

**THE FUTURE OF DIRECT-TO-CONSUMER GENETIC TESTING:  
REGULATION AND INNOVATION**

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*Direct-to-consumer (“DTC”) genetic testing companies face regulation from numerous parties. The Food and Drug Administration has taken the lead role in the regulation of this industry. The Federal Trade Commission must make sure that consumers are not misled by unscrupulous marketing and false advertising. The Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments should ensure that genetic tests are analytically and clinically valid. State laws and federal statutes like the Genetic Information Discrimination Act address consumer privacy concerns. The recent *Molecular Pathology v. Myriad Genetics, Inc.* Supreme Court decision will shape the direction of DTC genetic testing patents. Case law is also influencing DTC genetic consumer protection. These various regulatory mechanisms must strike a balance between protecting DTC genetic test consumers without stifling important innovations in this industry.*

**I. INTRODUCTION**

Imagine the possibility of medical treatments tailored to your DNA. Although personalized medicine might be a long way off,<sup>1</sup> a simple medical test taken in the privacy of your home could tell

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<sup>1</sup> See Press Release, Am. Chem. Soc’y, Personalized Medicine Has Finally Arrived – or Has It? (Feb. 26, 2014) available at <http://www.acs.org/content/acs/en/pressroom/presspacs/2014/acs-presspac-february-26-2014/personalized-medicine-has-finally-arrived-or-has-it.html>.

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you the likelihood of contracting a specific disease.<sup>2</sup> Genetic testing can identify changes in your gene expression<sup>3</sup> to determine your risk of developing a genetic disorder, or serve to confirm the existence of a genetic condition.<sup>4</sup> Some companies market genetic tests directly to consumers.<sup>5</sup> These companies have provided consumers with access to genetic information without involving doctors or insurance companies in the process.<sup>6</sup>

Direct-to-Consumers (“DTC”) genetic tests have generated a great deal of controversy.<sup>7</sup> Since the Human Genome Project concluded in April 2003,<sup>8</sup> DNA sequencing has become exponentially faster and much more affordable.<sup>9</sup> In the late 2000’s, several companies emerged to take advantage of the burgeoning consumer demand for genetic information via the Internet.<sup>10</sup> Rather

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<sup>2</sup> See *Direct to Consumer Genetic Tests*, U.S. FTC (Jan. 2014), <http://www.consumer.ftc.gov/articles/0166-direct-consumer-genetic-tests>.

<sup>3</sup> The epigenome consists of chemical compounds from things like food, medicine, or pesticides that mark and change the genome over time. Epigenetics might help explain differences between identical twins. Although twins might have almost the exact same genome and DNA, one identical twin could develop arthritis, for example, due to environmental changes over the course of his or her lifetime. *Epigenomics*, NAT’L HUMAN GENOME RESEARCH INST. (May 7, 2012), <http://www.genome.gov/27532724>.

<sup>4</sup> *What is Genetic Testing?*, GENETICS HOME REFERENCE (Nov. 4, 2014), <http://ghr.nlm.nih.gov/handbook/testing/geneticstesting>.

<sup>5</sup> See Pascal Su, *Direct-to-Consumer Genetic Testing: A Comprehensive View*, 86 YALE J. BIOL. MED. 359, 359 (2013).

<sup>6</sup> *What is Direct-to-Consumer Genetic Testing?*, GENETICS HOME REFERENCE (Nov. 4, 2014), <http://ghr.nlm.nih.gov/handbook/testing/directtoconsumer>.

<sup>7</sup> James P. Evans & Robert C. Green, Commentary, *Direct to Consumer Genetic Testing: Avoiding a Culture War*, 11 GENETICS IN MED. 568, 568 (2009).

<sup>8</sup> *All about the Human Genome Project (HGP)*, NAT’L HUMAN GENOME RESEARCH INST., <http://www.genome.gov/10001772> (last updated Mar. 18, 2014).

<sup>9</sup> The Human Genome Project cost \$1 billion and 8 years to complete. As of 2013, Eric D. Green, the director of the National Human Genome Research Institute, estimated it would take several days and as little as \$4000–\$5000 to sequence an entire human genome. Gina Kolata, *Human Genome, Then and Now*, N.Y. TIMES (Apr. 15, 2013), [http://www.nytimes.com/2013/04/16/science/the-human-genome-project-then-and-now.html?\\_r=0](http://www.nytimes.com/2013/04/16/science/the-human-genome-project-then-and-now.html?_r=0).

<sup>10</sup> In 2011, the Genetics and Public Policy Center released an updated list of twenty Direct-to-Consumer Genetic Testing companies, including: 23andMe, Advanced Healthcare, Inc., deCODE Genetics, Holistic Health, and Map My

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than sequencing the entire human genome as the Human Genome Project did, these companies examined single nucleotide polymorphisms<sup>11</sup> (“SNPs”)—DNA sequences in the genome that usually differ between individuals.<sup>12</sup> SNP tests analyze a person’s ancestry and health, as well as a number of other traits.<sup>13</sup> Generally, DTC genetic testing companies advertise and operate online.<sup>14</sup> Although the specifics between DTC genetic testing companies may vary, generally a consumer purchases the product online, and then receives a test kit in the mail.<sup>15</sup> Next, the consumer performs a cheek swab or obtains a saliva sample.<sup>16</sup> The consumer then sends the test kit back to the genetic testing company where it is analyzed by a lab.<sup>17</sup> The consumer receives the results either online or by mail.<sup>18</sup>

In 2010, about 30 companies offered more than 400 different DTC genetic tests.<sup>19</sup> However, due to increased state and federal

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Gene, among others. See GENETICS & PUB. POLICY CTR., GPPC RELEASES UPDATED LIST OF DTC GENETIC TESTING COMPANIES (2012), *available at* <http://www.dnapolicy.org/resources/DTCTableAug2011Alphabydisease.pdf>.

<sup>11</sup> SNPs occur throughout a person’s DNA, sometimes acting as genetic markers. Although most SNPs do not have any effect on human health and development, researchers have found that some SNPs can predict drug responses and track inheritance of disease genes. There are about 10 million SNPs in the human genome, occurring once every 300 nucleotides. *What are Single Nucleotide Polymorphisms (SNPs)?*, GENETICS HOME REFERENCE (Nov. 4, 2014), <http://ghr.nlm.nih.gov/handbook/genomicresearch/snp>.

<sup>12</sup> *Direct-to-Consumer Genetic Testing*, PERS. GENETICS EDUC. PROJECT, <http://www.pged.org/direct-to-consumer-genetic-testing> (last visited Oct. 20, 2014).

<sup>13</sup> DTC genetic testing companies report traits ranging from “a person’s ability to taste bitter flavors or the photic sneeze reflex (uncontrollable sneezing when exposed to bright light) to risk for developing heart disease or diabetes.” *Id.*

<sup>14</sup> Kayte Spector-Bagdady & Elizabeth Pike, *Consuming Genomics: Regulating Direct-to-Consumer Genetic and Genomic Information*, 92 NEB. L. REV. 677, 689 (2014).

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> Arthur L. Beaudet & Gail Javitt, *Which Way For Genetic-Test Regulation?*, 466 NATURE 816, 817 (2010).

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regulation, many DTC genetic testing companies have discontinued selling their health-related products.<sup>20</sup>

On November 22, 2013, 23andMe Inc.—the last major DTC genetic testing company offering health-related genetic test services—received a formal warning letter from the Food and Drug Administration (“FDA”) forcing the company to cease marketing its health-related Personal Genome Service.<sup>21</sup> The FDA warned that 23andMe was selling its Personal Genome Service “without marketing clearance or approval in violation of the Federal Food Drug and Cosmetic Act.”<sup>22</sup> The FDA seemed especially frustrated that 23andMe stopped communicating with the agency in May 2013 while initiating new marketing strategies including televised commercials for the Personal Genome Service.<sup>23</sup>

Despite the agency’s harsh rebuke, as of June 20, 2014, 23andMe is again in talks with the FDA to gain preliminary approval<sup>24</sup> for its test for Bloom syndrome, a rare genetic disorder

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<sup>20</sup> Spector-Bagdady & Pike, *supra* note 14, at 680. The FDA started to enforce against DTC genetic testing companies in May 2010, after Pathway Genomics announced plans to start selling its home use saliva kit at more than 6000 Walgreens Stores, making the product the company had been selling online for years much more accessible to consumers. The FDA was concerned about the health-related claims the company was making, and announced its concern that the company was marketing an unapproved medical device. The FDA sent out five additional letters to genetic testing companies (23andMe, Knome, Navigenics, deCODE Genetics and Illumina) in June 2010, and fourteen more in July 2010 to companies that appeared to be marketing FDA defined medical devices without clearance. *Id.* at 706–08.

<sup>21</sup> Letter from Alberto Gutierrez, Dir. Office of In Vitro Diagnostics and Radiological Health, Ctr. For Devices and Radiological Health, Food and Drug Admin., U.S. Dep’t. of Health and Human Servs., to Anne Wojcicki, C.E.O., 23 and Me, Inc. (Nov. 22, 2013), <http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm376296.htm> [hereinafter Warning Letter to Wojcicki].

<sup>22</sup> *Id.*

<sup>23</sup> *See id.*

<sup>24</sup> According to the FDA’s website, a 510(k) application is required for premarket approval for a new medical device to demonstrate that the device is at least as safe and effective as a legally marketed device. *510(k) Clearances*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/> (last updated June 6, 2014).

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involving a single mutation to one gene.<sup>25</sup> If 23andMe's 510(k) application for Bloom syndrome is successful, the submission will help establish parameters for future genetic test submissions, and will serve to assure DTC genetic testing consumers that the tests are valid.<sup>26</sup>

This Recent Development argues that the Federal Trade Commission ("FTC"), FDA, Centers for Medicare and Medicaid Services ("CMS"), and other federal regulatory agencies should enforce regulations against DTC genetic testing companies making dubious scientific claims, but exercise enforcement discretion against companies that demonstrate robust scientific findings in order to make these DTC genetic tests safe for consumers without stifling important innovations. Part II examines the current regulatory status of the DTC genetic testing industry and analyzes the role of the various stakeholders in the ongoing efforts to regulate this industry. Part III considers the implications of the latest developments in the DTC genetic testing industry in a case study of one DTC genetic testing company, Interleukin Genetics. This Recent Development argues for more coordinated regulation of the DTC genetic testing industry because concerns of consumer autonomy and industry innovation outweigh the potential harm of most of these tests.

### **II. THE CURRENT REGULATORY STATUS: INSTITUTIONAL PERSPECTIVES**

Various institutions regulate the DTC genetic testing companies, and several federal agencies will likely play oversight roles. These agencies include the FDA, CMS under the Clinical Laboratory Improvement Amendments ("CLIA"), the FTC, and the Equal Opportunity Employment Commission ("EEOC") under the Genetic Information Nondiscrimination Act ("GINA"). States also play an important part in the regulation of this industry.

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<sup>25</sup> *Update on the Regulatory Review Process with the FDA*, 23ANDME BLOG (June 20, 2014), <http://blog.23andme.com/news/update-on-the-regulatory-review-process-with-the-fda/>.

<sup>26</sup> *See id.*

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Finally, this part considers important case law affecting the DTC industry.

A. *Food and Drug Administration: Regulation of the DTC Industry*

The FDA leads the regulation of the DTC genetic testing industry.<sup>27</sup> The FDA derives its authority to regulate the sale and distribution of medical devices from the Food Drug and Cosmetic Act.<sup>28</sup> Genetic tests, as a category of in vitro diagnostic (“IVD”) devices,<sup>29</sup> generally fall under the definition of medical device<sup>30</sup> and are therefore subject to regulation by the FDA.<sup>31</sup> IVD refers to

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<sup>27</sup> See *Direct to Consumer Genetic Testing and the Consequences to the Public: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 111th Cong. (2010) (statement of Jeffrey Shuren, M.D., Dir. For Devices and Radiological Health, Food & Drug Admin., Dep’t. of Health and Human Serv’s.), available at <http://www.fda.gov/NewsEvents/Testimony/ucm219925.htm> [hereinafter Shuren—*Statement*].

<sup>28</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301–399f (2006).

<sup>29</sup> In Vitro Diagnostic Products for Human Use, 21 C.F.R. § 809.3(a) (2013) (“[I]n vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to section 351 of the Public Health Service Act.”).

<sup>30</sup> Medical device is defined as:

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part, or accessory that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or is intended to affect the structure or function of the body of man or other animals.

21 U.S.C § 321(h) (2013).

<sup>31</sup> AMANDA K. SARATA & JUDITH A. JOHNSON, CONG. RESEARCH SERV., R43438, REGULATION OF CLINICAL TESTS: IN VITRO DIAGNOSTIC (IVD) DEVICES, LAB. DEV. TESTS (LDTs), AND GENETIC TESTS 1 (2014). *But see* Michael Eisen, *FDA vs. 23andMe: How Do We Want Genetic Testing to be Regulated?*, IT IS NOT JUNK (Nov. 26, 2013), <http://www.michaeleisen.org/blog/?p=1480> (arguing that the FDA’s definition of a medical device is too broad to be useful in the case of DTC genetic testing as genetic tests “are closer to a family history than an accurate diagnostic”).

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a method of performing a diagnostic test outside of the living body in an artificial environment, usually in a laboratory.<sup>32</sup> IVDs differ from other medical devices because a false positive or false negative result could potentially harm a patient.<sup>33</sup>

Between 2007<sup>34</sup> and 2010, the FDA did not take a substantial role in regulating DTC genetic testing companies.<sup>35</sup> However, by 2010, the FDA stated that it had reconsidered its position regarding the non-enforcement of these tests because the tests put the patients at risk for incorrect diagnosis and treatment.<sup>36</sup> On July 22, 2010, Jeffrey Shuren, the Director for Devices and Radiological Health for the FDA, testified before the U.S. House of Representatives, explaining that the DTC companies had recently begun “aggressively market[ing]” to consumers.<sup>37</sup> The FDA was particularly concerned that one company, Pathway Genomics, was planning to sell its DTC genetic testing product on 6,000 Walgreen’s store shelves, making their product much more accessible to the average consumer.<sup>38</sup> Additionally, Shuren pointed out that 23andMe’s product was accessible to consumers on Amazon.com.<sup>39</sup> Shuren commented that although many genetic tests were approved after 2003, none of the DTC genetic tests currently on the market had undergone FDA premarket approval to “ensure that the test results being provided to patients are accurate, reliable, and clinically meaningful.”<sup>40</sup> FDA decided to strictly regulate DTC genetic

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<sup>32</sup> In vitro diagnostic comes from the Latin “within the glass.” IVDs vary widely—from pregnancy tests to cervical cancer screening tests. IVDs contrast with other medical technologies because these tests never directly interact with the human body, but rather derive their use value from the health information they can provide to a patient. *About In Vitro Diagnostics*, EUROPEAN DIAGNOSTIC MFRS. ASS’N, <http://www.edma-ivd.be/index.php?page=About-In-Vitro-Diagnostics> (last visited November 1, 2014).

<sup>33</sup> See SARATA & JOHNSON, *supra* note 31, at 1.

<sup>34</sup> The first DTC companies 23andMe and deCODEme launched in 2007. Spector-Bagdady & Pike, *supra* note 14, at 688.

<sup>35</sup> See SARATA & JOHNSON, *supra* note 31, at 1.

<sup>36</sup> Spector-Bagdady & Pike, *supra* note 14, at 703–04.

<sup>37</sup> Shuren—*Statement*, *supra* note 27.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

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testing companies because these companies were assessing high-risk diseases, and many of these test manufacturers were corporations rather than hospitals or public laboratories that the FDA originally wanted to exempt from regulation.<sup>41</sup>

Laboratory Developed Tests<sup>42</sup> (“LDTs”) are a specific type of IVD that are designed for clinical use and are manufactured in a single laboratory.<sup>43</sup> Some DTC genetic testing companies conducting their own analysis and using their own genetic data offer LDTs.<sup>44</sup> Traditionally, the FDA exercised discretion not to enforce against LDTs because these types of tests were relatively simple.<sup>45</sup> However, in recent years, the FDA has noted that these types of tests have become increasingly complex and “almost indistinguishable” from other IVDs.<sup>46</sup> On July 31, 2014, in a major shift, the FDA issued new regulatory draft guidance for LDTs “based on risk to patients rather than whether they were made by a conventional manufacturer or a single laboratory.”<sup>47</sup> The regulatory guidance imposes the strictest guidelines for the highest risk LDTs, and recommends enforcement discretion for lower risk LDTs and LDTs for rare diseases, among others.<sup>48</sup> The FDA is currently seeking feedback to determine what constitutes a rare disease, and whether the enforcement discretion should be limited to tests that are designed, manufactured, and used within a single laboratory.<sup>49</sup>

The FDA’s planned discretion not to enforce for rare diseases might have influenced 23andMe’s decision to submit their 510(k)

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<sup>41</sup> Spector-Bagdady & Pike, *supra* note 14, at 702.

<sup>42</sup> *Laboratory Developed Tests*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm407296.htm> (last updated Oct. 3, 2014).

<sup>43</sup> “Single laboratory” refers to a facility with a single CLIA certificate as described in 42 C.F.R. § 493.43(a)–(b).

<sup>44</sup> Spector-Bagdady & Pike, *supra* note 14, at 703.

<sup>45</sup> U.S. FOOD AND DRUG ADMIN., *supra* note 42.

<sup>46</sup> Alexander Gaffney, *In Major Shift, the FDA to Regulate Lab-Developed Tests as Normal Devices*, REGULATORY AFFAIRS PROF’LS SOC’Y (Aug. 1 2014), <http://www.raps.org/Regulatory-Focus/News/2014/08/01/19934/In-Major-Shift-FDA-to-Regulate-Lab-Developed-Tests-as-Normal-Devices/>.

<sup>47</sup> U.S. FOOD AND DRUG ADMIN., *supra* note 42.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

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application for Bloom syndrome.<sup>50</sup> Although some have heralded this submission as the first step in getting hundreds of its tests approved,<sup>51</sup> many of 23andMe's tests are for much more complex diseases, which might not necessarily fit the FDA's definition of a "rare disease" subject to planned LDT enforcement discretion.<sup>52</sup> Anne Wojcicki, CEO of 23andMe, has commented that their tests are difficult to regulate on a case-by-case basis because the company does not just offer "a single type of test."<sup>53</sup>

While the new regulatory guidance will be phased in over the next decade or so, politicians, doctors' groups, and industry leaders have already reacted negatively to these proposed regulations.<sup>54</sup> For example, the American Medical Association, a powerful lobbying group for doctors,<sup>55</sup> and the Association for Molecular Pathology, an association representing molecular testing companies,<sup>56</sup> have expressed concern about the new framework.

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<sup>50</sup> "Bloom syndrome is a very rare disorder in most populations, and its overall frequency is unknown. The disorder is more common in people of Central and Eastern European (Ashkenazi) Jewish background, among whom about 1 in 50,000 are affected. Approximately one-third of people with Bloom syndrome are of Ashkenazi Jewish descent." *Bloom Syndrome*, GENETIC HOME REFERENCE, <http://ghr.nlm.nih.gov/condition/bloom-syndrome> (last updated Nov. 2010).

<sup>51</sup> Robert Hof, *Seven Months After FDA Slapdown, 23andMe Returns with New Health Report Submission*, FORBES (June 20, 2014, 12:04 PM), <http://www.forbes.com/sites/roberthof/2014/06/20/seven-months-after-fda-slapdown-23andme-returns-with-new-health-report-submission/>.

<sup>52</sup> For example, nearly 5 million people live with Alzheimer's disease. *Alzheimer's Facts and Figures*, ALZHEIMER'S ASS'N, [http://www.alz.org/alzheimers\\_disease\\_facts\\_and\\_figures.asp](http://www.alz.org/alzheimers_disease_facts_and_figures.asp) (last visited Oct. 21, 2014).

<sup>53</sup> Robert Hof, *'We Are Going For Change': A Conversation with 23andMe CEO Anne Wojcicki*, FORBES (Aug. 15, 2014, 10:50 AM), <http://www.forbes.com/sites/roberthof/2014/08/15/we-are-going-for-change-a-conversation-with-23andme-ceo-anne-wojcicki/>.

<sup>54</sup> Gaffney, *supra* note 46.

<sup>55</sup> Barbara L. McAneny, MD, Chair of the Board, Am. Med. Assoc., *AMA Statement on FDA Proposal Regarding Diagnostic Testing*, AM. MED. ASS'N (Aug. 1, 2014), <http://www.ama-assn.org/ama/pub/news/news/2014/2014-08-01-fda-proposal-diagnostic-testing.page>.

<sup>56</sup> *The Association for Molecular Pathology Voices Concern with U.S. FDA Anticipated Details of Laboratory Developed Test Draft Guidance*, ASS'N FOR MOLECULAR PATHOLOGY, <http://www.businesswire.com/news/home/20140731006689/>

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However, AdvaMed, the medical device's largest trade association, expressed support for the new regulation, indicating that the guidance would create parity between currently regulated devices and unregulated LDTs.<sup>57</sup> The new guidance could ultimately affect up to 11,000 of these DTC genetic tests in up to 2,000 different laboratories.<sup>58</sup>

B. *Centers for Medicare and Medicaid Services and the Clinical Laboratory Improvement Act: More Stringent Requirements Necessary*

CMS is another important player in the regulation of the DTC genetic testing industry. CMS regulates the DTC genetic testing industry under the Clinical Laboratory Improvement Amendments Act of 1988 ("CLIA")<sup>59</sup> Under CLIA, CMS sets standards for laboratories that provide information about health-related conditions.<sup>60</sup> However, there are no special requirements for laboratories performing genetic tests under CLIA.<sup>61</sup>

Clinical genetic tests are typically evaluated using the ACCE framework, which includes testing for "analytical validity, clinical validity, clinical utility, and ethical, social and legal implications."<sup>62</sup> Although CLIA assures that genetic tests are

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en/Association-Molecular-Pathology-Voices-Concern-U.S.-FDA (last updated July 31, 2014 8:37 PM).

<sup>57</sup> *AdvaMedDx Commends FDA's Issuance of LDT Draft Framework*, ADV. MED. TECH. ASS'N (July 31, 2014), <http://advamed.org/news/117/advameddx-commends-fdas-issuance-of-ldt-draft-framework>.

<sup>58</sup> Matthew Harper, *FDA To Regulate Thousands Of Cancer, Genetic, And Other Diagnostics*, FORBES, <http://www.forbes.com/sites/matthewherper/2014/07/31/fda-to-regulate-thousands-of-cancer-genetic-and-other-diagnostics/> (last updated July 31, 2014, 1:03 PM).

<sup>59</sup> 42 C.F.R. § 493.1253 (2003).

<sup>60</sup> Kathryn Schleckser, *Physician Participation in Direct-to-Consumer Genetic Testing: Pragmatism or Paternalism?*, 26 HARV. J.L. & TECH. 695, 707 (2013).

<sup>61</sup> See *Genetic Testing: Understanding Your Genes and What They Mean for Your Health*, GENETIC ALLIANCE, <http://www.geneticalliance.org/advocacy/policyissues/genetictesting> (last visited Oct. 20, 2014).

<sup>62</sup> The ACCE takes its name from the four main criteria for evaluating a genetic test. *ACCE Model Process for Evaluating Genetic Tests*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/genomics/gtesting/ACCE/> (last updated Jan. 3, 2010).

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analytically valid (“how well a test recognizes a genetic variant”), CLIA does not ensure clinical validity (“the association of the variant with a disease or medical condition”) or clinical utility (“whether the information of the disease or medical condition can be of clinical use to a consumer”) of the genetic medical information.<sup>63</sup> Therefore, it is possible that a test could satisfy the highest analytical standard, but still be inaccurate if there is not a strong relationship between the genetic variant and the clinical manifestation of disease.<sup>64</sup>

In addition, while it is widely recognized that genetic testing is very complex, there are no proficiency standards for a genetic testing subspecialty.<sup>65</sup> Because specific proficiency testing for these genetic tests is not mandated under CLIA, laboratories determine their own competencies.<sup>66</sup>

Even if the FDA restricts access to DTC genetic tests, CMS needs to assure the quality of these tests.<sup>67</sup> The government must correct the systemic gaps in oversight that make consumers vulnerable to inaccurate results.<sup>68</sup> For example, the Government Accountability Office (“GAO”) has criticized CMS’s oversight of CLIA laboratories, finding in 2006 that “CMS failed to sanction labs with ‘serious, condition-level deficiencies on consecutive surveys.’”<sup>69</sup> CLIA theoretically requires laboratories to ensure the validity of all tests performed, but as previous GAO reports have

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<sup>63</sup> Spector-Bagdady & Pike, *supra* note 14, at 719.

<sup>64</sup> *Id.* at 721.

<sup>65</sup> *Id.*

<sup>66</sup> Gail H. Javitt & Kathy Hudson, *Federal Neglect: Regulation of Genetic Testing*, ISSUES IN SCI. & TECH. (Nov. 27, 2013), <http://issues.org/22-3/javitt/>.

<sup>67</sup> *See id.*

<sup>68</sup> *Id.*

<sup>69</sup> Jessica Elizabeth Palmer, *Genetic Gatekeepers: Regulating Direct-to-Consumer Genomic Services in an Era of Participatory Medicine*, 67 FOOD & DRUG L.J. 475, 503 (2012) (citing US GOV’T ACCOUNTABILITY OFFICE, GAO-06-416, CLINICAL LAB QUALITY: CMS AND SURVEY ORGANIZATION OVERSIGHT SHOULD BE STRENGTHENED, 8 (2006)) (“CMS’s oversight of clinical lab quality is inadequate to ensure that labs are meeting CLIA requirements.”).

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found,<sup>70</sup> CMS could do much more to “ensure that their test results are accurate, reliable, timely, and confidential and do not present the risk of harm to patients.”<sup>71</sup> CMS should do more to make sure that consumers are getting analytically valid and clinically valid test results.

C. *Federal Trade Commission and the Prevention of Misleading DTC Genetic Test Marketing*

The FTC has broad investigative and enforcement authority to protect consumers from unfair and deceptive trade practices under the Federal Trade Commission Act.<sup>72</sup> In 2014, the FTC started regulating DTC genetic testing companies for the first time, indicating that the agency plans to play a bigger role in protecting consumers of DTC genetic tests.<sup>73</sup> For example, the FTC filed charges against Genelink, Inc in January and L’Oréal USA Inc. in June for offering purported personalized genetics testing services.<sup>74</sup>

Genelink and its subsidiary foru<sup>TM</sup> made claims that its nutritional products could help compensate for “disadvantaged” genes.<sup>75</sup> The FTC charged that Genelink and foru<sup>TM</sup> engaged in unfair and deceptive trade practices, and made misleading advertisements in violation of sections 5(a) and 12 of the FTC Act.<sup>76</sup> The FTC wanted to prevent these companies from making

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<sup>70</sup> US GOV’T ACCOUNTABILITY OFFICE, GAO-06-416, CLINICAL LAB QUALITY: CMS AND SURVEY ORGANIZATION OVERSIGHT SHOULD BE STRENGTHENED, 8 (2006), available at <http://www.gao.gov/assets/260/250504.pdf>.

<sup>71</sup> 42 C.F.R. § 493.1253(b)(2)(vii) (2013).

<sup>72</sup> See 15 U.S.C. § 45(a)(1) (2013).

<sup>73</sup> Jennifer K. Wagner, *FTC Takes Action to Protect Consumers from False Genetic Advertising Claims*, GENOMICS LAW REPORT, <http://www.genomicslawreport.com/index.php/2014/07/03/ftc-takes-action-to-protect-consumers-from-false-genetic-advertising-claims/#more-13323> (last updated July 3, 2014).

<sup>74</sup> *Id.*

<sup>75</sup> Complaint at 1, In re GeneLink, Inc. & Foru Int’l Corp., No. 112-3095 (F.T.C. Jan. 7, 2014).

<sup>76</sup> *Id.* On May 8, 2014, the Commission voted 3-1 to approve the final orders against the companies. Wagner, *supra* note 73.

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health-related genetic claims “unless the claim is true and supported by at least two adequate and well-controlled studies.”<sup>77</sup>

The Council for Responsible Nutrition raised concerns in public comment that requiring two studies would become a “de-facto standard,” and that this type of testing by respondents would create an “undue burden.”<sup>78</sup> Furthermore, the Natural Products Association asserted, “If the FTC intends to depart from its traditional competent and reliable scientific evidence standard, then new formal guidance is necessary.”<sup>79</sup> The FTC rejected the concerns in each of these public comments, clarifying that “[t]he optimal amount and type of evidence to substantiate a future claim will vary from case to case.”<sup>80</sup>

In the L’Oréal decision and order, the Commission did not mandate that the company have two random clinical trials to substantiate its claims for its Lancôme Génifique and L’Oréal Paris Youth Code skincare products.<sup>81</sup> Rather, the FTC indicated that L’Oréal must have “competent and reliable scientific evidence”<sup>82</sup>

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<sup>77</sup> Order at 4, In re GeneLink, Inc. & Foru Int’l Corp., No. 112-3095 (F.T.C. May 8, 2014). Well controlled studies are defined in the consent order as:

[A] human clinical study that: is randomized and adequately controlled; utilizes valid end points generally recognized by experts in the relevant disease field; yields statistically significant between-group results; and is conducted by persons qualified by training and experience to conduct such a study. Such study shall be double-blind and placebo-controlled . . . .

*Id.* at 2.

<sup>78</sup> Letter from Donald S. Clark, Sec’y, Fed. Trade Comm’n, to Rend Al-Mondhiry, Esq., Regulatory Counsel, Council For Responsible Nutrition (May 8, 2014) *available at* [http://www.ftc.gov/system/files/documents/cases/140512genelinkcouncilletter\\_0.pdf](http://www.ftc.gov/system/files/documents/cases/140512genelinkcouncilletter_0.pdf).

<sup>79</sup> Letter from Donald S. Clark, Re: *Genelink, Inc., & Foru™ Int’l Corp FTC File No. 112-3095 and Docket Nos. C-4456 and C-4457* (May 8, 2014), *available at* [http://www.ftc.gov/system/files/documents/cases/140512genelinknaturalletter\\_0.pdf](http://www.ftc.gov/system/files/documents/cases/140512genelinknaturalletter_0.pdf).

<sup>80</sup> Joshua D. Wright, *Statement of Comm’r Joshua D. Wright*, FED. TRADE COMM’N (Jan. 7, 2014), *available at* [http://www.ftc.gov/system/files/documents/public\\_statements/567801/140107genelinkstatement.pdf](http://www.ftc.gov/system/files/documents/public_statements/567801/140107genelinkstatement.pdf).

<sup>81</sup> Order at 1, In re L’Oréal USA, Inc., No. 122-3016 (F.T.C. Sept. 24, 2014).

<sup>82</sup> *Id.* at 2. “Competent and reliable scientific evidence shall mean evidence, consisting of tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.” *Id.*

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before claiming that any of its products can affect gene activity or growth.<sup>83</sup>

The FTC clarified three main takeaways from the L'Oréal decision.<sup>84</sup> First, when advertisers claim that “studies show,” or “doctors recommend,” advertisers must have at least the level of substantiation purported in the advertisement.<sup>85</sup> Second, the support for the product must be “fit to be tried.”<sup>86</sup> Third, “once companies make objective product representations, long standing substantiation principles apply.”<sup>87</sup> These principles apply to other DTC genetic testing companies claiming that their products affect genes.

#### D. Genetic Information Nondiscrimination Act

The Genetic Information Nondiscrimination Act (“GINA”)<sup>88</sup> prevents employers and health insurance companies from discriminating based on genetic information.<sup>89</sup> This act offers protection to consumers from the unauthorized use of their DTC genetic test results.<sup>90</sup>

In 2013, the Equal Opportunity Employment Commission (“EEOC”) settled its first lawsuit alleging violations of the Genetic Information Nondiscrimination Act.<sup>91</sup> The EEOC found that Fabricut, Inc. (“Fabricut”), one of the world’s largest distributors of decorative fabrics, violated GINA when it requested prohibited

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<sup>83</sup> *Id.* at 3.

<sup>84</sup> Lesley Fair, *FTC to L'Oréal: Scientific Claims Need Proof that's More than Just Skin Deep*, BUS. CTR. BLOG, <http://business.ftc.gov/blog/2014/06/ftc-loreal-scientific-claims-need-proof-thats-more-just-skin-deep> (last updated June 30, 2014).

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (2008).

<sup>89</sup> *Genetic Testing*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/handbook/testing?show=all#geneticstesting> (last updated Nov. 11, 2014) (explaining that Title I prevents genetic discrimination in health insurance, and Title II prevents genetic discrimination by employers).

<sup>90</sup> *Su*, *supra* note 5, at 361.

<sup>91</sup> *Fabricut to Pay \$50,000 to Settle EEOC Disability and Genetic Information Discrimination Lawsuit*, U.S. EQUAL EMP'T OPPORTUNITY COMM'N, <http://www.eeoc.gov/eeoc/newsroom/release/5-7-13b.cfm> (last updated May 7, 2013).

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family medical history in its post-offer medical examination.<sup>92</sup> On May 7, 2013 Fabricut agreed to pay \$50,000 and to take action to prevent future discrimination.<sup>93</sup>

Barbara Seely, EEOC Regional Attorney, noted that many employers still do not understand that requesting family medical history is prohibited.<sup>94</sup> Additionally, according to a 2010 study, less than 20% of the adult population in Connecticut, Michigan, Ohio and Oregon had knowledge of genetic non-discrimination laws, while 80% perceived that these laws were very or somewhat important.<sup>95</sup> Over two-thirds were concerned with insurance companies using genetic test results to determine life insurance coverage and costs.<sup>96</sup> This study suggests that further public education is necessary to raise awareness of the protections provided by current genetic nondiscrimination laws.<sup>97</sup>

While GINA creates additional safeguards through genetic nondiscrimination by health insurance companies and by employers, GINA is silent on a number of issues.<sup>98</sup> For example, GINA does not bar genetic discrimination outside the health insurance and employment contexts, and does not address concerns

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<sup>92</sup> *Id.* Fabricut required Rhonda Jones to fill out a questionnaire and disclose separately listed disorders in her family medical history. Although Jones indicated in the questionnaire that she did not have Carpal Tunnel Syndrome (CTS), Fabricut required her to submit to further testing. Fabricut's contract medical examiner, Knox Laboratories, found that Jones did have CTS, and Fabricut rescinded her application. The EEOC found that Fabricut engaged in illegal conduct when it discriminated against Jones based on genetic information—which includes family medical history. *Id.*

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> Alicia A. Parkman et. al., *Public Awareness of Genetic Nondiscrimination Laws in Four States and Perceived Importance of Life Insurance Protections*, J. GENETIC COUNSELING 1, 4–6 (2014), available at <http://www.ncbi.nlm.nih.gov/pubmed/25242499>.

<sup>96</sup> *Id.*

<sup>97</sup> *Id.* at 7.

<sup>98</sup> Colin McFerrin, *DNA, Genetic Material, and A Look at Property Rights: Why You May Be Your Brother's Keeper*, 19 TEX. WESLEYAN L. REV. 967, 984 (2013) (citing Elizabeth E. Joh, *DNA Theft: Recognizing the Crime of Nonconsensual Genetic Collection and Testing*, 91 B.U. L. REV. 665, 686 (2011)).

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surrounding abandoned DNA or the nonconsensual collection and testing of genetic material.<sup>99</sup> Additionally, GINA only covers asymptomatic individuals as compared to state insurance laws which cover symptomatic individuals.<sup>100</sup> Moreover, GINA does not indicate how DTC genetic tests should be interpreted and communicated.<sup>101</sup>

Although GINA was enacted in 2008, the EEOC only started enforcing the law in 2013.<sup>102</sup> However, the EEOC has indicated that it plans to enforce GINA against employers, by also settling an action against Founders Pavilion, Inc. in early 2014.<sup>103</sup> David Lopez, EEOC General Counsel, commented that illegal questions will not be tolerated and the “EEOC will be vigilant in ensuring that no one is denied employment opportunities on a prohibited basis.”<sup>104</sup> Furthermore, the EEOC stated that addressing genetic discrimination is one of the six national priorities of the EEOC’s Strategic Enforcement Plan.<sup>105</sup>

*E. State Laws: Further Complications or a Model for the Future?*

Further complicating matters, various state laws govern the status of DTC genetic tests. Twenty-five states,<sup>106</sup> including New York<sup>107</sup> and California,<sup>108</sup> have passed statutes or regulations that

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<sup>99</sup> *Id.* at 985.

<sup>100</sup> *Id.* (citing Mark A. Rothstein, *GINA’s Beauty is Only Skin Deep*, GENEWATCH, <http://www.councilforresponsiblegenetics.org/GeneWatch/GeneWatchPage.aspx?pageId=184> (last visited Mar. 3, 2013)).

<sup>101</sup> Michelle D. Irick, *Age of an Information Revolution: The Direct-to-Consumer Genetic Testing Industry and the Need for A Holistic Regulatory Approach*, 49 SAN DIEGO L. REV. 279, 290 (2012).

<sup>102</sup> *Founders Pavilion Will Pay \$370,000 to Settle EEOC Genetic Information Discrimination Lawsuit*, U.S. EQUAL OPPORTUNITY EMP’T COMM’N, <http://www.eeoc.gov/eeoc/newsroom/release/1-13-14.cfm>, (last updated Jan. 13, 2014).

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> GENETICS & PUB. POLICY CTR., JOHNS HOPKINS UNIV., SURVEY OF DIRECT-TO-CONSUMER TESTING STATUTES AND REGULATIONS 1-14 (2007), available at <http://www.dnapolicy.org/resources/DTCStateLawChart.pdf> [hereinafter DTC Testing Survey].

<sup>107</sup> See, e.g., N.Y. PUB. HEALTH LAW § 576-b(1) (2002) (requiring that any clinical laboratory services be FDA approved); N.Y. PUB. HEALTH LAW § 577 (2011);

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specifically restrict or prohibit DTC genetic testing.<sup>109</sup> Accordingly, observers fear that “conflicts between the laws of various states, and between state and federal law, will increase legal and regulatory uncertainty.”<sup>110</sup> The variety in state laws regarding genetic testing could serve to fuel further confusion about the legality of DTC genetic testing.

However, some states could serve as models for other states’ genetic testing and privacy laws, or as a model for the federal government to follow. For example, Alaska’s Genetic Testing Statute is more comprehensive than GINA.<sup>111</sup> The Alaska statute provides a private cause of action against individuals who analyze, collect, or retain DNA samples without consent, or individuals that release the results of DNA testing.<sup>112</sup> The statute requires written consent before a person can collect, analyze, retain, or disclose an individual’s DNA analysis results.<sup>113</sup>

Three other states, Colorado, Florida, and Georgia, also declare genetic information to be the private property of the individual to which it pertains.<sup>114</sup> The Colorado and Georgia statutes are in each state’s insurance code, and prohibit the unauthorized testing and disclosure, and discrimination of individuals’ DNA for insurance

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10 NYCRR 19.1(j) (2014); 10 NYCRR 58-1.7 (2014); 10 NYCRR § 58-1.8 (2014); 10 NYCRR § 63.3(e) (2014).

<sup>108</sup> See, e.g., CAL. BUS. & PROF. CODE § 1246.5 (2005) (providing that “[t]he tests that may be conducted pursuant to this section are: pregnancy, glucose level, cholesterol, occult blood, and any other test for which there is a test for a particular analyte approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit”).

<sup>109</sup> Alabama, Connecticut, Georgia, Hawaii, Idaho, Kentucky, Michigan, New Hampshire, Pennsylvania, Rhode Island, South Carolina, Tennessee, and Wyoming specifically prohibit DTC genetic testing; Arizona, California, Colorado, Florida, Illinois, Maine, Maryland, Massachusetts, Nevada, New Jersey, New York, and Oregon limit DTC genetic testing. DTC Testing Survey, *supra* note 106.

<sup>110</sup> *Id.*

<sup>111</sup> McFerrin, *supra* note 98, at 986.

<sup>112</sup> ALASKA STAT. § 18.13.010 (2004).

<sup>113</sup> *Id.*

<sup>114</sup> SETH AXELRAD, STATES DECLARING GENETIC INFORMATION TO BE PERSONAL PROPERTY (2005), available at [https://www.aslme.org/dna\\_04/reports/axelrad4.pdf](https://www.aslme.org/dna_04/reports/axelrad4.pdf).

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purposes.<sup>115</sup> The Colorado and Georgia statutes also establish civil remedies when insurers engage in unfair practices based on the use of DNA.<sup>116</sup> Florida and Alaska, on the other hand, both establish criminal penalties for misuse of genetic information,<sup>117</sup> which might serve to more effectively deter the misappropriation of genetic information. These state statutes—all arguably more comprehensive than GINA—might not only serve to create a more confusing framework for DTC genetic testing companies; rather, they may actually serve as a model for future amendments to GINA and demonstrate how the EEOC might go about enforcing the Act against a DTC genetic testing company under GINA.

F. *Association for Molecular Pathology v. Myriad Genetics, Inc.: Implications to DTC Genetic Testing Companies*

The Supreme Court in *Association for Molecular Pathology v. Myriad Genetics, Inc.*<sup>118</sup> removed a potential barrier to large-scale DTC genetic testing and genomic sequencing<sup>119</sup> because the holding limited the patentability of human genetic material. The Supreme Court held that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated.”<sup>120</sup> Moreover, research indicates that limiting genetic patents will continue to allow the DTC industry to flourish.<sup>121</sup> For example, one study found that patents do not appear to be

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<sup>115</sup> COLO. REV. STAT. § 10-3-1104.7(1)(a) (2009); GA. CODE ANN. § 33-54-1(1) (1995).

<sup>116</sup> Axelrad, *supra* note 114; COLO. REV. STAT. § 10-3-1104.7(11) (2009); GA. CODE ANN. § 33-54-8 (1995).

<sup>117</sup> FLA. STAT. § 760.40(2)(a) (2009); ALASKA STAT. § 18.13.010(a)-(b) (2004).

<sup>118</sup> 133 S. Ct. 2107 (2013).

<sup>119</sup> Spector-Bagdady & Pike, *supra* note 14, at 683.

<sup>120</sup> Myriad, 133 S. Ct. at 2111.

<sup>121</sup> Fifty-nine percent of the nation’s basic genetic research is federally funded, and therefore patents are not necessary for much of basic research to occur. U.S. DEPT OF HEALTH & HUMAN SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS: REPORT OF THE SEC’YS ADVISORY COMM. ON GENETICS, HEALTH, & SOC’Y, 2 (Apr. 2010), available at [http://osp.od.nih.gov/sites/default/files/SACGHS\\_patents\\_report\\_2010.pdf](http://osp.od.nih.gov/sites/default/files/SACGHS_patents_report_2010.pdf) (citing *Science and Engineering Indicators 2008*, NAT’L SCIENCE FOUND., <http://www.nsf.gov/statistics/seind08/c4/c4h.htm#c4hs> (last visited Oct. 20, 2014)).

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necessary to promote genetic research or to develop genetic tests.<sup>122</sup> The study also indicated that the prospect of patenting a genetic research discovery does not play a significant role in motivating scientific research.<sup>123</sup>

Despite *Myriad*'s holding that naturally occurring sequences of DNA are not patentable,<sup>124</sup> other DTC genetic testing companies, like 23andMe, Inc. ("23andMe"), currently hold patents related to naturally occurring DNA sequences.<sup>125</sup> For example, 23andMe's first patent "Polymorphisms Associated with Parkinson's Disease," which relates to the discovery of a "variation in the SGK1 gene that may be protective against Parkinson's disease in individuals who carry the rare risk-associated LRRK2 G2019S mutation," seems extremely similar to Myriad's patents of the BRCA1 and BRCA2 genes that were struck down in *Myriad*.<sup>126</sup> It is theoretically possible that 23andMe's patent could be struck down under a similar theory as the *Myriad* decision came out after the 23andMe patent was submitted.

However, it is unlikely that gene patents will disappear post-*Myriad*.<sup>127</sup> Inventors could utilize trade secret protection, although there is a risk another inventor could come up with the same invention and the original inventor would lack the legal tools to prevent the competitor from profiting from the invention.<sup>128</sup> An

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<sup>122</sup> U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 121, at 2.

<sup>123</sup> *Id.*; John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 153–54 (2001) (describing that scientists are primarily motivated by idealistic desires like "contributing to scientific and technological progress.").

<sup>124</sup> *Myriad*, 133 S. Ct. 2107, 2115–20 (2013) (holding "[a] naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring.").

<sup>125</sup> *Announcing 23andMe's First Patent*, 23ANDME BLOG (May 28, 2012), <http://blog.23andme.com/news/announcements/announcing-23andmes-first-patent/>.

<sup>126</sup> *See id.* (referring to the *Myriad* case ruling in which Myriad's proposed patent was a genetic patent like 23andMe's).

<sup>127</sup> Jessica L. Marks, et al., *Gene Patents Won't Disappear Post-Myriad*, LAW360 (July 22, 2013), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=b4a7795a-bee4-431a-bab2-47ee02ea5608>.

<sup>128</sup> *Id.*

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inventor could also attempt to patent isolated nucleic acids rather than straightforward, complementary DNA,<sup>129</sup> which the court stated is not naturally occurring.<sup>130</sup> DTC genetic testing companies could continue to “get around” the loophole that naturally occurring DNA sequences are not patentable. The *Myriad* decision will continue to affect the DTC industry as various companies are allowed to compete with one another to find the best SNP<sup>131</sup> sites to conduct genetic tests, or as the companies discover new SNP sites with the potential for predicting health risks.

G. *Tompkins v. 23andMe Inc. and Regulatory Repercussions*

A case recently decided in the Northern District of California, *Tompkins v. 23andMe Inc.*,<sup>132</sup> involved a class action related to defendant 23andMe’s advertising and marketing of its Personal Genome Service.<sup>133</sup> 23andMe’s “FDA takedown” last November might have influenced some lawyers to “move in for their cash grab,” demonstrating how regulatory decisions can sometimes prompt litigation.<sup>134</sup> The primary issue between the parties arose

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<sup>129</sup> *Id.*

<sup>130</sup> *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2107 (2013).

<sup>131</sup> Single Nucleotide Polymorphism or SNP, *supra* note 11 and accompanying text.

<sup>132</sup> 5:13-CV-05682-LHK, 2014 WL 2903752, at \*1 (N.D. Cal. June 25, 2014).

<sup>133</sup> *Id.* (“PGS is a service that consists of a DNA saliva collection kit (‘DNA kit’) and DNA test results with certain genetic information derived from a consumer’s saliva sample.”).

<sup>134</sup> Linda A. Willett, *Litigation As an Alternative to Regulation: Problems Created by Follow-on Lawsuits with Multiple Outcomes*, 18 GEO. J. LEGAL ETHICS 1477, 1482 (2005) (“During the past few years, when the FDA has used its technical review process to challenge language, photos, or footage in a DTC advertisement, a series of private lawsuits, now known as ‘follow-on’ actions, has quickly followed. For example, an FDA decision to require withdrawal of DTC advertising may be followed by one or more federal and state court actions, including class action suits brought under broadly written state consumer protection laws by those purporting to represent the citizens of a state. Some of these actions are without merit and ultimately result in nothing more than a drain on the court system.”); Eric Goldman, *23andMe’s Browserwrap Fails, But It’s Post-Purchase Clickthrough Works Anyway—Tompkins v. 23andMe*, TECH. & MKTG. LAW BLOG (July 2, 2014), <http://blog.ericgoldman.org/archives/>

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out of the arbitration provision in the Terms of Service (section 28(b)) in the miscellaneous section).<sup>135</sup> The California court dismissed the plaintiffs' class action claims, with 23andMe defending an arbitration agreement<sup>136</sup> consumers signed in the company's Terms of Service ("TOS").<sup>137</sup>

The court found that the method of accepting the TOS resembled "clickwrap agreements, where an offeree receives an opportunity to review terms and conditions and must affirmatively

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2014/07/23andmes-browsewrap-fails-but-its-post-purchase-clickthrough-works-anyway-tompkins-v-23andme.htm.

<sup>135</sup> *Tompkins*, 2014 WL 2903752 at \*2.

<sup>136</sup> *Id.* at \*1. The arbitration agreement read as follows:

Applicable law and arbitration. Except for any disputes relating to intellectual property rights, obligations, or any infringement claims, any disputes with 23andMe arising out of or relating to the Agreement ("Disputes") shall be governed by California law regardless of your country of origin or where you access 23andMe, and notwithstanding of any conflicts of law principles and the United Nations Convention for the International Sale of Goods. Any Disputes shall be resolved by final and binding arbitration under the rules and auspices of the American Arbitration Association, to be held in San Francisco, California, in English, with a written decision stating legal reasoning issued by the arbitrator(s) at either party's request, and with arbitration costs and reasonable documented attorneys' costs of both parties to be borne by the party that ultimately loses. Either party may obtain injunctive relief (preliminary or permanent) and orders to compel arbitration or enforce arbitral awards in any court of competent jurisdiction.

*Id.* at \*2.

<sup>137</sup> During the account creation and registration processes, each named Plaintiff clicked a box near a hyperlink to indicate acceptance of the terms of service. *Id.* at \*3. 23andMe argued that it was "impossible to register for and receive the Service without clicking 'I ACCEPT' to the TOS." *Id.* at \*6 (internal quotations omitted). However, the court held that because the only way consumers could see the TOS at the time of purchase was to scroll to the bottom of the screen, a better practice would be to show or require acknowledgement of such terms at the point of sale. *Id.* at \*7. Therefore, the court held that 23andMe's TOS would have been ineffective to bind website visitors or consumers who purchased a DNA kit without creating an account or registering a kit. *Id.* After the consumers made the purchase, in order to get the results, they had to accept the terms of service by clicking a button that appeared near a hyperlink of the terms of service. *Id.* at \*8.

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indicate assent.”<sup>138</sup> However, the court’s reasoning here is unsatisfying for two reasons. First, the court ignores the possibility of a consumer buying the service for another party (like a minor or a friend) and second, the court does not take into account economic realities because at that point the consumer cannot receive a full refund for their results.<sup>139</sup> While the court acknowledges that it is possible for a consumer to buy the DNA kit as a gift for someone else without creating an account or registering the kit, the court moves on without addressing this potential issue.<sup>140</sup> If someone were to purchase the kit as a gift for a minor or third party, his or her autonomy and privacy concerns might not be addressed.

The court held that although the terms of service were hyperlinked and not on the same screen, the consumers still had adequate notice of the terms of service.<sup>141</sup> Although the court ultimately upheld the arbitration clause in the agreement and dismissed the case without prejudice,<sup>142</sup> the plaintiffs have the opportunity to appeal to the Ninth Circuit.<sup>143</sup>

While consumer freedom to purchase these products is important, agencies like the FTC should work with other regulatory bodies (including the FDA, CMS under the CLIA, and various state agencies) to draft better procedures to allow consumers to fully understand the terms of service. In this case, one of the most reputable genetic testing companies arguably

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<sup>138</sup> *Id.* at \*8.

<sup>139</sup> Goldman, *supra* note 134.

<sup>140</sup> *Tompkins*, 2014 WL 2903752 at \*3.

<sup>141</sup> *Id.* at \*8. The plaintiffs finally argued that the arbitration agreement in the TOS was unconscionable. *Id.* at \*9. The court agreed that the clause was procedurally unconscionable because 23andMe’s website provided minimal notice of the TOS to consumers. *Id.* at \*14. Additionally, the clause is a standardized clause presented as a take-it-or-leave-it agreement, leaving consumers without any negotiating power. *Id.* at \*15. The court held that the arbitration agreement was not substantively unconscionable. *Id.* The court held that 23andMe’s headquarters as the arbitration forum, a carve out for claims by 23andMe, and limitations of legal remedies were “not so unduly harsh or one-sided” to become substantively unconscionable. *Id.* at \*16.

<sup>142</sup> *Id.* at \*18.

<sup>143</sup> The case could become “a flagship cyberlaw case.” Goldman, *supra* note 134.

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“obscured the terms of service” in an “unfair way.”<sup>144</sup> Protecting consumers from this type of behavior is squarely in the realm of the FTC, whose mission is to help protect consumers from deceptive and unfair business practices.<sup>145</sup>

### III. IMPLICATIONS AND RECOMMENDATIONS

This part analyzes how a genetic service like Interleukin Inc.’s “Inherent Health” might be regulated under the current regulatory framework. Each of the various regulatory stakeholders, including the FDA, FTC, CLIA, GINA, state genetic testing statutes, and the *Tompkins* decision might become relevant for Interleukin. The FTC should enforce regulations against this particular type of genetic testing service, informed by heightened CLIA standards.

#### A. *Inherent Health: Different than 23andMe Under FDA Regulation?*

Interleukin Genetics, Inc., a personalized health company, introduced Inherent Health™ in 2009.<sup>146</sup> Inerleukin’s Inherent Health product includes genetic tests for heart health, weight management, nutritional needs, and bone health, among others.<sup>147</sup>

Interleukin was among the DTC genetic testing companies that received untitled letters<sup>148</sup> in 2010 because the FDA had not preapproved Inherent Health.<sup>149</sup> However, since that letter, the

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<sup>144</sup> *Tompkins*, 2014 WL 2903752 at \*7.

<sup>145</sup> *About the FTC*, FED. TRADE COMM’N, <http://www.ftc.gov/about-ftc> (last visited Sept. 26, 2014).

<sup>146</sup> *About Interleukin Genetics*, INTERLEUKIN GENETICS, <http://www.ilgenetics.com/content/about-interleukin> (last visited Nov. 1, 2014).

<sup>147</sup> *Our Genetic Tests*, INTERLEUKIN GENETICS, <http://www.inherenthealth.com/our-tests.aspx> (last visited Nov. 1, 2014).

<sup>148</sup> “Unlike a warning letter, an untitled letter does not include a statement that warns the individual or firm that failure to correct the violation may result in enforcement action.” U.S. FED. DRUG ADMIN, WARNING AND UNTITLED LETTERS 1 (2011) *available at* <http://www.fda.gov/downloads/AboutFDA/Transparency/PublicDisclosure/GlossaryofAcronymsandAbbreviations/UCM212064.pdf> (last visited Nov. 20, 2014).

<sup>149</sup> Letter from James Woods, Deputy Dir., Patient Safety and Product Quality, Office of *In Vitro* Diagnostic Device Evaluation and Safety, Ctr. for Devices & Radiological Health, to Lewis H. Bender, CEO, Interleukin Genetics,

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FDA has not taken further action against the company. The FDA probably does not think that Inherent Health posed much of a risk to consumers because its genetic test sales have been slipping.<sup>150</sup> For example, in 2013 Inherent Health received a much needed \$12 million injection of capital into its business to “prolong its survival.”<sup>151</sup> Additionally, Interleukin Genetics never intended to sell its brand in national stores like Walgreens like Pathway Genomics, nor has it attempted a nationwide televised advertising campaign like 23andMe.<sup>152</sup> Like all agencies, the FDA has limited resources and a finite budget.<sup>153</sup> Attempting to enforce regulations against every single DTC genetic testing company, however small, might not be the best utilization of these resources.

DTC genetic testing companies like Interleukin should make sure to stay in contact with the FDA if they ever receive a warning letter. The FDA issued a harsh rebuke to 23andMe because the company essentially stopped communicating with the FDA for eleven months without completing the certification for its tests and planned an aggressive new marketing campaign.<sup>154</sup> If 23andMe had been more forthcoming with the FDA, the agency might not have needed to resort to such harsh measures.

To be sure, 23andMe arguably offered a better, more reliable product than Interleukin Genetics currently does. While Interleukin Genetics claims that its Inherent Health product is supported by various studies, some argue that companies like Interleukin

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Inc. (July 19, 2010), available at <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/UCM219587.pdf>.

<sup>150</sup> See Mark Hollmer, *Interleukin Genetics Raises \$12M in Last-Ditch Save*, FIERCE MEDICAL DEVICES (May 20, 2013), <http://www.fiercemedicaldevices.com/story/interleukin-genetics-raises-12m-last-ditch-save/2013-05-20>.

<sup>151</sup> *Id.*

<sup>152</sup> See *supra* notes 20–21 and accompanying text.

<sup>153</sup> John Lehmann, *Budget Constraints Impacting FDA Strategic Priorities*, IMARC RESEARCH (July 25, 2014 6:48 AM), <http://www.imarcresearch.com/blog/bid/351768/Budget-Constraints-Impacting-FDA-Strategic-Priorities>.

<sup>154</sup> See Warning Letter to Wojcicki, *supra* note 21.

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Genetics, among others, are bringing the industry down by marketing suspect tests.<sup>155</sup>

Perhaps Interleukin is the type of company the FDA should be regulating. The FDA should worry about the unreliability of the “weight loss management product”<sup>156</sup> from Interleukin.<sup>157</sup> DTC genetic test critics already fear that science cannot offer certainty based on a predictive DTC genetic test.<sup>158</sup> Few resources are available to gauge the reliability of the DTC genetic tests.<sup>159</sup> Furthermore, each test varies according to the specific SNP sites analyzed by the test and the capabilities of the individual lab performing the test.<sup>160</sup>

Studies have questioned the reliability of DTC genetic tests. For example, the GAO has conducted a number of investigations and other oversight activities related to DTC genetic testing.<sup>161</sup> A 2006 GAO investigation of four companies selling DTC genetic tests found that these companies “misled consumers by providing test results that were both medically unproven and so ambiguous as to be meaningless.”<sup>162</sup> In 2008, the Secretary’s Advisory Committee on Genetics, Health, and Society discovered that there were significant gaps related to the oversight of genetic testing in five

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<sup>155</sup> See Helen Wallace, *Misleading Marketing of Genetic Tests, Will the Genome Become the Source of Diagnostic Miracles or Potential Scams?* COUNCIL FOR RESPONSIBLE GENETICS, <http://www.councilforresponsiblegenetics.org/ViewPage.aspx?pageId=88> (last visited Oct. 30, 2014).

<sup>156</sup> Inherent Health advertises weight loss solutions tailored to your genes on its main webpage. INHERENT HEALTH, <http://www.inherenthealth.com> (last visited Nov. 1, 2014) [hereinafter *inherenthealth.com*].

<sup>157</sup> This column reminds readers that while nutrigenomic research is an exciting, growing area, diets tailored to your genes are still unproven. *Ask the Nutritionist*, DANA-FARBER CANCER INST., <http://www.dana-farber.org/Health-Library/The-Inherent-Health--Weight-Management-DNA-Test.aspx> (last visited Nov. 1, 2014).

<sup>158</sup> Jessica D. Gabel, *Redeeming the Genetic Groupon: Efficacy, Ethics, and Exploitation in Marketing DNA to the Masses*, 81 MISS. L.J. 363, 407 (2012).

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> SARATA & JOHNSON, *supra* note 31, at 17.

<sup>162</sup> *Id.* (internal quotations omitted).

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areas.<sup>163</sup> Two years later, the GAO concluded that these tests were still “misleading” and “yielded contradictory predictions.”<sup>164</sup> Although these DTC genetic tests might have some scientific validity,<sup>165</sup> Inherent Health may be among the genetic testing products with unproven and misleading claims.

B. *The FTC: Is Inherent Health “Fit to be Tried?”*

The FTC should regulate companies like Interleukin. Interleukin’s Inherent Health tells consumers, “Don’t waste a day on the wrong diet! The Weight Management Genetic Test may help you lose more weight by properly matching diet and exercise to your personal genotypes. No guessing!”<sup>166</sup> While Interleukin’s Inherent Health may have validity as a CLIA certified testing company, this type of blanket statement might simply confuse consumers who will believe that a genetic test holds the key to their weight loss.<sup>167</sup> Because Inherent Health claims to be “CLIA certified,” there seems to be a discrepancy between the high

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<sup>163</sup> These areas include:

(1) the regulations governing clinical laboratory quality; (2) oversight of the clinical validity of genetic tests; (3) the transparency of genetic testing; (4) the level of current knowledge about the clinical usefulness of genetic tests; and (5) the educational needs of health professionals, the public health community, patients and consumers.

Spector-Bagdady & Pike, *supra* note 14, at 694 (internal quotations omitted).

<sup>164</sup> U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-10-847T DIRECT-TO-CONSUMER GENETIC TESTS: MISLEADING TEST RESULTS ARE FURTHER COMPLICATED BY DECEPTIVE MKTG. AND OTHER QUESTIONABLE PRACTICES 4 (2010), available at <http://www.gao.gov/new.items/d10847t.pdf>. “The fact that different companies, using the same samples, predict different . . . directions of risk is telling and is important. It shows that we are nowhere near really being able to interpret [such tests].” *Id.* at 8.

<sup>165</sup> See Schleckser, *supra* note 60, at 712 (arguing that the GAO’s conclusions might have been “vastly overstated” and the discrepancies in the testing results could be accounted for in the diverse standards for SNP site selections between different companies).

<sup>166</sup> *Take the Guesswork out of Losing Weight*, INHERENT HEALTH, <http://www.inherenthealth.com/our-tests/weight-management.aspx> (last visited Sept. 26, 2014) [hereinafter *Take the Guesswork out of Losing Weight*].

<sup>167</sup> *Id.*

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standards promulgated by other government agencies, and the claims this company is making.

Inherent Health seems to validate concerns that the FTC warned against in the L'Oréal matter and the Genelink foru™ matter. For example, Inherent Health claims: “Finally—the answers you need to get results faster, stay confident and motivated, and take control of your weight. Order today!”<sup>168</sup> Interleukin claims that these conclusions are based on a study, partly funded by the company itself.<sup>169</sup> However, it is unclear if this single study would meet the FTC’s standard that “once companies make objective product representations, long standing substantiation principles apply.”<sup>170</sup> Inherent Health also has a report “showing the science behind the test.”<sup>171</sup> The “Science Behind the Weight Management Genetic Test” demonstrates how the company came to the conclusion that five variations in four genes impact various pathways that influence body weight and have a related risk for obesity.<sup>172</sup> Because the company substantiated its decision to test those particular genes with multiple scientific studies, it is unclear whether this method would be enough to survive the FTC’s standard that the product must be “fit to be tried.”<sup>173</sup> Additionally, “The Science Behind the Weight Management Genetic Test” might be too jargon-heavy and inaccessible for the

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<sup>168</sup> *Id.*

<sup>169</sup> *Id.* In this study:

240 overweight pre-menopausal women followed either a very-low carbohydrate diet, a low-carbohydrate diet, a low-fat high-carbohydrate diet, or a very high-carbohydrate diet for one year. Study participants were provided instructions by a registered dietician for 2 months concerning how to follow their assigned diets; some instructions included behavioral modification techniques. Participants' DNA were analyzed and the study concluded that after 12 months participants who possessed specific genetic markers lost, on average, more weight following one type of diet plan than another.

*Id.*

<sup>170</sup> Fair, *supra* note 84.

<sup>171</sup> *Take the Guesswork out of Losing Weight*, *supra* note 166.

<sup>172</sup> INHERENT HEALTH, THE SCIENCE BEHIND THE WEIGHT MANAGEMENT GENETIC TEST, 2 available at [http://www.inherenthealth.com/media/4759/wm\\_scientific%20summary.pdf](http://www.inherenthealth.com/media/4759/wm_scientific%20summary.pdf) (last visited Nov. 2, 2014).

<sup>173</sup> Fair, *supra* note 84.

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average consumer attempting to verify that the test is scientifically accepted. The FTC should make sure that the tests are (1) supported by substantial evidence, and (2) consumers can understand that these studies are valid.

*C. Make CLIA Certification Meaningful*

Interleukin's Inherent Health also demonstrates that CLIA should be doing more to regulate these DTC genetic testing companies. The "CLIA certified"<sup>174</sup> label on the Inherent Health product might convince consumers that the product is reliable. The Interleukin Genetics lab in Waltham, Massachusetts has achieved a CLIA "Certificate of Compliance."<sup>175</sup> This CLIA certification seems to be in contradiction with the FDA's 2010 letter expressing concern about Interleukin's DTC genetic testing and the FTC's stance on DTC genetic testing. A better practice would be to make sure that a company in compliance with one of the federal regulatory mechanisms is in compliance with all of them; it is misleading to consumers to say that it is certified by one federal regulatory mechanism but not another.

*D. GINA and State Genetic Testing Statutes: A Privacy Paradigm*

DTC genetic testing opponents are concerned about a consumer's privacy after these consumers purchase the Inherent Health product.<sup>176</sup> Specifically, critics are concerned with what

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<sup>174</sup> There are five different CLIA Certificates including: Certificate of Waiver; a certificate for microscopy procedures; a certificate of registration for midlevel or high complexity tests; a certificate of compliance after inspection; and a certificate of accreditation on the basis of an accreditation organization approved by the Healthcare Financing Administration. CTRS. FOR MEDICARE AND MEDICAID SERVS., TYPES OF CLIA CERTIFICATES 1 (2003), available at [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/TYPES\\_OF\\_CLIA\\_CERTIFICATES.pdf](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/TYPES_OF_CLIA_CERTIFICATES.pdf) (last visited Nov. 11, 2014).

<sup>175</sup> 22D1038543 CLIA Number - Interleukin Genetics, Inc., HEALTH PROVIDERS DATA [http://healthprovidersdata.com/hipaa/codes/CLIA\\_22D1038543.aspx](http://healthprovidersdata.com/hipaa/codes/CLIA_22D1038543.aspx) (last visited Nov. 11, 2014).

<sup>176</sup> See Lauren B. Solberg, *Over the Counter but Under the Radar: Direct-to-Consumer Genetics Tests and FDA Regulation of Medical Devices*, 11 VAND. J. ENT. & TECH. L. 711, 721 (2009) ("Although genetic testing services may inform consumers that their genetic material or information may be sold to third

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should and will happen to genetic testing information from minors.<sup>177</sup> Despite critics' fears, companies like Interleukin Genetics do expressly address the issues associated with genetic testing information from minors. For example, Interleukin's Inherent Health privacy policy specifically indicates, "Our Website is not intended for, or designed to attract, children under the age of 13."<sup>178</sup>

The Interleukin privacy policy also explains that the company utilizes several different procedures to protect a client's personal information, including using assigned usernames and passwords, anonymous barcodes for DNA, server firewalls, and an encrypted website.<sup>179</sup> Interleukin also specifically acknowledges GINA under a section entitled "Federal Laws Protecting You."<sup>180</sup> The company explains that a consumer is not required to share the genetic information with an insurer or an employer.<sup>181</sup> The company also explains that there are "state laws that prevent insurers, employers, and others from using genetic tests for discriminatory purposes," depending on the state.<sup>182</sup> While consumers would have to read the privacy policy to find the information that could potentially address their privacy concerns, the policy seems relatively comprehensive to help educate consumers about their privacy rights.

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parties and used for research purposes, questions arise as to whether individuals are aware of this practice and understand the ramifications of consenting to this use of their genetic material.").

<sup>177</sup> See Pascal Borry et al., *Is There A Right Time to Know? The Right Not to Know and Genetic Testing in Children*, 42 J.L. MED. & ETHICS 19, 20 (2014).

<sup>178</sup> *Privacy Policy*, INHERENT HEALTH, <http://www.inherenthealth.com/privacy-policy.aspx> (last updated June 15, 2009).

<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

<sup>181</sup> *Id.*

<sup>182</sup> *Id.*

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E. *Interleukin Genetics, Tompkins, and Consumer Autonomy Concerns related to DTC Genetic Testing*

Like in *23andMe v. Tompkins*, Interleukin's terms of use might be obscured in an unfair way.<sup>183</sup> In order to sign up for a new account on Interleukin's website, one must create a user name, password, and fill out your email with a security question and security answer.<sup>184</sup> Next, a consumer must certify that they are at least eighteen years old and they agree to comply with Inherenthealth.com's terms of use.<sup>185</sup> The terms of use are hyperlinked to another page.<sup>186</sup> Interleukin does not require a consumer to acknowledge the terms of service after creating an account in order to purchase the product. This formulation seems similar to 23andMe's former practice, which might give rise to similar criticisms.<sup>187</sup> Theoretically, a third party could use the account to purchase the product without ever seeing the terms of service. A better practice would be for a consumer to acknowledge the terms again at the time of purchasing the product.<sup>188</sup>

The terms of use also indicate service limitations, including a recommendation that consumers discuss any health-related findings with a physician or health care professional regarding the diagnosis, prevention, or treatment of a condition.<sup>189</sup> Interleukin also does not warrant that the information on the website, including information about the products actually offered, is completely accurate and current, including information about the products actually offered.<sup>190</sup> These terms of use highlight the arguments in favor of a role for a learned intermediary, such as a physician, in the interpretation of the genetic test results.

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<sup>183</sup> See *Tompkins v. 23andMe Inc.*, 5:14-CV-00429-LHK, 2014 WL 2903752 at \*1 (N.D. Cal. June 25, 2014).

<sup>184</sup> *Sign up for a new Account*, INHERENT HEALTH, <http://www.inherenthealth.com/store/register.aspx> (last visited Nov. 2 2014).

<sup>185</sup> *Id.*

<sup>186</sup> *Terms of Use*, INHERENT HEALTH (June 5, 2009), <http://www.inherenthealth.com/terms-of-use.aspx> [*hereinafter* Terms of Use].

<sup>187</sup> See *Tompkins*, 2014 WL 2903752, at \*1.

<sup>188</sup> *Id.*

<sup>189</sup> *Terms of Use*, *supra* note 186.

<sup>190</sup> *Id.*

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Without the help of physician interpretation, consumers who receive their genetic tests from a company like Interleukin could misunderstand the results—a misunderstanding that could lead to severe psychological trauma.<sup>191</sup> It could be traumatic to learn that a DTC genetic test predicts an increased risk for diseases such as Alzheimer’s or Huntington’s, which are incurable or have limited treatment options.<sup>192</sup> While Interleukin is selling health-related genetic tests, these tests are related to weight management and nutrition, and none purport to predict disease risks.<sup>193</sup> These types of tests seem more analogous to various weight loss apps like “MyFitnessPal,” where users can track their weight, calorie intake, and exercise habits.<sup>194</sup> While users could and perhaps should consult with physicians regarding their weight, exercise, and other habits, ultimately the decisions to exercise or eat certain foods should be left to the individual.

Furthermore, genetic counseling for consumers who wish to seek advice to better inform their decisions may be prohibitively expensive.<sup>195</sup> For example, 23andMe offered genetic counseling for a price range of \$99 to speak to a genetic counselor, and up to \$250 to have “comprehensive” clinical genetic counseling.<sup>196</sup>

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<sup>191</sup> See Solberg, *supra* note 176, at 720; see also Gabrielle Kohlmeier, *The Risky Business of Lifestyle Genetic Testing: Protecting Against Harmful Disclosure of Genetic Information*, 2007 UCLA J.L. & TECH. 5, 5 n.75 (2007) (explaining that many individuals who learn that they have Huntington’s disease allele, suffer from depression and many have committed suicide). *But see* Shweta U. Dhar et al., *Enhancing Exposure to Genetics and Genomics Through an Innovative Medical School Curriculum*, 14 GENETICS MED. 163, 163 (2012) (explaining that many doctors are not prepared to assist their patients in interpreting results); Schleckser, *supra* note 60, at 712 (explaining that involving physicians in the genetic test interpretation process could exacerbate privacy concerns).

<sup>192</sup> Solberg, *supra* note 176, at 720.

<sup>193</sup> See *inherenthealth.com*, *supra* note 156.

<sup>194</sup> Parmy Olson, *MyFitnessPal Starts Tracking Steps to Grow The World’s Largest Nutrition Database*, FORBES (May 1, 2014, 10:00 AM) <http://www.forbes.com/sites/parmyolson/2014/05/01/myfitnesspal-starts-tracking-steps-to-grow-the-worlds-largest-nutrition-database/>.

<sup>195</sup> *Id.*

<sup>196</sup> Gabel, *supra* note 158, at 407 (explaining that 23andMe collaborated with a third party provider to give consumers optional access to genetic counselors).

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Geneticists and medical professionals maintain that this limited counseling available from the companies is inadequate because the company providing the counseling has an interest in selling more tests.<sup>197</sup>

In addition, while consumers might misunderstand the results of their genetic tests from companies like Interleukin; patients might also misunderstand any type of diagnosis from their doctor, or the results from any other medical test. While there is always a chance of miscommunication, the vast majority of consumers are interpreting their results correctly.<sup>198</sup> Evidence also conflicts with critics' fears that consumers who learn they have an increased risk for certain diseases might take extreme actions.<sup>199</sup> Many DTC genetic test consumers understand there are many variables influencing the risk of disease.<sup>200</sup>

Based on this information, it is clear that many consumers can understand the results of the genetic test itself, but that it might be best to involve a physician to ensure that consumers are interpreting their results correctly and take the best course of action regarding their results. Involvement of medical professionals could impede the autonomy some patients might value from DTC genetic testing,<sup>201</sup> but some individuals are using these DTC genetic tests to make a significant medical decision based on their health risks for

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<sup>197</sup> Jennifer A. Gniady, *Regulating Direct-to-Consumer Genetic Testing: Protecting the Consumer Without Quashing A Medical Revolution*, 76 *FORDHAM L. REV.* 2429, 2450 (2008).

<sup>198</sup> For example, in one survey, between 91% and 95% of participants interpreted straightforward messages correctly, demonstrating that most consumers understand how to interpret increased risk, decreased risk, or equal risk correctly. Robert C. Green & Nita A. Farahany, *The FDA is Overcautious on Consumer Genomics*, 505 *NATURE* 286, 287 (2014). In a different study, 90% of participants answered questions correctly about their results. Schleckser, *supra* note 60, at 719.

<sup>199</sup> Green & Farahany, *supra* note 198, at 287.

<sup>200</sup> Colleen M. McBride et al., *Consumers' Views of Direct-to-Consumer Genetic Information*, 11 *ANN. REV. GENOMICS HUM. GENETICS* 427, 434 (2010) (citing seven scientific studies supporting this premise).

<sup>201</sup> Gabel, *supra* note 158, at 400 (explaining that DTC genetic testing companies focused on recreational purposes in the industry's infancy).

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serious conditions like Huntington's or Alzheimer's.<sup>202</sup> Therefore, physician involvement might outweigh autonomy concerns when interpreting results for incurable diseases, but not for companies like Interleukin that provide weight-loss plans.

#### *G. Bringing the Regulatory Framework Together for Interleukin Genetics*

Perhaps Interleukin Genetics will stay off the FDA's radar because its consumer base is relatively small in comparison to other DTC genetic testing companies. However, if Interleukin makes major marketing plans or stops communicating with the FDA regarding any key changes, the company should expect to be sanctioned similarly to 23andMe. The FDA has indicated its displeasure at being kept out of the loop.<sup>203</sup> Silicon Valley start-ups and genetic researchers might not be as concerned with regulatory agencies in Washington when their goals include innovating toward the future. However, the agency's decision to curtail 23andMe's health-related Personal Genome Service has sent shockwaves through the industry, and other companies offering health-related products should pay attention. Some speculate 23andMe's recent negative experience is why Apple's new "HealthKit" update was released without much fanfare.<sup>204</sup>

The FTC seems to be the natural choice to enforce regulations against Interleukin and expose whether the company is misleading consumers or making unsubstantiated claims about the Inherent Health product. The FTC's recent enforcements against Genelink and L'Oreal indicate that the agency is willing to put companies to the test to make sure their products are "fit to be tried."

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<sup>202</sup> Deepthy Kishore, *Test at Your Own Risk: Your Genetic Report Card and the Direct-to-Consumer Duty to Secure Informed Consent*, 59 EMORY L.J. 1553, 1567 (2010) (explaining that consumer may make decisions "like whether to have children, undergo prophylactic surgery, or continue routine surveillance for certain cancers").

<sup>203</sup> See Warning Letter to Wojcicki, *supra* note 21.

<sup>204</sup> See Nick Paul Taylor, *Application of Regulatory Handbrake to 23andMe Offers Cautionary Tale to Silicon Valley*, FIERCEBIOTECHIT (Sept. 15, 2014), <http://www.fiercebiotechit.com/story/application-regulatory-hand-brake-23andme-offers-cautionary-tale-silicon-va/2014-09-15>.

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In order to make sure that Interleukin is consistently able to make health-related claims credibly, CLIA certification needs to mean something more. A CLIA certification should indicate that laboratories are clinically and analytically valid to be useful to potential consumers. Systematic gaps in the oversight of these laboratories need to be addressed. If a laboratory is CLIA certified, the FDA and the FTC should not indicate that the genetic tests are unreliable.

State genetic testing statutes and GINA should serve to ameliorate consumer concerns about privacy. The *Tompkins v. 23andMe* decision should inform Interleukin and other DTC genetic testing companies about the appropriate ways to formulate their terms of use. The *Myriad* decision should remind genetic testing companies and Interleukin that patenting a natural DNA sequence will not withstand a reviewing court's scrutiny. Genetic testing companies should be regulated in a way that allows for innovation.

#### IV. CONCLUSION

Despite the obvious limitations and shortcomings of the current DTC testing market, the current regulatory framework might inhibit future innovation rather than save consumers from themselves. For example, 23andMe's fight to go forward with premarket approval for one test demonstrates how the company's battle with the FDA will be long and time-consuming.<sup>205</sup> In the meantime, 23andMe is looking for new markets abroad, where standards are less restrictive and the consumers will not be bound by the FDA's ruling.<sup>206</sup> The FDA's attempts to slow the growth of the industry may prove fruitless due to other open-data source

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<sup>205</sup> See Robert Hof, *Seven Months After FDA Slapdown, 23andMe Returns with New Health Report Submission*, FORBES (June 20, 2014, 12:04 PM), <http://www.forbes.com/sites/roberthof/2014/06/20/seven-months-after-fda-slapdown-23andme-returns-with-new-health-report-submission/>.

<sup>206</sup> Christina Farr, *Gene Startup 23andMe Casts Eyes Abroad After U.S. Regulatory Hurdle*, REUTERS (May 6, 2014, 4:03 PM), <http://www.reuters.com/article/2014/05/06/23andme-geneticstesting-idUSL2N0NS0Y820140506>.

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desktop applications<sup>207</sup> and the growth of other internationally based genetic sequencing firms.<sup>208</sup> While the FDA's concerns are not completely unfounded, regulators might not understand the true nature of the risk involved in receiving genetic information from these DTC genetic testing services.<sup>209</sup>

Between the FDA banning all health-related genetic tests by 23andMe and Interleukin's unfettered offering of Inherent Health lies a compromise. First, while the FDA should certainly play a role in the regulation of these genetic tests, it should allow for an acceleration of genetic test approval after 23andMe's pending initial approval of the Bloom syndrome test. Second, the FTC should step in to help make sure that consumers are not misled into purchasing products with unfounded health-related claims and are able to read and understand the terms of service of these products. Third, CMS under CLIA should ensure that Interleukin's Inherent Health tests are analytically valid, but that they also have clinical validity and utility. Fourth, legislators should clarify what the role of GINA should be for DTC genetic testing companies. While there is still room for state regulation, in an increasingly international platform for these tests, it might be prudent for the federal government to take a larger role in the regulation of DTC tests. Finally, while isolated naturally occurring DNA sequences may no longer be patentable, there remain significant opportunities for DTC genetic testing companies to patent their discoveries. These different regulatory mechanisms need to coordinate together to help this burgeoning industry grow in a responsible, sustainable way.

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<sup>207</sup> See, e.g., Roberta Estes, *Promethease- Genetic Health Information Alternative*, DNAEXPLAINED (Dec. 20, 2013) <http://dna-explained.com/2013/12/30/promethease-genetic-health-information-alternative/>. For \$5, at you can upload raw DNA data files from companies like 23andMe to a service called "Promethease." The service processes your raw data and provides you a copy of your report that will remain online for 45 days. *Id.*

<sup>208</sup> Razib Khan, *The FDA's Battle with 23andME Won't Mean Anything in the Long Run*, SLATE (Nov. 25, 2013 2:46 PM), [http://www.slate.com/blogs/future\\_tense/2013/11/25/fda\\_letter\\_to\\_23andme\\_won\\_t\\_mean\\_anything\\_in\\_the\\_long\\_run.html](http://www.slate.com/blogs/future_tense/2013/11/25/fda_letter_to_23andme_won_t_mean_anything_in_the_long_run.html).

<sup>209</sup> *Id.*