the “healthy” DNA sequence and one that corresponds to the “mutated” sequence. *See id.*; Affymetrix, *supra*. The probes for the healthy and mutated sequences consist of DNA molecules that are complementary to the healthy and mutated sequences, respectively. *See Affymetrix, supra*. That is, the probe for the healthy sequence would read “TGGAC $\overline{C}$ ,” (because it is complementary to the healthy sequence of “ACCTGC”), while the probe for the mutated sequence would read “TGGAC $\overline{C}$ ” (because it is complementary to the mutated sequence of “ACCTGG”). *See id.* A customer’s DNA is cut into small pieces and then “washed” over the chip. *Genotyping Technology, supra* note 48. A piece of the customer’s DNA will stick to the chip because it is complementary to either the healthy or the mutated probe. *Id.*; Affymetrix, *supra*. Next, specially “tagged” DNA molecules are washed over the chip. *Id.* These tags can be made to glow when they come into contact with a piece of the customer’s DNA bound to its complementary probe. *See id.* By figuring out which probe lights up, 23andMe can determine which genotype the customer possesses. *See id.* For example, if the probe reading “TGGAC $\overline{C}$ ” glows, then the individual’s DNA contains the “mutated” genotype. Affymetrix, *supra*. In reality, a single chip contains enough probes to analyze roughly one million genotypes. *See Genotyping Technology, supra* note 48.

54. *See Genotyping vs. Sequencing, supra* note 49; Luke Jostins, *Personal Genomics: The Importance of Sequencing*, GENOMES UNZIPPED (July 13, 2010), <http://www.genomesunzipped.org/2010/07/personal-genomics-the-importance-of-sequencing.php>; *see also* Wetterstrand, *supra* note 15 (reporting that the cost of sequencing a human-sized genome in October of 2012 was \$6,618).

55. Jostins, *supra* note 54.

56. *Id.* (“Of course, single-base mutations are not the only source of variation . . .”).

57. *Id.* (“Each individual will have around 800,000 small insertions or deletions of DNA . . . very few of which are well covered by genotyping chips. Then there are the larger . . . variants [of] thousands of bases or more that have been deleted, inserted, moved around or inverted; each individual will have a few thousand of these, and looking at them in . . . detail . . . is virtually impossible with chips.”).

58. *See, e.g., Products, DNA DTC*, <http://www.dnadt.com/products.aspx> (last visited Apr. 11, 2013). DTC DNA offers whole genome sequencing for \$6,995. *Id.* At one time, 23andMe offered a data sequencing pilot program for \$999, but this product did not offer whole genome sequencing. *See Exome 80x Pilot Program, 23ANDME*, <https://www.23andme.com/exome> (last visited Apr. 11, 2013). Instead, it offered exome sequencing — that is, sequencing of the “50 million DNA bases” comprising the protein-coding portion of the genome. *Id.* The pilot program is currently closed to new enrollees. *Id.* For an excellent analysis of DNA DTC’s services, 23andMe’s pilot program, and the history of commercial sequencing products, see Vorhaus, *supra* note 40.



ers with only their raw data and no interpretation of their genetic code.<sup>59</sup>

#### *D. Explore the Results*

23andMe provides results for over two hundred conditions, including disease risks, drug responses, carrier statuses, and general traits.<sup>60</sup> These range from the innocuous, such as earwax type,<sup>61</sup> to the serious, such as risk for Alzheimer's disease.<sup>62</sup> Each test is categorized according to the degree of scientific support for the relevant genetic association.<sup>63</sup> "Preliminary [r]esearch reports" are based on peer-reviewed findings that "still need to be confirmed by the scientific community,"<sup>64</sup> while "[e]stablished research reports" are "supported by multiple, large, peer-reviewed studies."<sup>65</sup> Of the 247 tests, one hundred meet the heightened standards for established reports.<sup>66</sup>

Test results are presented graphically and numerically, displaying a consumer's lifetime risk for a given condition and comparing the consumer's risk with that of the average population.<sup>67</sup>

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59. See Vorhaus, *supra* note 40 ("[N]ever has any meaningful participant in the DTC marketplace offered a product without any interpretation or analysis whatsoever (i.e., raw data only). That appears to have changed with DNA DTC.").

60. *Conditions Tested*, *supra* note 19.

61. *Get Tested To Learn What Your Genetics Say About: Earwax Type*, 23ANDME, <https://www.23andme.com/health/Earwax-Type/> (last visited Apr. 11, 2013) (explaining that individuals either have wet or dry ear wax).

62. *Get Tested To Learn What Your Genetics Say About: Alzheimer's Disease*, 23ANDME, <https://www.23andme.com/health/alzheimers> (last visited Apr. 11, 2013) (explaining that variants of the APOE gene contribute to the emergence of Alzheimer's disease).

63. *Conditions Tested*, *supra* note 19.

64. *Id.*

65. *Id.*

66. *Id.*

67. *Get Tested To Learn What Your Genetics Say About: Alzheimer's Disease*, *supra* note 62; *Review: 23andMe DNA Testing for Health, Disease & Ancestry*, PAUL STAMATIOU (Mar. 5, 2010), <http://paulstamatiou.com/review-23andme-dna-testing-for-health-disease-ancestry> [hereinafter *Review: 23andMe*] (chronicling one consumer's 23andMe experience and displaying screenshots of results).

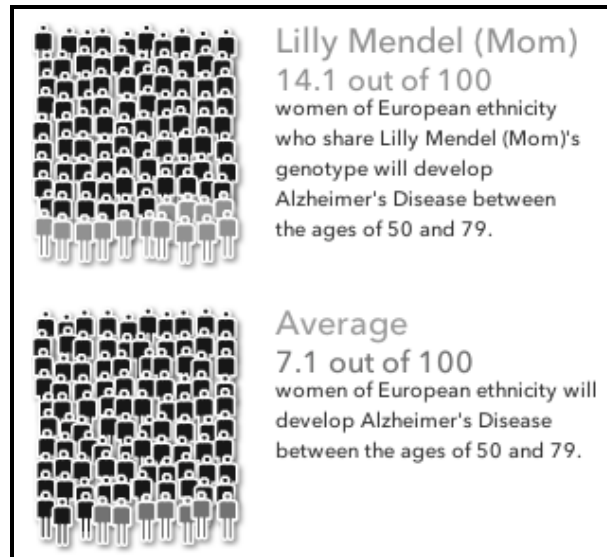


Figure 1: Sample Data for “Lily Mendel” Demonstrating Her Elevated Risk for Alzheimer’s Disease as Compared to That of the Average European Woman.<sup>68</sup>

Another schematic illustrates the extent to which genetic factors are believed to cause the disease or condition — as compared with environmental ones.<sup>69</sup> Customers can also access more technical information — such as the precise SNPs evaluated<sup>70</sup> — and read about the biology behind the trait.<sup>71</sup> Finally, particularly curious consumers can download their raw data — consisting of their genotypes at each of the approximately one million SNPs tested — into a text file,<sup>72</sup> or ex-

68. *Health Risks: Alzheimer’s Disease*, 23ANDME, <https://www.23andme.com/you/journal/alzheimers/overview> (last visited Mar. 27, 2013). This site is accessible only with a 23andMe account, but interested users can sign up for a free demo account. 23andMe provides the following explanation immediately above the graphic presented in Figure 1: “Lilly Mendel (Mom) has one copy of the APOE ε4 variant. APOE ε4 is not the only factor contributing to Alzheimer’s disease. Although it is associated with increased risk of Alzheimer’s, many people with the APOE ε4 variant never develop it.” *Id.*

69. *Get Tested To Learn What Your Genetics Say About: Alzheimer’s Disease*, *supra* note 62 (“The heritability of [Alzheimer’s disease] is estimated to be 60–80%. This means that genetic factors contribute more to individual differences in risk for [Alzheimer’s disease] than environmental factors do.”); *Review: 23andMe*, *supra* note 67.

70. *Get Tested to Learn What Your Genetics Say About: Alzheimer’s Disease*, *supra* note 62.

71. *See id.*

72. *Download Raw Data*, 23ANDME, <https://www.23andme.com/you/download> (last visited Feb. 28, 2013).

plore the data using a 23andMe application.<sup>73</sup> Follow-up phone calls with genetic counselors are available for a fee through InformedDNA.<sup>74</sup>

### III. REGULATION OF THE DTC GENETICS INDUSTRY: LEGAL SOURCES FOR PHYSICIAN PARTICIPATION REQUIREMENTS

Regulation of DTC genetic testing is a hodgepodge at best. The three main federal players are FDA, the Centers for Medicare and Medicaid Services (“CMS”), and FTC.<sup>75</sup> Of the three agencies involved, FDA is the most likely to require physician involvement. State law further complicates matters — the requirements vary widely from state to state, are frequently ambiguous, and seldom address genetic testing directly. Nevertheless, several states do require physician involvement.

#### *A. Food and Drug Administration*

The Food, Drug, and Cosmetics Act empowers FDA to review all new medical devices for safety and effectiveness.<sup>76</sup> The agency may also designate certain devices as available by prescription only.<sup>77</sup> If FDA were to classify services like that of 23andMe as prescription medical devices, pure DTC testing would cease to exist because patients would need a doctor’s consent to order the testing.

To date, FDA has not acted to regulate DTC genetic testing, even though these services likely fall within the expansive definition of medical devices.<sup>78</sup> Commentators have explained the lack of agency

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73. *Browse Raw Data*, 23ANDME, <https://www.23andme.com/you/explorer> (last visited Feb. 28, 2013) (providing an online application that allows you to select each chromosome and view the corresponding gene, position, and SNPs).

74. *Have Questions About Your 23andMe Reports or Your Genetic Health? Speak with a Board-Certified Genetic Counselor*, INFORMEDDNA, <http://informeddna.com/index.php/23andme.html> (last visited Apr. 11, 2013); *23andMe Enlists Informed Medical Decisions To Make Independent Genetic Counseling Services Available to Customers*, 23ANDME (June 3, 2010), <https://www.23andme.com/about/press/20100603> [hereinafter *23andMe Genetic Counseling*].

75. See Matthew Piehl, *Regulating Hype and Hope: A Business Ethics Model Approach to Potential Oversight of Direct-to-Consumer Genetic Tests*, 16 MICH. ST. J. MED. & L. 59, 66 (2011).

76. Charles J. Walsch & Alyssa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS L. REV. 883, 886, 894 (1996).

77. 21 C.F.R. § 801.109 (2013); Memorandum from Dir., Office of Device Evaluation, FDA to ODE Review Staff (Mar. 8, 1991) [hereinafter ODE Memorandum], available at <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm081368.htm>.

78. Devices include “instrument[s], apparatus[es], implement[s], machine[s], contrivance[s], implant[s], in vitro reagent[s], or other similar or related article[s]” which are “in-

involvement by assuming that DTC genetics fall under the subcategory of “laboratory developed tests” (“LDTs”),<sup>79</sup> an area that FDA has traditionally made the discretionary choice not to regulate.<sup>80</sup> In mid-2010, however, FDA debunked this conventional wisdom.<sup>81</sup> That year, FDA sent “letters to industry” to twenty DTC firms notifying them that their tests<sup>82</sup> could be regulated as medical devices.<sup>83</sup> Within these letters, the agency dispelled the notion that DTC firms were protected by an LDT exception.<sup>84</sup> As the agency explained in its letter to 23andMe, “FDA does not consider your device to be [an LDT] because [it] is not developed by and used in a single laboratory.”<sup>85</sup> One author suggests that FDA’s approach reflects the fact that DTC samples are typically handled by two separate locations: the laboratory that contracts to perform the genotyping and the DTC company that interprets and returns the results.<sup>86</sup>

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tended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.” 21 U.S.C. § 321(h) (2006).

79. Jessica Palmer, *Genetic Gatekeepers: Regulating Direct-to-Consumer Genomic Services in an Era of Participatory Medicine*, 67 FOOD & DRUG L.J. 475, 501 (2012); Piehl, *supra* note 75, at 70–71. FDA has described LDTs as “tests that are developed by a single clinical laboratory for use only in that laboratory.” College of American Pathologists, Comments on Oversight of Laboratory Developed Tests 1, 9 (2010), available at [http://www.cap.org/apps/docs/advocacy/comments/comments\\_fda\\_oversight\\_developed\\_tests.pdf](http://www.cap.org/apps/docs/advocacy/comments/comments_fda_oversight_developed_tests.pdf) (citing FDA, DRAFT GUIDANCE FOR INDUSTRY, CLINICAL LABORATORIES, AND FDA STAFF: IN VITRO DIAGNOSTIC MULTIVARIATE INDEX ASSAYS (2007), available at <http://www.fda.gov/downloads/MedicalDevices/.../ucm071455.pdf>).

80. Palmer, *supra* note 79, at 476. In 2010, however, FDA announced its intention to regulate LDTs. *Id.* at 493. Though the agency requested comments and held a meeting, it has not yet taken further steps to formalize the decision. *Id.*

81. See Palmer, *supra* note 79, at 501 (indicating that FDA may not view DTC tests as LDTs).

82. A later document, distributed to focus discussion at a March 2011 DTC advisory panel meeting specifically singled out a subset of DTC tests:

Clinical (medical) genetic tests that provide clinical or health information such as for diagnosis, prevention or treatment of a disease are considered to be medical devices under the Federal Food Drug and Cosmetic Act. Tests that do not provide such information are not considered medical devices; examples of tests not used for medical purpose include ancestry tests, forensic tests, and tests for non-medical phenotypes such as hair curliness.

*Questions for DTC Advisory Panel Meeting*, FDA, <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MolecularandClinicalGeneticsPanel/UCM245661.pdf> (last visited Apr. 11, 2012).

83. Letter from Alberto Gutierrez, Office of In Vitro Diagnostic Device Evaluation & Safety, FDA, to Anne Wojcicki, President & Co-Founder, 23andMe (June 10, 2010), available at <http://www.fda.gov/downloads/medicaldevices/resourcesforyou/industry/UCM215240.pdf>; see also Piehl, *supra* note 75, at 72 (explaining the sequence of warning letters).

84. Palmer, *supra* note 79, at 501.

85. *Id.* (quoting Gutierrez, *supra* note 83, at 1).

86. *Id.* at 502.

23andMe pressed on<sup>87</sup> under the shadow of possible regulation until mid-2012, when it decided to actually seek FDA approval.<sup>88</sup> In July 2012, the company submitted its first set of 510(k) applications<sup>89</sup> for seven tests.<sup>90</sup> In seeking regulatory approval, 23andMe emphasized that the company was not departing from its DTC model,<sup>91</sup> but rather was seeking to legitimize the clinical relevance of its services.<sup>92</sup> A 23andMe blog post reiterated the company's goal of "remain[ing] the world's trusted source of genetic information — not just for people with a doctor's order, but for everyone regardless of why or how they choose to learn about their DNA."<sup>93</sup> With FDA in the picture, however, 23andMe may not have the final say — if the agency designates the 23andMe service as a prescription medical device, consumers will need a doctor's help to access the company's tests.<sup>94</sup>

### B. Centers for Medicare and Medicaid Services

CMS impacts the DTC industry via regulation of laboratory protocols and personnel qualifications under the Clinical Laboratory Improvement Amendments Act ("CLIA") of 1988.<sup>95</sup> Under CLIA, CMS sets standards for any laboratory that "examin[es] . . . materials de-

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87. Kerry Xie, *Pandora's Box Opened, What's in the Future for Direct-to-Consumer (DTC) Genomics?*, SCIENTIA ADVISORS BLOG (Dec. 21, 2010), <http://www.scientiaadv.com/blog/2010/12/21/pandora-s-box-opened-what-s-in-the-future-for-direct-to-consumer-dtc-genomics>.

88. *23andMe Takes First Step Toward FDA Clearance*, 23ANDME BLOG (July 30, 2012), <http://blog.23andme.com/news/23andme-takes-first-step-toward-fda-clearance>.

89. See Malorye Allison, *Direct-to-Consumer Genomics Reinvents Itself*, 30 NATURE BIOTECH. 1027, 1027 (2012). Reportedly, 23andMe filed a de novo 510(k). See *id.*; Turna Ray, *Seeking 510(k) Clearance for Genomic Testing Service, 23andMe Maintains Direct-to-Consumer Ethos*, PHARMACOGENOMICS REP. (Aug. 1, 2012), <http://www.genomeweb.com/mdx/seeking-510k-clearance-genomic-testing-service-23andme-maintains-direct-consumer> [hereinafter Ray, *Seeking 510(k)*]. Ordinarily, novel devices not similar to any currently marketed product are classified as Class III devices and must undergo FDA's extensive "premarket approval" process (as opposed to the 510(k) "premarket notification" process). FDA, DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF — DE NOVO CLASSIFICATION PROCESS (EVALUATION OF AUTOMATIC CLASS III DESIGNATION) (2011), available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm273902.htm>; Adam Lewin, *Medical Device Innovation in America*, 26 HARV. J.L. & TECH. 403, 407–08 (2012). The de novo 510(k) process "provides a route to market for medical devices that are low to moderate risk" but would otherwise be required to undergo premarket approval due to their novel nature. *Id.*

90. Allison, *supra* note 89.

91. Ray, *Seeking 510(k)*, *supra* note 89.

92. *23andMe Personalized DNA Test Seeks FDA Approval*, CBS NEWS (July 31 2012), [http://www.cbsnews.com/8301-504763\\_162-57483267-10391704/23andme-personalized-dna-test-seeks-fda-approval](http://www.cbsnews.com/8301-504763_162-57483267-10391704/23andme-personalized-dna-test-seeks-fda-approval).

93. *23andMe Takes First Step Toward FDA Clearance*, *supra* note 88.

94. See 21 C.F.R. § 801.109 (2012); ODE Memorandum, *supra* note 77.

95. Piehl, *supra* note 75, at 74–75.

rived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.”<sup>96</sup> Though not all of 23andMe’s covered conditions are health-related,<sup>97</sup> many of the company’s two-hundred-plus tests arguably fall under the CLIA mandate.<sup>98</sup>

Under CLIA, laboratory tests are grouped into one of three categories: waived, moderate complexity, or high complexity.<sup>99</sup> Any laboratory performing non-waived tests must complete proficiency testing in order to become CLIA accredited.<sup>100</sup> Furthermore, labs that engage in certain specialty testing must adhere to discipline-specific requirements.<sup>101</sup> While no genetic testing specialty exists,<sup>102</sup> the Centers for Disease Control and Prevention published the Clinical Laboratory Improvement Advisory Committee’s recommendations for “Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions” in 2009.<sup>103</sup> These non-binding recommendations do not substitute for the stringent requirements of a specialty, but they do provide guidance on industry standards regarding laboratory testing procedures, personnel, and confidentiality.<sup>104</sup>

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96. 42 C.F.R. § 493.2 (2013).

97. See *Conditions Tested*, *supra* note 19. FDA has declared that “ancestry tests, forensic tests, and tests for non-medical phenotypes such as hair curliness” are “examples of tests not used for medical purpose[s].” *Questions for DTC Advisory Panel Meeting*, *supra* note 82.

98. FDA considers “clinical (medical) genetic tests that provide clinical or health information such as for diagnosis, prevention or treatment of a disease . . . to be medical devices under the Federal Food Drug and Cosmetic Act.” *Questions for DTC Advisory Panel Meeting*, *supra* note 82. Because FDA sent letters to several DTC companies asserting regulatory control over their products as medical devices, see Gutierrez, *supra* note 83, it is clear that at least some DTC testing does provide health information from FDA’s perspective.

99. 42 C.F.R. § 493.5(a) (2013); Piehl, *supra* note 75, at 74–75. Waived tests are procedures approved by FDA for use at home; they involve such simple, accurate methods that the risk of erroneous results is very small, or “[p]ose no reasonable risk of harm to the patient if . . . performed incorrectly.” 42 C.F.R. § 493.15(b)(3) (2013). To distinguish between moderate and high complexity tests, seven criteria are examined, reflecting the knowledge and skill required of personnel or the tricky nature of the materials involved. See 42 C.F.R. § 493.17 (2013).

100. 42 C.F.R. § 493.801 (2013).

101. *Id.* Without a specialty designation, labs must merely adhere to general guidelines with respect to the accuracy of their results. *Id.* Each specialty is further divided into subspecialties. Piehl, *supra* note 75, at 75–76. For instance, microbiology divides into subspecialties of bacteriology, mycobacteriology, mycology, parasitology, and virology. 42 C.F.R. §§ 493.821–865 (2013).

102. Piehl, *supra* note 75, at 76.

103. BIN CHEN ET AL., CTNS. FOR DISEASE CONTROL AND PREVENTION, GOOD LABORATORY PRACTICES FOR MOLECULAR GENETIC TESTING FOR HERITABLE DISEASES AND CONDITIONS, MORBIDITY AND MORTALITY WEEKLY REPORT (2009), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5806a1.htm>.

104. *Id.*

### C. Federal Trade Commission

Through regulation of industry advertising, FTC can ensure that providers do not mislead consumers about the risks and benefits of DTC genetic testing. FTC is empowered to prevent “unfair or deceptive acts or practices in or affecting commerce,”<sup>105</sup> and false advertising falls within the scope of this mandate.<sup>106</sup> To date, FTC has not taken action against any DTC companies, but the agency did issue a warning to consumers in 2006<sup>107</sup> that cautioned the public to “[b]e wary of claims about the benefits these products supposedly offer.”<sup>108</sup> This general publication is far from targeted enforcement, but it at least signals FTC’s interest in the industry. Specific enforcement actions against DTC companies that make questionable claims could help ensure informed consumer consent to testing and obviate the need for a physician intermediary.<sup>109</sup>

### D. State Regulation

State regulation of DTC genetic testing varies dramatically across the country. A 2007 survey by the Genetics and Public Policy Center found that twenty-five states and the District of Columbia permitted DTC genetic testing without any physician involvement.<sup>110</sup> However, industry proponents should hardly rejoice in this fifty-percent endorsement rate. Those states that permitted testing did so largely because their laws did not address the topic.<sup>111</sup> States that update their healthcare laws in the future may decide upon increased regulation.

In many states, the laws regulating genetic testing are ambiguous. For instance, several states permit doctors and “persons authorized by law” to order and use laboratory tests.<sup>112</sup> Whether this phrase includes consumers is frequently unclear.<sup>113</sup> In other states, whether DTC ge-

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105. 15 U.S.C. § 45(a)(2) (2006).

106. 15 U.S.C. § 52(b) (2006).

107. Katherine Drabiak-Syed, *Baby Gender Mentor: Class Action Litigation Calls Attention to a Deficient Federal Regulatory Framework for DTC Genetic Tests, Politicized State Statutory Construction, and a Lack of Informed Consent*, 14 MICH. ST. U. J. MED. & L. 71, 77 (2010); Piehl, *supra* note 75, at 77.

108. FTC, FACTS FOR CONSUMERS: AT-HOME GENETIC TESTS: A HEALTHY DOSE OF SKEPTICISM MAY BE THE BEST PRESCRIPTION (2006), available at <http://www.consumer.ftc.gov/articles/0166-home-genetic-tests>.

109. See discussion *infra* Part IV.H.

110. See GENETICS & PUB. POLICY CENTER, SURVEY OF DIRECT-TO-CONSUMER TESTING STATUTES AND REGULATIONS 1–15 (2007) [hereinafter STATE LAWS], available at <http://www.dnapolicy.org/resources/DTCStateLawChart.pdf>.

111. See *id.*

112. Drabiak-Syed, *supra* note 107, at 79.

113. Compare STATE LAWS, *supra* note 110, at 10–11 (explaining that in Oregon, “[t]he phrase ‘other person authorized . . .’ has been interpreted by several practitioner boards to include different types of licensed practitioners, but not consumers”), with *id.* at 13 (explain-

netic testing is permitted depends upon whether state law considers these services to be the practice of medicine.<sup>114</sup>

Some states clearly forbid DTC genetic testing. Maryland, for example, permits laboratory testing when authorized by a court, a doctor, or “[a]nother person authorized to order laboratory tests under the Annotated Code of Maryland.”<sup>115</sup> Consumers are excluded from this catchall provision,<sup>116</sup> creating a de facto ban on DTC genetic testing within the state.<sup>117</sup> The Maryland Department of Health actively enforces the embargo, calling DTC genetic testing “dangerous because it occurs without physical examination or medical assistance.”<sup>118</sup> 23andMe does not offer services in the state.<sup>119</sup> Nor does it offer services in New York,<sup>120</sup> which sent cease-and-desist letters to twenty-six DTC companies in November 2007.<sup>121</sup> California also had a brief tussle with the DTC industry in June 2008 when the state sent cease-and-desist letters to thirteen DTC providers.<sup>122</sup> California asserted that the companies were violating two state laws: one that “prohibits the

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ing that Washington “defines ‘authorized person’ as ‘any individual allowed by . . . state law or rule to order tests or receive test results,’” and further clarifying that “[a]n official with the Washington State Department of Health stated that nothing in Washington State law prohibits DTC testing”).

114. See Drabiak-Syed, *supra* note 107, at 79. Compare STATE LAWS, *supra* note 110, at 7 (quoting the Michigan Department of Community Health as saying that “DTC testing is prohibited because ordering tests and receiving results is part of the practice of medicine”), with *id.* at 12 (quoting a Utah Department of Health official as saying “that ordering a test, performing the test, and giving the results of that test to a person does not constitute the ‘practice of medicine’”). For a detailed discussion of whether DTC genetics should be considered “the practice of medicine,” see generally Cynthia Marietta & Amy L. McGuire, *Direct-to-Consumer Genetic Testing: Is it the Practice of Medicine?*, 37 J.L. MED. & ETHICS 369 (2009).

115. Judy G. Russell, *NY and MD Limits on 23andMe*, LEGAL GENEALOGIST (Dec. 23, 2012), <http://www.legalgenealogist.com/blog/2012/12/23/ny-and-md-limits-on-23andme/#fn-4644-6> (quoting MD. CODE REGS. 10.10.06.02 (2013)).

116. STATE LAWS, *supra* note 110, at 6.

117. See Russell, *supra* note 115.

118. *Id.* (quoting MD. DEP’T OF HEALTH, FISCAL YEAR 2012 ANNUAL REPORT & STAFFING ANALYSIS 12 (2012), available at [http://dhmh.maryland.gov/ohcq/docs/Reports/HG19-308-OHCQAnnual-Report-11022012\\_OGA.pdf](http://dhmh.maryland.gov/ohcq/docs/Reports/HG19-308-OHCQAnnual-Report-11022012_OGA.pdf)).

119. *Id.*; *Is 23andMe Service Available in the State of Maryland?*, 23ANDME CUSTOMER CARE (Feb. 14, 2013), <https://customer.care.23andme.com/entries/23176758-Is-the-23andMe-service-available-in-the-state-of-Maryland-> (“The 23andMe Personal Genome Service is not available in the state of Maryland due to state-specific clinical laboratory testing statutes in place there.”).

120. See Russell, *supra* note 115. However, 23andMe will ship test kits to New York addresses, provided the customer “affirm[s] under penalty of law that the sample . . . [will] not [be] collected in or mailed from the state of New York.” *Is 23andMe Service Available in the State of New York?*, 23ANDME CUSTOMER CARE (Feb. 14, 2013), <https://customer.care.23andme.com/entries/23150752-Is-the-23andMe-service-available-in-the-state-of-New-York->.

121. See Meredith Wadman, *Gene-Testing Firms Face Legal Battle*, 453 NATURE 1148, 1149 (2008), available at <http://www.nature.com/news/2008/080625/full/4531148a.html>.

122. *US-California’s “Cease and Desist” Letters*, DTC WATCH (June 11, 2008, 7:13 PM), <http://dtcwatch.blogspot.com/2008/06/us-californias-cease-desist-letters.html>.



offering of a clinical laboratory test directly to the consumer without a physician order,<sup>123</sup> and another that requires laboratories processing specimens from California to have a California license.<sup>124</sup> 23andMe obtained a California license by August of 2008<sup>125</sup> and continues to offer services in the state. How the company satisfied California's demand for physician involvement, however, remains unclear.<sup>126</sup>

#### IV. PHYSICIAN PARTICIPATION REQUIREMENTS ARE UNNECESSARY AND ILL-ADVISED

Rationales for legal intervention in the DTC industry center around exaggerated claims of speculative harm. Opponents of DTC testing argue that doctors should be involved when the consumer makes the decision to order a genetic test, when the consumer receives results, or both.<sup>127</sup> These critics worry that consumers without a doctor's guidance are duped into purchasing inaccurate products,<sup>128</sup>

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123. Letter from Karen L. Nickel, Chief, Lab. Field Servs., Cal. Dep't of Pub. Health, to Phil Robinson, Dir., DNA Traits (June 9, 2008), available at [http://www.wired.com/images\\_blogs/wiredscience/files/madrigal.PDF](http://www.wired.com/images_blogs/wiredscience/files/madrigal.PDF). California Business and Professions Code Section 1288 provides that “[a]ny person conducting or operating a clinical laboratory may accept assignments for tests only from and make reports only to persons licensed under the provisions of law relating to the healing arts or their representatives.” CAL. BUS. & PROF. CODE § 1288 (West 2012).

124. *Id.* California Business and Professions Code Section 1241 extends the state laboratory licensing requirement to “all clinical laboratories . . . receiving biological specimens originating in California for the purpose of performing a clinical laboratory test or examination.” CAL. BUS. & PROF. CODE § 1241 (West 2012).

125. Andrew Pollack, *California Licenses 2 Companies To Offer Gene Services*, N.Y. TIMES, Aug. 20, 2008, at C3, available at [www.nytimes.com/2008/08/20/business/20gene.html](http://www.nytimes.com/2008/08/20/business/20gene.html). Navigenics received a California license at same time, see *id.*, and deCODEme followed in 2009, see *deCODE Receives California Clinical Laboratory License*, DECODE YOU (Feb. 19, 2009), <http://www.decodeyou.com/decode-receives-california-clinical-laboratory-license>.

126. 23andMe's blog contains a post acknowledging receipt of the cease-and-desist letter. See Linda Avey, *The Path to Personalized Healthcare in Step with Regulatory Oversight*, 23ANDME BLOG (July 6, 2008), <http://blog.23andme.com/health-traits/the-path-to-personalized-healthcare-in-step-with-regulatory-oversight>. Two months after the initial cease-and-desist letter, a California Public Health official stated that 23andMe had “satisfied the requirement for a doctor to be involved . . . [but] Linda Avey, a founder of 23andMe, declined to say . . . what the company was doing regarding doctors.” Pollack, *supra* note 125; see also Alexis Madrigal, *23andMe to California: We're Not Ceasing or Desisting*, WIRED (June 24, 2008), <http://www.wired.com/wiredscience/2008/06/23andme-were-no/> (quoting a statement made by 23andMe and released to Wired that the company “utilize[d] the services of a California licensed physician”).

127. See Bernstein, *supra* note 24, at 283 (asserting “the need for a law mandating the guidance of a medical professional not only at the interpretation stage but also at the outset of the process — to guide individuals through the selection of tests”).

128. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-847T, DIRECT-TO-CONSUMER GENETIC TESTS: MISLEADING TEST RESULTS ARE FURTHER COMPLICATED BY DECEPTIVE MARKETING AND OTHER QUESTIONABLE PRACTICES 1–2 (2010) [hereinafter GAO REPORT], available at <http://www.gao.gov/new.items/d10847t.pdf>.

are unable to understand the risks or limitations of testing,<sup>129</sup> cannot interpret their results,<sup>130</sup> and are likely to take drastic medical action<sup>131</sup> or experience psychological harm as a result.<sup>132</sup> These concerns are empirically unsupported. Leaders of the DTC industry provide accurate genotyping services<sup>133</sup> and adequately explain the risks of their products.<sup>134</sup> Furthermore, early research demonstrates that most consumers do not misunderstand their data,<sup>135</sup> take very little medical action in response to their results,<sup>136</sup> and do not experience lasting psychological distress.<sup>137</sup> Finally, most doctors are ill-prepared to assist their patients in either selecting among tests or interpreting results,<sup>138</sup> and including doctors in the process exacerbates privacy

129. Rebecca Antar Novick, *One Step at a Time: Ethical Barriers to Home Genetic Testing and Why the U.S. Health Care System Is Not Ready*, 11 N.Y.U. J. LEGIS. & PUB. POL'Y 621, 637 (2008).

130. Andrew S. Robertson, Note, *Taking Responsibility: Regulations and Protections in Direct-to-Consumer Genetic Testing*, 24 BERKELEY TECH. L.J. 213, 225–27 (2009) (citing EDWARD LANGSTON, AM. MED. ASS'N, REPORT OF THE BOARD OF TRUSTEES: DIRECT-TO-CONSUMER ADVERTISING AND PROVISION OF GENETIC TESTING (2008), available at <http://www.ama-assn.org/resources/doc/hod/a08botreports.pdf> (explaining the American Medical Association's stance that "the complexity of many of these tests warrants proper interpretation by medical professionals").

131. See, e.g., Kishore, *supra* note 23, at 1589.

132. See, e.g. Novick, *supra* note 129, at 635–36.

133. Pauline C. Ng et al., *An Agenda for Personalized Medicine*, 461 NATURE 724, 724 (2009); see also Ronald Bailey, *You Can't Handle the Truth*, REASON (May 27, 2009), <http://reason.com/archives/2009/05/27/you-cant-handle-the-truth> ("Princeton University molecular biologist Lee Silver . . . 'ran an analysis on personal genome results obtained from 23andMe and DeCODE . . . [and found that] [t]here were about 300,000 data points that overlapped between the two tests. There was not a single data point (among 300,000) that was scored positive in one test and negative in the other.' Silver [was] satisfied with [the] accuracy of such screening tests."); *Direct-to-Consumer Genetic Testing: Reliable or Risky?*, AM. ASS'N FOR CLINICAL CHEMISTRY 3 (2012), available at [http://www.aacc.org/publications/clin\\_chem/podcast/Documents/011211Spencer.pdf](http://www.aacc.org/publications/clin_chem/podcast/Documents/011211Spencer.pdf) ("Most of these platforms, the concordance is more than 98%, looking across several 100,000 genotypes. So they are very accurate analytically . . .").

134. See Norman P. Lewis et al., *DTC Genetic Testing Companies Fail Transparency Prescriptions*, 30 NEW GENETICS & SOC'Y 291, 303 (2011) (disparaging the large number of lesser-known DTC companies who fail to present the risks of testing, but noting that "three companies [23andMe, DeCode Genetics and Navigenics] . . . met at least 90% of the [American Society of Human Genetics'] transparency standards").

135. See generally David J. Kaufman et al., *Risky Business: Risk Perception and the Use of Medical Services Among Customers of DTC Personal Genetic Testing*, 21 J. GENETIC COUNSELING 413 (2012). But see generally J.W. Leighton et al., *The General Public's Understanding and Perception of Direct-to-Consumer Genetic Test Results*, 15 PUB. HEALTH GENOMICS 11 (2011).

136. Timothy Caulfield, *Direct-to-Consumer Testing: If Consumers Are Not Anxious, Why Are Policymakers?*, 130 HUM. GENETICS 23, 24 (2011).

137. Colleen M. McBride et al., *Consumers' Views of Direct-to-Consumer Genetic Information*, 11 ANN. REV. GENOMICS HUM. GENETICS 427, 436 (2010).

138. Shweta U. Dhar et al., *Enhancing Exposure to Genetics and Genomics Through an Innovative Medical School Curriculum*, 14 GENETICS MED. 163, 163 (2012) ("Several studies have shown that most physicians are unable to interpret even simple genetic tests . . ."); Robert Klitzman et al., *Attitudes and Practices Among Internists Concerning Genetic Test-*

concerns.<sup>139</sup> In the absence of physician participation, FTC enforcement can ensure that DTC companies do not make exaggerated claims and that only reputable services remain on the market.<sup>140</sup>

#### *A. DTC Tests Are Not Misleading Products*

In 2006, the Government Office of Accountability (“GAO”) performed an audit of four websites<sup>141</sup> selling DTC genetic tests,<sup>142</sup> ultimately concluding that “the test results . . . [were] misleading and of little or no practical use to consumers.”<sup>143</sup> If this statement were true — and if DTC companies nonetheless remained on the market — GAO’s findings would argue strongly in favor of involving physicians at the pre-testing stage because doctors could help dissuade consumers from investing time and money on fraudulent products. Fortunately, GAO’s conclusions were vastly overstated.

GAO’s criticism of DTC testing centered around two primary complaints: (1) “risk predictions often conflicted with the donors’ factual illnesses and family medical histories,” and (2) the same individual received different risk predictions from different companies.<sup>144</sup> GAO’s first complaint<sup>145</sup> represents a serious misconception of genetic principles because it conflates probability with fact.<sup>146</sup> Reduced risk

ing, 22 J. GENETIC COUNSELING 90, 90, 93 (2013) (surveying 220 “internists from two academic medical centers” and finding that the substantial majority “rated their knowledge as very/somewhat poor concerning genetics . . . and guidelines for genetic testing”); Matthew R. Taylor et al., *Lost in Transition: Challenges in the Expanding Field of Adult Genetics*, 142 AM. J. MED. GENETICS 294, 297 (2006) (“There is reason for concern that primary care physicians have not been adequately trained in the area of clinical genetics.”).

139. See discussion *infra* Part IV.G.

140. See discussion *infra* Part IV.H.

141. GAO REPORT, *supra* note 128, at 1–2. Though not named in the report, testimony at a congressional hearing on the subject identified the companies as 23andMe, deCODEme, Pathway Genomics, and Navigenics. See Daniel MacArthur, *A Sad Day for Personal Genomics*, GENOMES UNZIPPED (July 22, 2010), <http://www.genomesunzipped.org/2010/07/a-sad-day-for-personal-genomics.php>.

142. GAO evaluated the DTC companies by sending two samples from five donors to all four selected companies. DTC companies ask for personal information along with the sample — each donor sent one sample with factual and one sample with fictitious personal information. GAO REPORT, *supra* note 128, at 2–3. Risk predictions for fifteen traits were compared. *Id.* at 2–3 (“We selected for comparison 15 common diseases and conditions that were tested by at least three of the four companies: Alzheimer’s disease, atrial fibrillation (a type of irregular heart beat), breast cancer, celiac disease (a chronic digestive problem caused by an inability to process gluten), colon cancer, heart attack, hypertension, leukemia, multiple sclerosis, obesity, prostate cancer, restless leg syndrome, rheumatoid arthritis, type 1 diabetes, and type 2 diabetes.”).

143. GAO REPORT, *supra* note 128, at 4.

144. *Id.*

145. *Id.* For example, the GAO report explains that “a donor who had a pacemaker implanted 13 years ago to treat an irregular heartbeat was told that he was at decreased risk for developing such a condition.” *Id.*

146. See Palmer, *supra* note 79, at 476.

is not inconsistent with disease incidence.<sup>147</sup> Our genes do not alter to reflect our current health: an individual with decreased genetic risk for colon cancer might nonetheless develop the disease, and his genotype will not change to reflect his diagnosis. Later genetic analysis will still accurately reveal his low genetic risk relative to other similarly situated individuals. In other words, “lesser” risk is not zero risk — sometimes, unfortunately, we simply defy the odds.

GAO’s second criticism of DTC testing holds more water, but it does not rob the tests of their value nor imply scientific practice. Instead, differences in risk prediction across DTC providers reflects the ever-evolving — though scientifically valid — process of associating genetic markers with disease, as well as the companies’ differing beliefs about the most useful ways to calculate risk. These concerns would be better remedied by the creation of industry standards than by involving physicians in the process.

First and foremost, DTC companies provide accurate genotyping services.<sup>148</sup> In 2009, *Nature* researchers examined thirteen disease risks and found that 23andMe and Navigenics reported the same genotypes 99.7% of the time.<sup>149</sup> Other scientists confirm or agree with this finding — the analytic validity of the tests is not in dispute.<sup>150</sup> Despite accurate genotyping, providers often disagree with respect to risk predictions.<sup>151</sup> The same *Nature* study that confirmed the DTC industry’s genotyping accuracy also identified discrepancies in risk prediction across major providers.<sup>152</sup> Ultimately, these differences are a function of diverse standards for genetic marker selection and do not represent sub-par science.

Instead of decrying genetic tests as useless, the *Nature* authors identified the companies’ methods for calculating baseline population risk as one source of the discrepancies.<sup>153</sup> 23andMe reported a population risk reflective of the age of the customer, while Navigenics reported a population risk that incorporated gender.<sup>154</sup> After accounting for these differences, the companies agreed qualitatively on the cus-

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147. See *GAO Studies Science Non-Scientifically*, 23ANDME BLOG (July 23, 2010), <http://blog.23andme.com/23andme-research/gao-studies-science-non-scientifically> (“This is a criticism that could be said of any risk prediction . . . [i]t is well accepted that not everyone with high cholesterol has a heart attack, and not all heart attacks happen in people with high cholesterol. Yet, cholesterol measurements are taken and used in clinical practice every day.”).

148. Ng et al., *supra* note 133.

149. *Id.*

150. *See id.*

151. *Id.*

152. *Id.*

153. *Id.*

154. *Id.*

sumer's relative risk for a given trait about two-thirds of the time.<sup>155</sup> The remaining discrepancies are probably caused by lack of agreement about the markers that should be used to predict risk for a given trait.<sup>156</sup> Once a new marker is discovered, companies use different standards to determine whether it is well-established enough to use.<sup>157</sup> Encouragingly, when 23andMe and Navigenics both included a particular marker, they tended to agree on how much it affected disease risk.<sup>158</sup>

While differing risk predictions should be addressed, they would not be remedied by physician participation. Suggestions that doctors could aid consumers by explaining the basis for differing predictions across multiple providers may sound intuitively appealing. However, there is no reason to believe that many customers are purchasing multiple tests and experiencing confusion from conflicting results. Furthermore, primary care practitioners are likely ill-equipped to explain why some markers might be preferable to others.<sup>159</sup> Industry-wide marker selection and risk reporting standards would address the issue — and DTC providers seem to welcome standardization along these lines.<sup>160</sup> Should FDA seek to impose such standards, it can and should do so without promulgating a physician participation requirement.

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155. *Id.* When the companies agreed qualitatively, they all reported increased (or decreased) risk for a given individual for a given trait.

156. *Id.*

157. *Id.*

158. *Id.*

159. See Linda M. Sandhaus et al., *Reporting BRCA Test Results to Primary Care Physicians*, 3 GENETICS MED. 327, 327 (2001) (“Many physicians may be unprepared to interpret genetic risk information, due to lack of understanding of basic epidemiologic terms used to express the risk of disease.”); see also Dhar et al., *supra* note 138, at 163; Klitzman et al., *supra* note 138; Taylor et al., *supra* note 138, at 297.

160. See Palmer, *supra* note 79, at 491. In testimony at a 2010 congressional hearing, 23andMe, Pathway Genomics, and Navigenics agreed that the companies needed to establish best practices and consistent standards for DTC testing. Dan Vorhaus, *The FDA and DTC Genetic Testing: Setting the Record Straight*, GENOMICS L. REP. (Mar. 11, 2011), <http://www.genomicslawreport.com/index.php/2011/03/11/the-fda-and-dtc-genetic-testing-setting-the-record-straight>. In its response to the *Nature* study, Navigenics concurred that “[a] standard set of markers would be valuable to the industry and personalized medicine in general, and it may be most practical for a third party to assess clinical validity.” Letter from 23andMe & Navigenics to *Nature* (Nov. 18, 2009), available at <http://blog.23andme.com/news/announcements/23andme-navigenics-open-letter-to-nature>. In 2010, 23andMe sent a letter to leadership of both FDA and NIH, suggesting collaboration towards “standards for the positive and negative predictive value of all tests.” Ashley Gould, on behalf of Anne Wojcicki, President & Co-Founder, 23andMe, to Dr. Margaret Hamburg, Comm’r of Food & Drugs, FDA, and Dr. Francis Collins, Dir., Nat’l Insts. of Health (June 24, 2010), available at <http://blog.23andme.com/2010/07/06/23andme-letter-to-heads-of-fda-and-nih>.

*B. DTC Industry Leaders Disclose the Risks of Testing*

In order to make an informed decision about whether to undergo genetic testing, a customer must have access to information about the risks involved.<sup>161</sup> Fortunately, DTC industry leaders make detailed information about the risks and benefits of testing available to consumers before product purchase.<sup>162</sup> Risks identified by the literature include the uncertain and probabilistic nature of results — including the multivariate nature of disease risk<sup>163</sup> — the possibility of deeply troubling revelations,<sup>164</sup> and concerns about genetic privacy or discrimination.<sup>165</sup> 23andMe addresses all of these issues via its website, terms of service, and privacy statement.<sup>166</sup> One recent study analyzed DTC providers' compliance with “transparency standards”<sup>167</sup> and ap-

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161. BLACK'S LAW DICTIONARY 346 (9th ed. 2009) (defining informed consent as “[a] person's agreement to allow something to happen, made with full knowledge of the risks involved and the alternatives”).

162. See Lewis et al., *supra* note 134.

163. Novick, *supra* note 129, at 635–40.

164. Kishore, *supra* note 23, at 1588–89.

165. See, e.g., Amy Foster, Note & Comment, *Critical Dilemmas in Genetic Testing: Why Regulations To Protect Confidentiality of Genetic Information Should be Expanded*, 62 BAYLOR L. REV. 537 (2010).

166. See 23ANDME, <https://www.23andme.com> (last visited Apr. 11, 2013); *Privacy*, 23ANDME, <https://www.23andme.com/about/privacy> (last visited Apr. 11, 2013) [hereinafter *Privacy Statement*]; *Terms of Service*, 23ANDME, <https://www.23andme.com/about/tos> (last visited Apr. 11, 2013). Certainly, the DTC genetics industry does not escape criticism merely because a major provider presents accurate information about risks and limitations. Other providers may not be as scrupulous. See generally, Amanda Singleton et al., *Informed Choice in Direct-to-Consumer Genetic Testing (DTCGT) Websites: A Content Analysis of Benefits, Risks, and Limitations*, 21 J. GENETIC COUNSELING 433, 437 (2012) (“[M]ost company websites did not provide a balanced representation of benefits, risks, and limitations, and in fact, often presented conflicting information.”).

167. Lewis et al., *supra* note 134, at 295. The six transparency standards were identified by the American Society for Human Genetics and are as follows:

- (1) Disclose the sensitivity, specificity, and predictive value of the test, and the populations for which this information is known.
- (2) Disclose the strength of scientific evidence on which any claims of benefit are based, as well as any limitations to the claimed benefits. For example, if a disease or condition may be caused by many factors, including the presence of a particular genetic variant, the company should disclose that other factors may cause the condition and that absence of the variant does not mean the patient is not at risk for the disease.
- (3) Disclose all risks associated with testing, including psychological risks and risks to family members.
- (4) Disclose the CLIA certification status of the laboratory performing the genetic testing.
- (5) Maintain the privacy of all genetic information and disclose their privacy policies, including whether they comply with HIPAA (Health Insurance Portability and Accountability Act of 1996).

plauded 23andMe (along with Navigenics and deCODEme) for “tak[ing] [its] mission seriously.”<sup>168</sup> Each of these leading providers met ninety-two percent of the measured standards;<sup>169</sup> 23andMe was dinged only for failing to disclose whether it complies with the Health Care Portability and Accountability Act.<sup>170</sup>

Potential customers can obtain information about the risks and benefits of 23andMe testing from several sources. The richest — and most intuitive — avenue is the 23andMe demo account.<sup>171</sup> Interested consumers can create a free demo account, and then log in to explore mock test results for fictional individuals<sup>172</sup> (appropriately named the Mendels).<sup>173</sup> In this manner, customers can see exactly what they will be getting. Via the demo account, as well as via the main “Conditions Tested” screen,<sup>174</sup> consumers can review the tests that 23andMe provides as well as the proportion of tests that meet the more stringent standards for “Established Research Reports.”<sup>175</sup> Clicking into an “established” condition provides sample data and hyperlinks to studies that validate the genetic marker.<sup>176</sup> The presentation includes graphical depictions of the heritability of the disease — that is, the extent to which the disease or condition is caused by genetic versus environmental factors.<sup>177</sup> These graphics should remind consumers that most diseases are not caused by genetics alone. Preliminary research reports provide links to cited studies, report their sample size, and show whether or not they have been replicated or contradicted.<sup>178</sup> These details should help consumers understand the scientific limits of 23andMe’s product.

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- (6) If making any lifestyle, nutritional, pharmacologic, or other treatment recommendations, disclose the clinical evidence for and against the efficacy of any such interventions.

*Id.*

168. *Id.* at 303.

169. *Id.* at 297–98.

170. *See id.* at 297.

171. *See Create Your Free Account*, 23ANDME, <https://www.23andme.com/user/signup> (last visited Apr. 11, 2013).

172. *Health Risks*, 23ANDME, <https://www.23andme.com/you/health/risk> (last visited Feb. 28, 2013). This site is accessible only with a 23andMe account, but interested users can sign up for a free demo account.

173. Gregor Mendel is considered the father of modern genetics. *See generally* ROGER KLARE, GREGOR MENDEL: FATHER OF GENETICS (1997).

174. *Conditions Tested*, *supra* note 19.

175. This information is boldly presented — either via a four-star ranking system through the demo account, see *Health Risks*, *supra* note 172, or at the very top of the “Conditions Tested” screen, see *Conditions Tested*, *supra* note 19.

176. *Health Risks: Alzheimer’s Disease*, *supra* note 68; see *infra* Figure 1.

177. *Health Risks: Alzheimer’s Disease*, *supra* note 68.

178. *See, e.g., Get Tested To Learn What Your Genetics Say About: Thyroid Cancer*, 23ANDME, <https://www.23andme.com/health/Thyroid-cancer> (last visited Apr. 11, 2013).

23andMe's terms of service agreement provides consumers with another source of information.<sup>179</sup> Here, the company explicitly enumerates many of the additional risks that DTC critics believe are essential to an informed testing decision.<sup>180</sup> 23andMe tells customers that they could receive unanticipated and unwelcome information that might "evoke strong emotions" or "alter [their] life and worldview."<sup>181</sup>

The reporting procedure for results of serious traits — such as Parkinson's disease risk — enhances this approach; customers must click through an additional warning message to receive these results.<sup>182</sup> Other enumerated risks include laboratory errors,<sup>183</sup> samples that cannot be processed,<sup>184</sup> the possibility that future research could change how results are interpreted,<sup>185</sup> and the chance that some findings may not apply to all ethnicities.<sup>186</sup> 23andMe cautions customers not to alter health-related behaviors on the basis of test results without consulting a physician. The company also reminds buyers that "23andMe Services are for research, informational, and educational use only," and that "[r]eliance on any information provided by 23andMe . . . is . . . solely at [their] own risk."<sup>187</sup> Finally, 23andMe addresses privacy concerns by informing customers that, given incomplete protection under the Genetic Information Nondiscrimination Act ("GINA"), "[g]enetic [i]nformation [they] share with others could be used against [their] interests."<sup>188</sup> Specifically, 23andMe warns customers that sharing genetic information with their doctors could make it part of their medical record, that currently meaningless information could gain importance in the future, and that declining to disclose the 23andMe report if insurers ask about genetic health information might

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179. *Terms of Service*, *supra* note 166.

180. *Id.* While the language used is straightforward and sections are clearly labeled, this document is visually intimidating for its dense nature and legal appearance. A user-friendly version might be in order. Such revision would further diminish any perceived need for physician participation in the testing choice.

181. *Id.* (giving the examples of "your father is not genetically your father" or "that someone with your genotype may have a higher than average chance of developing a specific condition or disease").

182. Ed Young, *How I Got My Genes Tested, and the Birth of Science Writer Disease Risk Top Trumps*, DISCOVER MAG. (July 21, 2010, 9:00 AM), <http://blogs.discovermagazine.com/notrocketscience/2010/07/21/how-i-got-my-genes-tested-and-the-birth-of-science-writer-disease-risk-top-trumps/> ("Before unlocking the LRRK2 information, [23andMe] tells you 'You are about to learn whether you have a relatively rare mutation in the LRRK2 gene that raises your lifetime Parkinson's risk to more than 50% compared to the population average of between 1% and 2%.'").

183. *Terms of Service*, *supra* note 166.

184. *Id.*

185. *Id.*

186. *Id.*

187. *Id.*

188. *Id.*



be considered fraud.<sup>189</sup> The terms of service include the risk of data breach,<sup>190</sup> while a 23andMe privacy statement addresses additional confidentiality concerns, including third party disclosures and research participation.<sup>191</sup>

Thus, 23andMe appears to address all the relevant risks of unwelcome results, uncertain results, and privacy concerns in an accessible format on its website. When a consumer is presented with accurate information about the risks and benefits of a choice in an accessible and readable manner, an assumption that they cannot make an informed decision seems grounded in paternalistic notions.<sup>192</sup>

Nonetheless, the presentation of this information could be streamlined and simplified — it is not always located in an obvious spot<sup>193</sup> and may be presented at an above-average reading level.<sup>194</sup> While early adopters of DTC testing are likely to be more educated than the average population,<sup>195</sup> continued improvement in this area will be valuable as DTC services become more widely adopted.

### *C. Research Shows That DTC Customers Understand Their Results*

A frequent critique of the DTC model is that laypersons should not attempt to interpret inherently complicated genetic results without professional guidance.<sup>196</sup> Beyond normative objections to paternalistic medicine, emerging evidence also suggests that this fear is unfounded. Major DTC companies have developed incredibly rich user interfaces

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189. *Id.*

190. *Id.* (limiting 23andMe's liability in the case of "unauthorized access to or alteration of your transmissions or data").

191. *Privacy Statement, supra* note 166. The company will only include a customer's genetic information and self-reported information in aggregated disclosures to third-party researchers for publication purposes if the customer has consented to participate in 23andMe research. *Id.* However, for research and development purposes, 23andMe may disclose "[a]ggregated [g]enetic and [s]elf-[r]eported [i]nformation to third-party non-profit and/or research partners who will not publish that information in a peer-reviewed scientific journal." *Id.* Note that "if [a customer] ha[s] given consent to participate in 23andMe Research, [the company] may also allow research contractors to access . . . individual-level [g]enetic and/or [s]elf-[r]eported [i]nformation onsite at 23andMe's offices for the purpose of conducting scientific research . . ." *Privacy Statement, supra* note 166. Individual-level information is not sold, leased, or rented without explicit consent from the customer. *Id.*

192. Robert VerBruggen, *The FDA's Genetic Paternalism*, NAT'L REV. ONLINE (Mar. 23, 2011), <http://www.nationalreview.com/content/fda's-genetic-paternalism>.

193. Lewis et al., *supra* note 134, at 300 ("23andMe tucked a single sentence warning against a false negative into its 8869-word terms of service document"); Palmer, *supra* note 79, at 522.

194. McBride et al., *supra* note 137, at 433 (citing C.R. Lachance et al., *Informational Content, Literacy Demands, and Usability of Websites Offering Health-Related Genetic Tests Directly to Consumers*, 12 GENETICS MED. 304, 309–11 (2010)).

195. Kaufman et al., *supra* note 135, at 422.

196. See, e.g., Stephanie Bair, *Direct-to-Consumer Genetic Testing: Learning from the Past and Looking Toward the Future*, 67 FOOD & DRUG L.J. 413, 421 (2012).

for the display of results in an intuitive format.<sup>197</sup> Even genetic counselors have commended 23andMe for “trying to put the information into some context and educate the consumer.”<sup>198</sup> This investment appears to be paying off, as early research indicates consumers have a reasonable understanding of their results.<sup>199</sup>

One recent study involved 1046 customers of 23andMe, deCODEme, and Navigenics.<sup>200</sup> Participants were asked to interpret two sets of fictitious results formatted according to their provider,<sup>201</sup> no fewer than ninety percent of participants answered both questions correctly.<sup>202</sup> Furthermore, only twelve percent of participants did not agree that the “reports are easy to understand.”<sup>203</sup> As early adopters of testing, these consumers might represent a more genetically literate group than the average population,<sup>204</sup> still, their results are encouraging.

*D. Evidence Does Not Suggest That Consumers Take Drastic or Ill-Advised Action in Response to Results Without Consulting a Physician*

Fatalistic predictions about extreme or poor medical choices in response to DTC results have also prompted concern in the literature.<sup>205</sup> Fortunately, empirical evidence suggests that people do not change their behavior drastically in response to test results<sup>206</sup> and that many people confer with their physician even though not required to do so.<sup>207</sup>

First, available research supports the belief that “the majority of Western populations appreciate that health is a product of variable

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197. See *Review: 23andMe*, *supra* note 67 (chronicling one consumer’s 23andMe experience including results screenshots).

198. Elizabeth A. Varga, *You Want To Do What? My Mother’s Choice To Have Direct-to-Consumer Genetic Testing*, 21 J. GENETIC COUNSELING 382, 384 (2012).

199. See Kaufman et al., *supra* note 135. *But see* Leighton, *supra* note 135.

200. The participants were invited randomly; it is not clear whether any of them took advantage of the genetic counseling services offered by their respective providers. Kaufman et al., *supra* note 135, at 414–15.

201. *Id.*

202. *Id.* at 416.

203. *Id.*

204. See *id.* at 421 (“In comparison to the U.S. adult population, our sample of relatively early adopters of DTC genetic testing had high levels of education and household income . . . . As the DTC genetic testing customer base expands to include larger numbers of lower-income and less well-educated individuals, the potential health benefits of DTC testing suggested by our findings may be less generalizable.”).

205. See Gabel, *supra* note 23, at 420–21.

206. Caulfield, *supra* note 136.

207. See Cinnamon S. Bloss et al., *Effect of Direct-to-Consumer Genomewide Profiling To Assess Disease Risk*, 364 NEW ENG. J. MED. 524, 532 (2011) [hereinafter Bloss et al., *Effect of DTC*]; Kaufman et al., *supra* note 135, at 413.

inputs of both personal behavior and familial inheritance.”<sup>208</sup> In other words, many DTC consumers already understand that their genes are not the sole determinant of disease. This knowledge alone should temper extreme responses to genetic risk information.

In fact, it seems that “the provision of genetic risk information . . . ha[s] little influence on . . . the recipient’s . . . subsequent behavior.”<sup>209</sup> For example, over two thousand Navigenics customers studied by Dr. Cinnamon Bloss showed no significant differences in dietary fat intake or exercise behavior after genetic testing.<sup>210</sup> Another recent study found that one-third of the sixty interviewed participants reported changing their health or lifestyle habits in response to their results, but that most of these changes were minor.<sup>211</sup>

Furthermore, many DTC customers share their results with a physician notwithstanding any legal requirement. Of the over one thousand participants in Dr. David J. Kaufman’s study, sixty percent of the participants changed a medicine or dietary supplement, but less than one percent altered a prescription medication regimen without consulting a doctor.<sup>212</sup> Overall, twenty-eight percent of participants in Kaufman’s study discussed their results with a doctor.<sup>213</sup>

Of course, Dr. Kaufman’s work made no effort to quantify the most extreme choices — such as prophylactic surgery — that a DTC consumer might possibly make in response to test results. On an intuitive level, the potential for such drastic measures is concerning. On the other hand, intensive medical responses are nearly impossible to undertake without some sort of physician guidance. A woman who opts for a prophylactic mastectomy in response to news that she is genetically predisposed to breast cancer will consult with doctors throughout the referral and pre-surgery process. During this time she will have ample access to qualified experts who can help her interpret her risk and evaluate her decision. A recent 23andMe study confirms the instinct that when serious diseases are involved, consumers will seek medical help. Out of sixteen women who learned for the first

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208. McBride et al., *supra* note 137, at 434 (citing seven scientific studies supporting this premise).

209. Caulfield, *supra* note 136, at 24.

210. Bloss et al., *Effect of DTC*, *supra* note 207.

211. *ASHG 2010: New Research on Implications of Direct-to-Consumer and Clinical Genetic Testing*, EUREKALERT! (Oct. 20, 2010), [http://www.eurekaalert.org/pub\\_releases/2010-11/asoh-a2n102010.php](http://www.eurekaalert.org/pub_releases/2010-11/asoh-a2n102010.php) (discussing the findings of Dr. Barbara Bernhardt’s study). These patients underwent in-person, informed consent procedures that explained testing limitations. Stephanie Pappas, *Scrutiny of Personal Gene Tests Increases*, LIVE SCI. (May 30, 2010), <http://www.livescience.com/9927-scrutiny-personal-gene-tests-increases.html> (explaining the informed consent procedure).

212. Kaufman et al., *supra* note 135, at 417.

213. *Id.*

time that they carried a BRCA<sup>214</sup> mutation, a majority spoke with a doctor, and “most did so immediately.”<sup>215</sup> Concerns about drastic medical decisions made without physician guidance seem exaggerated and poorly supported by the available evidence.

*E. Early Evidence Suggests That DTC Genetic Testing Does Not Cause Psychological Harm*

Research on consumer reactions to DTC testing is still emerging, but evidence does not support the view that consumers who lack physician guidance suffer psychological damage when receiving their results. In general, studies demonstrate one of two findings: (1) that DTC testing has minimal psychological impact, or (2) that consumers experience some short-term increase in anxiety right after receiving a “bad” result, but that this stress dissipates within a year.<sup>216</sup> For example, a 2010 review of existing research revealed “no evidence of any unintended detrimental effects on motivation or mood.”<sup>217</sup> An earlier review of the literature concurs: “[o]verall, predispositional genetic testing has no significant impact on psychological outcomes . . . .”<sup>218</sup> In fact, any anxiety produced by genetic testing may be at least partially attributable to privacy concerns,<sup>219</sup> a problem mandatory physician involvement only exacerbates.<sup>220</sup>

Individual study results are illuminating. A 2011 New England Journal of Medicine study surveyed over two thousand Navigenics customers<sup>221</sup> and found that “90.3% of subjects . . . [had] scores indi-

214. BRCA mutations “predispose [individuals] to hereditary breast and ovarian cancer.” Uta Francke et al., *Dealing with the Unexpected: Consumer Responses to Direct-Access BRCA Mutation Testing*, PEERJ 1, 2 (2013), <https://peerj.com/articles/8.pdf>.

215. *Id.* at 10. The three women who did not contact a doctor were already aware they were BRCA-mutation positive. *Id.* at 11.

216. McBride et al., *supra* note 137, at 436.

217. Caulfield, *supra* note 136, at 24 (quoting T.M. Marteau et al., *Effects of Communicating DNA-Based Disease Risk Estimates on Risk-Reducing Behaviours*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS, Oct. 6 2010, at 2, available at <http://www.ncbi.nlm.nih.gov/pubmed/20927756>).

218. Jodi T. Heshka et al., *A Systematic Review of Perceived Risks, Psychological and Behavioral Impacts of Genetic Testing*, 10 GENETICS MED. 19, 19 (2008).

219. Caulfield, *supra* note 136, at 24 (“[S]ome studies have shown that a segment of the general public has a range of concerns about DTC services (though the protection of privacy . . . rather than increased anxiety about test results, is usually identified as the primary issue). . . .”) (citing C.S. Bloss et al., *Consumer Perceptions of Direct-to-Consumer Personalized Genomic Risk Assessments*, 12 GENETICS MED. 556, 560 (2010) [hereinafter Bloss et al., *Consumer Perceptions*]).

220. See discussion *infra* Part IV.G.

221. Bloss et al., *Effect of DTC*, *supra* note 207, at 524. It is important to note several factors about the study participants that may distinguish them from the average population. First, they received Navigenics testing at a subsidized rate. *Id.* at 525. Participants were also recruited from health-related companies, perhaps meaning they had greater familiarity with genetic testing. *Id.* at 524. Finally, subjects not only received access to the standard Navi-

cating no test-related distress.”<sup>222</sup> Researchers concluded that “testing did not result in any measurable short-term changes in psychological health.”<sup>223</sup> Interestingly, about half of these subjects had expressed concern about undergoing genetic testing before they participated, though a strong majority said they would wish to know their risk for even a non-preventable disease.<sup>224</sup>

These findings appear to hold even if testing includes serious diseases, such as Alzheimer’s.<sup>225</sup> In a 2009 study, 162 adults with a family history of the disease were randomly assigned to receive, or to not receive, genotyping results.<sup>226</sup> Participant levels of anxiety, depression, and test-related distress were measured at intervals afterwards.<sup>227</sup> Comparisons between the group that received no results, and the group that learned they were genetically pre-disposed to Alzheimer’s “revealed no significant differences” in anxiety.<sup>228</sup> Researchers concluded that “[t]he disclosure of . . . genotyping results to adult children of patients with Alzheimer’s . . . did not result in significant short-term psychological risks.”<sup>229</sup> Because participants received a ninety-minute briefing on testing limitations and medical inutility,<sup>230</sup> and because family histories of disease likely affected their expectations, these results are not readily generalizable to DTC participants at large.<sup>231</sup> Nonetheless, they are encouraging.

More recently, 23andMe published a small-scale study exploring the psychological harm of testing for BRCA gene mutations.<sup>232</sup> Researchers surveyed thirty-two individuals who tested positive for BRCA mutations via 23andMe; twenty-five of these people were pre-

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genics genetic counseling services (provided free of charge via telephone) but “Navigenics [also] provided proactive outreach to study subjects on the basis of their risk results.” *Id.* at 527. For a more detailed description of the methods used, see Bloss et al., *Consumer Perceptions*, *supra* note 219.

222. Bloss et al., *Effect of DTC*, *supra* note 207, at 524.

223. *Id.*

224. Bloss et al., *Consumer Perceptions*, *supra* note 219, at 556. Though this paper was published separately from Bloss et al., *Effect of DTC*, *supra* note 207, both studies analyze data from the Scripps Genomic Health Initiative.

225. See generally Robert C. Green et al., *Disclosure of APOE Genotype for Risk of Alzheimer’s Disease*, 361 NEW ENG. J. MED. 245 (2009).

226. *Id.* at 245. The APOE genotype provides risk information for Alzheimer’s disease. *Id.*

227. *Id.*

228. *Id.*

229. *Id.*

230. *Id.* at 246, 252.

231. *Id.* at 252. DTC consumers who do not have a family history of Alzheimer’s (or who are unaware of such a history) would not have the “benefit” of preparing for a bad test result, and so might suffer more shock if they receive one. *Id.*

232. Francke et al., *supra* note 214.

viously unaware that they carried a BRCA mutation.<sup>233</sup> Ten participants were “surprised” or “shocked” by their results,<sup>234</sup> but none characterized themselves as “extremely upset.”<sup>235</sup> Three “surprised” individuals reported that they felt “moderately upset,”<sup>236</sup> and three reported feeling “somewhat upset.”<sup>237</sup> Strikingly, however, eleven of the twenty-five individuals who learned they carried a BRCA mutation for the first time “reported feeling ‘neutral.’”<sup>238</sup> Of the thirty-two participants, only two indicated ex-post that they would “prefer not to know their result.”<sup>239</sup> Overall, researchers found an “absence of evidence for serious emotional distress.”<sup>240</sup> Further research is needed in this burgeoning field, but current evidence does not support arguments that devastating psychological impacts accompany DTC testing.

*F. Primary Care Physicians Are Ill-Prepared to Assist Patients with the Genetic Testing Process*

Adding a physician to the mix would not necessarily benefit consumers. Studies demonstrate that primary care providers are woefully unprepared to work with genetic information,<sup>241</sup> and this seems unlikely to change in the near future.<sup>242</sup> Primary care physicians may be unable to contribute to an informed consent discussion because they “lack knowledge and confidence about how to counsel or when to refer patients to genetic services.”<sup>243</sup> One survey of North Carolina general practitioners revealed that less than half of respondents were

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233. *See id.* at 1, 4, 6. Seven people in the study were already aware that they possessed BRCA mutations. *Id.* at 6.

234. *Id.* at 8 tbl.4. Those who were not surprised indicated that they knew that close relatives were carriers, had a strong family history of breast or ovarian cancer, or realized their Ashkenazi Jewish heritage placed them at risk. *Id.* at 7–8.

235. *Id.* at 8. “Extremely upset” was defined as “cried, lost sleep, had thoughts of suicide.” *Id.* at 8 tbl.4.

236. *See id.* at 8. “Moderately upset” was defined as “couldn’t stop thinking about the result, felt moderate anxiety.” *Id.* at 8 tbl.4.

237. *Id.* at 8. “Somewhat upset” was defined as “initial disappointment, felt anxious at first but then anxiety went away.” *Id.* at 8 tbl.4.

238. *Id.* (reporting that seventeen of the thirty-two survey participants reported feeling “neutral,” but explaining that this count included six individuals who were already aware that they carried BRCA mutations).

239. *Id.* at 18. Interestingly, one of these individuals tested negative. *Id.*

240. *Id.* at 1.

241. Dhar et al., *supra* note 138, at 163; Klitzman et al., *supra* note 138, at 93; Taylor et al., *supra* note 138, at 294.

242. Bruce R. Korf, *Competencies for the Physician Medical Geneticist in the 21st Century*, 13 *GENETICS MED.* 911, 911 (2013) (noting that “the number of physicians who complete medical genetics training . . . has remained flat in recent years”).

243. McBride et al., *supra* note 137, at 435 (citing M.T. Scheuner et al., *Delivery of Genomic Medicine for Common Chronic Adult Diseases: A Systematic Review*, 299 *JAMA* 1320, 1320 (2008)).

even aware of DTC genetic testing.<sup>244</sup> In another study, only thirteen percent of responding physicians reported feeling comfortable ordering a genetic test for drug responsiveness (a pharmacogenetic test), despite the majority's belief that the service would soon be an important medical tool.<sup>245</sup> Likewise, most doctors will be unable to interpret test results because they often have deficient knowledge in the field<sup>246</sup> and feel ill-equipped to answer their patients' questions.<sup>247</sup> Perhaps most disturbingly, even some *genetic counselors* confess they can be underequipped to explain concepts of genomic testing to the average population.<sup>248</sup>

Thus, a physician participation requirement is unlikely to benefit patients unless qualified experts are used. Unless physicians understand how genetic markers are selected by the companies, how genetic risk is reported, and how environmental factors may contribute to risk, it is not clear they could help consumers decide whether to get tested — beyond reading the companies' information out loud.<sup>249</sup> As one author quips, “designating [non-geneticist physicians] as gatekeepers’ could be tantamount to ‘sticking healthcare in a time capsule for a decade or more, until physicians get up to speed.’”<sup>250</sup>

Unfortunately, affording universal access to genetic experts is easier said than done. Membership in the National Society of Genetic Counselors is concentrated in certain urban areas.<sup>251</sup> Within forty miles of San Francisco, New York City, and Philadelphia there are 121, 191, and 118 counselors respectively.<sup>252</sup> However, within one

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244. Karen P. Powell et al., *Educational Needs of Primary Care Physicians Regarding Direct-to-Consumer Genetic Testing*, 21 J. GENETIC COUNSELING 469, 469 (2012).

245. S.B. Haga et al., *Primary Care Physicians' Knowledge of and Experience with Pharmacogenetic Testing*, 82 CLINICAL GENETICS 388, 388 (2012).

246. Dhar et al., *supra* note 138, at 163; Klitzman et al., *supra* note 138.

247. Powell et al., *supra* note 244, at 472.

248. See Amy C. Sturm et al., *Direct-to-Consumer Personal Genomic Testing: A Case Study and Practical Recommendations for “Genomic Counseling,”* 21 J. GENETIC COUNSELING 402, 409 (2012) (explaining that “preconceived notions” that DTC customers were genetically savvy caused one counselor to be “caught somewhat off guard and underprepared”). “For example, during the session itself, [one counselor was] not prepared with educational visual aids to help explain genomics concepts and [the] patient’s personal genomic testing results.” *Id.*

249. Of course, a trip to the doctor’s office could ensure that customers actually receive the information (as opposed to paging through consent documents absentmindedly). This benefit is unlikely to outweigh the privacy concerns addressed below, see discussion *infra* Part IV.G, and frustrates notions of consumer autonomy.

250. Palmer, *supra* note 79, at 490 (alteration in the original) (quoting Thomas Goetz, *Is Your DNA Dangerous to Your Health?*, HUFFINGTON POST (June 18, 2010), [http://www.huffingtonpost.com/thomas-goetz/dna-test-is-your-dna-dang\\_b\\_616568.html](http://www.huffingtonpost.com/thomas-goetz/dna-test-is-your-dna-dang_b_616568.html) [hereinafter Goetz, *Is Your DNA Dangerous*]).

251. *Find a Genetic Counselor by US Zip Code*, NAT’L SOC’Y OF GENETIC COUNSELORS, <http://www.nsgc.org/tabid/69/Default.aspx> (last visited Apr. 11, 2013) (search conducted by zip code).

252. *Id.*

hundred miles of Boise, Fargo, and New Orleans, there are only nine, two, and six counselors respectively.<sup>253</sup> If part of DTC's promise is its wide accessibility, then a requirement for in-person genetic counseling would undermine this achievement. 23andMe has partnered with Informed DNA to assist its customers in obtaining genetic counseling by telephone.<sup>254</sup> Regulators should consider whether optional services like these might offer the best, low-cost access to genetic counselors many individuals can reasonably obtain.

### *G. Mandatory Disclosure of Genetic Testing Results Creates Privacy Concerns*

Involving a physician in a patient's choice to undergo genetic testing has important privacy implications. If a prescription requirement were imposed, doctors would — at a minimum — become aware that a patient who requested testing would soon receive genetic information. Even if the doctor was not automatically given access to his patient's results, he might reasonably think to ask about them. Given the immensely personal nature of DNA, some people may feel even this is a violation of privacy.<sup>255</sup> Furthermore, communicating test results to a doctor may make them part of the patient's medical record.<sup>256</sup>

GINA prevents genetic discrimination by health insurance providers, but not by life insurance, disability insurance, or long-term care insurance providers.<sup>257</sup> Under GINA, employers may not discriminate on the basis of genetic information, but the U.S. Military and very small employers are exempt.<sup>258</sup> Providing easy access to genetic information via medical records could make such coverage more expensive for individuals with adverse results. On a more cynical level, GINA does not prohibit discrimination by health insurance provid-

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<sup>253</sup> *Id.*

<sup>254</sup> 23andMe Genetic Counseling, *supra* note 74; *Have Questions About Your 23andMe Reports or Your Genetic Health?*, INFORMED DNA, <http://informeddna.com/index.php/23andme.html> (last visited Apr. 11, 2013).

<sup>255</sup> See Jonathan Hsu, *Genetic Testing: Balancing Preventative Medicine with Privacy and Nondiscrimination*, 6 ISJLP 557, 573 (2011).

<sup>256</sup> *Terms of Service*, *supra* note 166; see also Amy Harmon, *Insurance Fears Lead Many To Shun DNA Tests*, N.Y. TIMES, Feb. 24, 2008, at A1, available at <http://www.nytimes.com/2008/02/24/health/24dna.html?pagewanted=all> (describing the efforts of many patients to undergo DNA testing without a doctor's guidance, and to conceal their results, in order to avoid insurance problems before GINA was enacted).

<sup>257</sup> DEP'T OF HEALTH & HUMAN SERVS., THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008: INFORMATION FOR RESEARCHERS AND HEALTH CARE PROFESSIONALS 2 (Apr. 6, 2009), <http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf>.

<sup>258</sup> *Genetic Discrimination*, NAT'L HUM. GENOME RESEARCH INST., <http://www.genome.gov/10002077> (last modified Jan. 15, 2013).



ers on the basis of a genetic disease for which a customer is already exhibiting symptoms.<sup>259</sup> With results in hand, it may be asking too much of potential insurers to avoid inventing a legally plausible basis for increased premiums that masks a genetically motivated one.<sup>260</sup>

*H. Federal Trade Commission Enforcement Actions Could Enhance Consumer Understanding and Remove Disreputable Companies from the Marketplace*

FTC's mandate includes preventing false advertising claims by genetic testing companies.<sup>261</sup> Because claims about health and safety are considered material,<sup>262</sup> any misleading statements or omissions with respect to health benefits or risks would be subject to FTC enforcement. Accordingly, FTC is well situated to ensure that DTC advertising neither overstates a test's utility nor omits necessary disclosures.<sup>263</sup> Two benefits would arise from FTC's decision to utilize this authority. First, the most reputable DTC companies would have an incentive to ensure that their advertising does not overstate product benefits. While such an abstract requirement might not seem useful, in the arena of DTC it holds great potential. Informed consent documents in DTC testing are extensive, with substantial risk enumeration.<sup>264</sup> Accordingly, it is the generalized advertising headlines on DTC homepages that possess the most potential to mislead. For example, one of 23andMe's leading competitors — until its December 2012 departure from the market<sup>265</sup> — was deCODEme. For years, the company's homepage tagline read “deCODE your health: Calculate genetic risk — Empower prevention: your genes are a road-map to

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259. *Id.*

260. See B. McClain, *Genetic Information Nondiscrimination Act (GINA): Will It Protect You?*, CENTER FOR PUB. AWARENESS IN BIOETHICS (CPAB) (May 22, 2008), [http://cpab.info/Documents/Gina\\_bam\\_5-22-08.htm](http://cpab.info/Documents/Gina_bam_5-22-08.htm) (“[I]f a health insurance company inadvertently or secretly finds that you have a genetic predisposition for a disease, they could deny health insurance coverage based on your, lets [sic] say, pre-existing high cholesterol condition while feigning any implications or knowledge to your genetic test results. Your battle in court would prove very difficult to win in this case.”). An archived version of this website is available at [http://web.archive.org/web/20090807063940/http://cpab.info/Documents/Gina\\_bam\\_5-22-08.htm](http://web.archive.org/web/20090807063940/http://cpab.info/Documents/Gina_bam_5-22-08.htm).

261. See discussion *supra* Part III.C; see also Palmer, *supra* note 79, at 522.

262. FTC considers “claims or omissions material if they significantly involve health, safety, or other areas with which the reasonable consumer would be concerned.” Letter from James C. Miller III, Chairman, FTC, to the Honorable John D. Dingell, Chairman, Comm. on Energy and Commerce, U.S. House of Representatives (Oct. 14, 1983), available at <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>; see also Drabiak-Syed, *supra* note 107, at 77.

263. Palmer, *supra* note 79, at 521–22.

264. See discussion *supra* Part IV.B.

265. Ray, *Decode Purchase*, *supra* note 37 (explaining that Amgen's purchase of deCODEme will remove deCODEme from the DTC market).

better health.”<sup>266</sup> A classic example of fanciful wording, the road map image misleadingly implies a concrete series of steps that can be taken to improve health. Ironically, deCODE’s CEO, Kári Stefánsson, agreed that the advertisement was misleading.<sup>267</sup> When asked about the statement in an interview, Stefánsson responded with the following: “I think that is both cheesy and somewhat incorrect . . . . I think it’s safe to say we’ll probably be removing that statement and putting up something that at least sounds better.”<sup>268</sup> As late as August 2012, the tagline was still emblazoned on deCODEme’s homepage,<sup>269</sup> representing a perfect example of how small-level FTC enforcement actions could improve conditions for informed consent among reputable providers.

The second potential benefit of FTC enforcement would be an exercise in housekeeping. While companies like 23andMe provide legitimate services, there are many questionable products on the market. Indeed, the 2013 study that commended 23andMe, Navigenics, and deCODEme for their disclosures also demonstrated that compliance with “transparency standards” was generally slim throughout the rest of the industry.<sup>270</sup> Eyebrow-raising claims by other DTC service providers might subside when confronted with regulatory pressure. Of particular concern are providers that combine genetic testing with recommendations to purchase expensive supplements.<sup>271</sup> For instance, Holistic Health sells “DNA Methylation Pathway with Methylation Pathway Analysis” for \$495.<sup>272</sup> Test results are supposed to “help you to understand what supplements . . . you can use to bypass weaknesses in a particular nutritional pathway in your body” so that you can “support the Methylation Cycle” and “help your body to detoxify

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266. Because deCODEme is no longer a DTC provider, the company’s website no longer displays the relevant slogan. DECODEME, <http://www.decodeme.com> (last visited Feb. 7, 2012). An archived version of the site captured on August 23, 2012 reveals the slogan was still used at that time. An archived version of the site is available at <http://web.archive.org/web/20120823014221/http://www.decodeme.com>.

267. Dan Vorhaus, *Closer Scrutiny Ahead for DTC Genetic Testing Claims*, GENOMICS L. REP. (Mar. 24, 2011), <http://www.genomicslawreport.com/index.php/2011/03/24/closer-scrutiny-ahead-for-dtc-claims>.

268. *Id.*

269. See deCODEme, *supra* note 266.

270. See Lewis et al., *supra* note 134, at 297–98.

271. See Robert Langreth & John Lauerman, *Autism Cures Promised by DNA Testers Belied by Regulators*, BLOOMBERG (Dec. 20, 2012), <http://www.bloomberg.com/news/2012-12-21/autism-cures-promised-by-dna-testers-belied-by-regulators.html> (decrying companies who offer “genetic tests costing hundreds of dollars to worried parents and patients, and then sell advice on supplements and diet based on results purporting to spot disease-causing deficiencies”).

272. *Nutrigenomic Testing*, HOLISTIC HEAL INT’L, <http://www.holisticheal.com/health-tests/nutrigenomic-testing>.

properly.”<sup>273</sup> Following one page of test results, customers receive a three-page-long list of potential supplements,<sup>274</sup> most of which can be purchased on Holistic Health’s website for somewhere between \$4.00 and \$144.95.<sup>275</sup>

Most disconcerting, however, are the implications that the test can be used to treat autism.<sup>276</sup> Dr. Amy Yasko, who is the architect of the Holistic Health approach,<sup>277</sup> “has been touting ‘nutrigenomics’ tests for autism for years”<sup>278</sup> and claims that the “[t]he thirty SNPs revealed by our Test are all located on . . . the Methylation Cycle” and that “long-term support for the Methylation Cycle can help to address . . . many of the multiple factors that contribute to autism.”<sup>279</sup> Not surprisingly, a spokesperson for one autism organization does not “see any evidence that it is useful.”<sup>280</sup> FTC enforcement against claims like these could protect consumers from exploitation.

## V. CONCLUSION

DTC genetics epitomizes the public’s increasing interest in all things DNA. Quashing this nascent industry via burdensome physician participation requirements would be both unwarranted and misguided. DTC leaders provide accurate genotyping, disclose the risks

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273. Dr. Amy Yasko, *Comprehensive Methylation Panel with Methylation Pathway Analysis*, NEUROLOGICAL RESEARCH INST. (2009) 2–3, <http://www.holisticheal.com/media/downloads/john-doe-mpa-sample.pdf>.

274. *Id.* at 10–14.

275. See *ACAT / BHMT — Fatty Acid Digestion / Energy Conversion 180 Capsules*, HOLISTIC HEALTH INT’L, <http://www.holisticheal.com/acet-bhmt.html> (last visited Apr. 11, 2013) (selling “ACAT / BHMT — Fatty Acid Digestion / Energy Conversion 180 Capsules” for \$144.95); *Vitamin A — Vitamin D 100 Softgels*, HOLISTIC HEALTH INT’L, <http://www.holisticheal.com/vitamin-avitamin-d.html> (selling “Vitamin A — Vitamin D 100 Softgels” for \$4.25) (last visited Apr. 11, 2013). Test results are “color coded to correspond with the level of support needed as listed in the suggested supplementation section.” Yasko, *supra* note 273, at 9.

276. See *Nutrigenomic Testing*, HOLISTIC HEALTH INT’L, <http://www.holisticheal.com/health-tests/nutrigenomic-testing> (last visited Mar. 9, 2013) (explaining that test results come with a CD containing several documents, including the “Autism: Pathways to Recovery” book and workbook).

277. See *Our Unique Approach*, DR. AMY, <http://www.dramyyasko.com/our-unique-approach> (last visited Mar. 9, 2013). Yasko’s website claims that “[o]ur comprehensive program typically starts with a special Nutrigenomic Test, created by Dr. Amy Yasko.” *Id.* The words “nutrigenomic test” provide a hyperlink to purchase Holistic Health’s “DNA Methylation Pathway with Methylation Pathway Analysis.” *Id.* Several other links on Dr. Yasko’s site, including one titled “Take the Test” also bring users to Holistic Health, referred to as an “allied site.” *Id.*

278. Langreth & Lauerman, *supra* note 271.

279. *Why this Test?*, DR. AMY, <http://www.dramyyasko.com/our-unique-approach/why-this-test> (last visited Apr. 11, 2012).

280. Langreth & Lauerman, *supra* note 271. In fact, the director of FDA’s Center for Drug Evaluation and Research suggests that “the use of DNA testing to recommend alternative therapies” could “skim[] on the edge of health fraud.” See *id.*

of testing, and present results in ways that consumers appear to understand. Furthermore, concerns over drastic medical responses or psychological harm appear to be exaggerated. Because many primary care doctors lack a sufficient understanding of genetics to meaningfully assist consumers, regulators should not exacerbate privacy concerns by requiring physician involvement and should instead emphasize strict enforcement of advertising standards. Undoubtedly, continued research will help DTC services improve their marker selection and results reporting, and genetics will undoubtedly find its way into the medical school curriculum. In the meantime, however, there is no need to “stick[] healthcare in a time capsule”<sup>281</sup> as long as we choose consumer autonomy over “genetic paternalism.”<sup>282</sup>

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281. Palmer, *supra* note 79 at 490 (quoting Goetz, *Is Your DNA Dangerous*, *supra* note 250).

282. VerBruggen, *supra* note 192.