

Age of an Information Revolution: The Direct-to-Consumer Genetic Testing Industry and the Need for a Holistic Regulatory Approach

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TABLE OF CONTENTS

I.	INTRODUCTION	280
II.	BACKGROUND.....	284
	A. <i>The Cruellest Months</i>	284
III.	THE SPARSE LEGAL LANDSCAPE TODAY	289
	A. <i>The Genetic Information Nondiscrimination Act: The First Step</i>	289
	B. <i>Federal Agencies and the Lack of Defined Authority</i>	290
IV.	CURRENT SHORTCOMINGS IN INDUSTRY: CONSUMER INTERFACING.....	292
	A. <i>The Government Accountability Office's Sting Operation</i>	292
	B. <i>Medical History and Risk Prediction</i>	295
	C. <i>Inconsistent Risk-Prediction Standards and the Need for Uniformity</i>	297
V.	THE PROBLEM WITH INTERPRETATION OF GENOME-WIDE ASSOCIATION STUDIES.....	299

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	A.	<i>History of Genome-Wide Association Studies</i>	299
	B.	<i>Limitations of Genome-Wide Association Studies</i>	302
	C.	<i>Definitional Issues Facing Future Legislation</i>	306
VI.		MEDICAL DEVICE OR EDUCATION AND INFORMATION: HAVING YOUR CAKE AND EATING IT TOO	308
	A.	<i>The Purpose of Genetic Tests and Regulatory Scope</i>	308
	B.	<i>FDA Definition of a Medical Device and the Need for Line-Drawing</i>	309
VII.		THE PROPER INTERPRETERS AND BEARING THE RISK OF LIABILITY	311
	A.	<i>Insufficient Genetics Expertise Amongst Today’s Physicians</i>	311
	B.	<i>Learned Intermediary Doctrine and Standard of Care in a Novel Arena</i>	313
	1.	<i>A Parallel Problem</i>	313
	2.	<i>Genetic Tests: A Service or Product</i>	315
	3.	<i>Direct-to-Consumer Advertising and Interpretation</i>	316
	4.	<i>Applying the Learned Intermediary Doctrine and Weighing Responsibility</i>	319
VIII.		RECOMMENDATION: A HOLISTIC APPROACH TO IMPROVING THE DTC GENETIC TESTING INDUSTRY	325
	A.	<i>Meeting the Challenge of Emerging Technologies with a Combination of Solutions</i>	326
	B.	<i>A Legislative and Regulatory Approach To Extending GINA: Reining In Advertising and Creating Uniform Standards for Interpretation</i>	328
	C.	<i>Self-Regulatory Approach: The Carrot, Not the Stick</i>	334
	D.	<i>Educational Improvements</i>	336
IX.		CONCLUSION	339

I. INTRODUCTION

As direct-to-consumer (DTC) genetic tests become more available and affordable for the general public, a woman orders a DTC genetic test that gives her results indicating she may be at risk for ovarian cancer.¹ Shocked by the possibility of getting cancer, she makes an appointment to see a doctor. Based on the test results, she persuades her doctor to order a procedure to remove her ovaries—just to be safe.² What she did not understand is that the test results indicate a mere *possibility*—not *certainty*—that she would ever get cancer. It sounds like a nightmare. There was just one problem: it may not be true. The story appeared, without much verifying detail, in a *Washington Post* article that came out just days before a congressional hearing took place on July 22, 2010,

1. Rob Stein, *Genetic Test Mix-Up Reignites Regulation Debate: ‘Wild West’ of Commercial Interests Weighed Against the Risk of Stifling Innovation*, WASH. POST, July 17, 2010, at A1, available at 2010 WLNR 26703791.

2. *Id.*

to evaluate the practices of the DTC genetic testing industry.³ Nevertheless, the truth or falsity of this story may not ultimately be the most poignant part. The story sheds light on the great deal of interest and major concern surrounding this exciting, but fledgling, industry. The conflict cuts deep and wide.⁴ Unsubstantiated accounts like the one above have been called “fear-mongering” by those reluctant to see the industry stifled by overregulation or a takeover by the medical profession.⁵ Perhaps fear does play some part in this saga because genetic issues have always engendered Orwellian visions of a parade of horrors just over the horizon.⁶ Others foresee in such accounts a serious problem in the

3. See Daniel MacArthur, *Did Washington Post's Rob Stein Exaggerate Negative Stories About Personal Genomics?*, WIRED (July 21, 2010), <http://www.wired.com/wiredscience/2010/07/did-washington-posts-rob-stein-exaggerate-negative-stories-about-personal-genomics/>. MacArthur expressed skepticism about Food and Drug Administration (FDA) employee Alberto Gutierrez's account, noting it was mere hearsay that failed to describe, in any particularity, under what circumstances the story was true. *Id.* MacArthur also noted that the same employee had been quoted before by the same *Washington Post* reporter as saying that the FDA regarded the DTC tests “illegal.” *Id.*

4. Sivan Tamir, *Direct-to-Consumer Genetic Testing: Ethical-Legal Perspectives and Practical Considerations*, 18 MED. L. REV. 213, 214 (2010) (“[Direct-to-consumer] testing is subject to frequent and fierce criticism on several issues, including reduced safety and accuracy due to inadequate scientific evidence to support it, use of unaccredited laboratories, lack of quality assurance and regulation, insufficient clinical and analytical validity, and the potential to mislead consumers.” (footnote omitted)). See generally Marcy Darnovsky, “Moral Questions of an Altogether Different Kind:” *Progressive Politics in the Biotech Age*, 4 HARV. L. & POL'Y REV. 99 (2010) (discussing liberal and conservative political divides regarding the morality of emerging technologies).

5. See MacArthur, *supra* note 3.

6. See, e.g., Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 2(2), 122 Stat. 881, 882 (describing the historical fear of sterilization spurred by the developing genetics field in the early twentieth century in its legislative findings prefacing Genetic Information Nondiscrimination Act (GINA) legislation); Dov Fox, *Silver Spoons and Golden Genes: Genetic Engineering and the Egalitarian Ethos*, 33 AM. J.L. & MED. 567, 567–70 (2007) (discussing the emerging trend of designer babies and describing it as “new eugenics”); Maxwell J. Mehlman, *Will Directed Evolution Destroy Humanity, and if So, What Can We Do About It?*, 3 ST. LOUIS U. J. HEALTH L. & POL'Y 93 (2009) (discussing potential perils of genetic engineering). During the early twentieth century, when growing tissue culture was still a new technology, French surgeon Alexis Carrel claimed to have grown an immortal chicken heart from cultured cells—which was untrue of course—and said in exaggeration that the cells “would reach a volume greater than that of the solar system.” REBECCA SKLOOT, *THE IMMORTAL LIFE OF HENRIETTA LACKS* 61 (2010) (internal quotation marks omitted). The mood of the country went wild. *Id.*

The Literary Digest reported that the cells could have already “covered the earth,” and a British tabloid said they could “form a rooster . . . big enough today to cross the Atlantic in a single stride, [a bird] so monstrous that when perched on this mundane sphere, the world, it would look like a weathercock.”

legal gaping chasm the industry operates within, and they call for clear guidelines to prevent fraud and misrepresentation.⁷

Direct-to-consumer genetic testing has been conceptualized in a variety of ways. Some call it “recreational genomics.”⁸ Some suggest that these DTC companies engage in the “practice of medicine.”⁹ Still others call it “educational” and “informational.”¹⁰ These different conceptualizations highlight how ill-defined the scope of the industry is.¹¹ This is important because the different ways in which the industry is understood militate toward different modes of regulating the communication and interpretation of genomic test results that consumers receive.

The traditional model for disseminating personal biological information depends solely on members of the medical profession.¹² Today, however, the growing trend has been for individuals to make more choices

Id. (alteration in original). At the time, this false statement, coupled with Carrel’s maniacal ethos for white supremacy and the sensational reports surrounding Carrel’s work, damaged the public image of cell culturing. *See id.* at 59–62. It took time for the public to recover and recognize the beneficial uses for cell culturing, including now-common vaccines for viruses. *See id.* at 98. This example from history reminds us to approach new technologies with a sober, reasoned perspective.

7. Stein, *supra* note 1. *But see* Paula Tironi, *Pharmaceutical Pricing: A Review of Proposals To Improve Access and Affordability of Prescription Drugs*, 19 ANNALS HEALTH L. 311, 313 (2010) (“Drug manufacturers are threatened by developments in personalized medicine because genetic testing for drug effectiveness could lead to a smaller market share for their products.”). In considering the controversy surrounding DTC genetic testing, one must not forget about personal interests, such as Tironi describes, that are at stake.

8. Andrea Mechanick Braverman, *How the Internet Is Reshaping Assisted Reproduction: From Donor Offspring Registries to Direct-to-Consumer Genetic Testing*, 11 MINN. J.L. SCI. & TECH. 477, 494 (2010) (quoting Jane Kaye, *The Regulation of Direct-to-Consumer Genetic Tests*, 17 HUM. MOLECULAR GENETICS 180, 180 (2008)) (internal quotation marks omitted).

9. *See Direct-to-Consumer Genetic Testing and the Consequences to the Public Health: Hearing Before the Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce*, 111th Cong. 67 (2010) [hereinafter *DTC Hearing*] (statement of Rep. Bart Stupak, Chairman, H. Subcomm. on Oversight & Investigations) (preliminary transcript on file with the San Diego Law Review) (asking if sending a bag of supplements based on genetic test results is the practice of medicine); EnergyCommerce, *July 22, 2010—A Hearing on “Direct-to-Consumer Genetic Testing & Consequences to Public Health,”* YOUTUBE (July 20, 2011), http://www.youtube.com/watch?feature=player_embedded&v=c0YfMbZ6F0 (posting video coverage of the hearing).

10. *DTC Hearing*, *supra* note 9, at 76, 95 (statement of Ashley Gould, General Counsel, 23andMe).

11. *See* SEC’Y’S ADVISORY COMM. ON GENETICS, HEALTH & SOC’Y, DEP’T OF HEALTH & HUM. SERVS., U.S. SYSTEM OF OVERSIGHT OF GENETIC TESTING: A RESPONSE TO THE CHARGE OF THE SECRETARY OF HEALTH AND HUMAN SERVICES 51 tbl.2-2 (2008) [hereinafter *SACGHS REPORT*], available at http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf (outlining gaps in genetic testing oversight).

12. Braverman, *supra* note 8, at 494.

independent of medical providers.¹³ One explanation for this trend is that patients are reconceptualizing themselves as consumers.¹⁴ This trend is not so surprising given the American penchant for individual autonomy and free-market ideals.¹⁵ Individuals want to know more about their biology, and with advances in genetics, technology, and the rise of the Internet, they now have affordable, ready access to part of their genomic data.¹⁶ Most fittingly, the search to uncover the secrets of one's own unique genomic data is the pinnacle of the American individualist

13. *Id.* at 493–94; see also Allyson M. Rucinski, Note, *Finding the Middle Ground: Acuna v. Turkish and the New Jersey Supreme Court's Reaffirmation of a Doctor's Role Under the Doctrine of Informed Consent in the Digital Age*, 29 PACE L. REV. 797, 797 (2009) (“With information readily available at the touch of a button, people are constantly using the Internet to read about their medical conditions, diagnose their symptoms, discover new medical breakthroughs, and even obtain a list of potential medications. The days of a doctor being a patient’s primary source for medical information are gone.”).

14. See Janet L. Dolgin, *The Evolution of the “Patient”: Shifts in Attitudes About Consent, Genetic Information, and Commercialization in Health Care*, 34 HOFSTRA L. REV. 137, 175 (2005).

15. See *id.* at 175–77; see also Tamir, *supra* note 4, at 213 (noting DTC testing is seen by some individuals “as an enabling tool for exercising one’s autonomous quest for personal health information”). This trend has also arisen against the backdrop of a collective conceptual shift in the institutional architecture of medicine from close relationships with compassionate family physicians to large and impersonal health care conglomerates. Dolgin, *supra* note 14, at 140–41; see also Darnovsky, *supra* note 4, at 100–01 (discussing the political conflicts involved in cutting-edge technologies such as stem cell research). Darnovsky writes:

Unfortunately, two currents in recent liberal and progressive thought leave us ill equipped for these challenges. One is a tendency to embrace technological and scientific developments without adequate attention to the risks they pose and the deep impact that they can have on our politics and culture. The other is a reluctance to directly address moral controversies, especially when strongly held religious beliefs are in play.

Id. Perhaps these kinds of political conflicts and interests are at play in the reluctance to see the long-sacred domain of physicians encroached upon by outsiders.

16. Contrast this model, which is at the heart of the capitalist ideal, to the model of current healthcare. See Rick J. Carlson, *Preemptive Public Policy for Genomics*, 33 J. HEALTH POL. POL’Y & L. 39, 47 (2008). Carlson discusses his view of how the healthcare infrastructure developed, stating that employer-financed healthcare, Medicare, and Medicaid have essentially “lock[ed] us into a delivery system free from public monitoring.” *Id.* Essentially, he says, we took a deal for healthcare—as it then stood—in exchange for employment, and then we made another deal with providers, and this is how it stayed thereafter. *Id.* The DTC genetic testing industry offers the promise of personalized medicine of the future, which, if shaped by strong public policy decisions, could be a closer realization of free-market ideals. See *id.* at 50. As the current state of healthcare is in flux, it remains to be seen what new architecture of healthcare shall emerge from the partisan rubble.

ideal.¹⁷ However, this path of consumer freedom is fraught with new challenges.¹⁸ Aspects of the DTC industry, including the communication and interpretation of such tests, are largely unregulated, leading consumers to risk receiving incorrect, even fraudulent, information from those who may want to exploit the persuasive power that scientific information tends to have on lay individuals.¹⁹

In order to safeguard consumers and ensure the continued progress of a fledgling industry, determining how to interpret results and communicate them with consumers poses one of the most challenging and important tasks. In discussing the challenges the law faces in this area, this Comment will discuss: (1) consumer interfacing issues, such as in advertising and results analysis, faced by the genetic testing industry; (2) the methods DTC companies use in arriving at results and corresponding problems; (3) who may interpret and communicate results; (4) how the DTC genetic testing industry's activities relate to the claims made regarding test results; and (5) who should bear the burden of responsibility. Finally, this Comment recommends a holistic approach that would take into account regulatory, legislative, self-regulatory, and educational methods to making the DTC genetic testing industry safer, more reliable, and poised to incorporate future advances in knowledge and technology.

II. BACKGROUND

A. *The Cruellest Months*²⁰

The summer of 2010 heralded a new chapter in the genomics era and the corresponding rising legal issues that must be confronted. In May

17. Braverman, *supra* note 8, at 493.

18. See, e.g., Rucinski, *supra* note 13, at 797 (comparing how, in the past, the medical community deferred all medical decisionmaking to doctors because it considered patients ignorant of medicine and how, now, there is a paradigm shift in that the "reasonable patient" is now the "informed consumer").

19. See, e.g., Giovanni Frazzetto, *The Science of Online Dating*, 11 EMBO REP. 25, 25 (2010). GenePartner.com and ScientificMatch.com have taken advantage of the rise of DTC genetic testing to build businesses based on matching people with compatible genetic material and neurochemistry. *Id.* Needless to say, ignoring the traditional elements of falling in love has cast a suspicious shadow on these companies' minimalist reduction of human courtship.

20. When considering the events of summer 2010, even though it was not springtime, I was reminded of T.S. Eliot's poem *The Waste Land*, which begins:

April is the cruellest month, breeding
Lilacs out of the dead land, mixing
Memory and desire, stirring
Dull roots with spring rain.

T.S. ELIOT, *The Waste Land*, in *THE WASTE LAND AND OTHER WRITINGS* 38, 38 (2001) (1922). The themes of birth, death, and turmoil seemed especially apt; therefore, I owe my inspiration—even flight of fancy—to Eliot.

2010, Pathway Genomics announced in partnership with Walgreens that it would offer over-the-counter, do-it-yourself genetic testing kits.²¹ This was to be the first such test available to the general public for purchase from a drug store.²² It was thought that the tests would likely popularize genetic tests in a way never before seen.²³ Alarmed, the Food and Drug Administration (FDA) sent a warning letter in response prohibiting the arrangement and stating that these kits were medical devices requiring premarket FDA approval.²⁴ The FDA then sent letters to 23andMe, Navigenics Health Compass, deCODE Genetics, and fourteen other DTC genetic testing companies, notifying them that these tests fell under the FDA definition of a “medical device.”²⁵

Then, in June 2010, personal genomics company 23andMe announced that a mix-up at its lab resulted in ninety-six customers’ receiving results based on genetic data belonging to other customers.²⁶ Even though this seems like the ultimate failure in accurate communication—not to mention a potential privacy-breach nightmare—many customers expressed that they would not prefer more regulation, fearing loss of consumer

21. *DTC Hearing*, *supra* note 9, at 12–15 (statement of Rep. Henry A. Waxman, Chairman, H. Subcomm. on Oversight & Investigations).

22. Andrew Pollack, *Walgreens Delays Selling Personal Genetic Test Kit*, N.Y. TIMES, May 13, 2010, at B5.

23. *See id.* (noting that selling DTC genetic tests over the counter would make them more accessible).

24. *DTC Hearing*, *supra* note 9, at 15 (statement of Rep. Henry A. Waxman, Chairman, H. Subcomm. on Oversight & Investigations); *see also* Lauren B. Solberg, *Over the Counter but Under the Radar: Direct-to-Consumer Genetic Tests and FDA Regulation of Medical Devices*, 11 VAND. J. ENT. & TECH. L. 711, 718 (2009) (noting that by 2009, while the FDA claimed it was “within its statutory mandate to regulate [DTC] genetic tests,” it had declined to do so yet (citing *Who Regulates Genetic Tests?*, GENETICS & PUB. POL’Y CENTER (Feb. 27, 2006), http://www.dnapolicy.org/policy.issue.php?action=detail&issuebrief_id=10)). As of 2010, the FDA has taken a more active role, but the scope of its power remains unclear. *See infra* note 282.

25. *DTC Hearing*, *supra* note 9, at 15 (statement of Rep. Henry A. Waxman, Chairman, H. Subcomm. on Oversight & Investigations).

26. Alejandro Martínez-Cabrera, *Lab Mix-Up Exposes Potential Dangers*, S.F. CHRON., June 11, 2010, at A1, *available at* 2010 WLNR 11915507. This is not the first time these companies have been sent letters of alarm. *See* Tamir, *supra* note 4, at 234. In June 2008, the state of California’s Department of Public Health sent warning letters to thirteen DTC genetic testing companies warning them that offering these tests without a physician’s order ran contrary to California law. *Id.* The companies are still in business today because they were required to comply with California’s laws regarding testing performance, obtain licensing from California’s Department of Public Health, and obtain Clinical Laboratory Improvement Act (CLIA) certification. *Id.* This still does not address the need for clear, robust guidelines regarding interpretation and communication of results.

independence and potential rising, prohibitive cost.²⁷ Others voiced concern regarding overly paternalistic treatment by the government and opposed placing doctors and genetic counselors between customers and their genomic data, believing that customers are capable of self-policing the results; after all, they were the ones who caught the 23andMe results mix-up in the first place.²⁸

Although many consumers feel they have a right to freely access their own genomes, the federal government and members of the medical field have been harsh critics.²⁹ The government's concern stems from investigations revealing troubling practices. On July 22, 2010, the Subcommittee on Oversight and Investigations for the Committee on Energy and Commerce held a hearing on DTC genetic testing and the consequences to public health.³⁰ Centrally highlighted at the hearing, the Government Accountability Office (GAO) conducted an investigation into the practices of some DTC genetic testing companies, and the investigation showed disturbing quality-control issues, inconsistent interpretive standards, and even fraud.³¹ The GAO had initiated the investigation to determine the accuracy of statements regarding results and advertisements made by DTC companies, and its findings indicate a need for change.³²

Amid the firestorm of controversy battering the DTC genetic testing industry, another blow capped off the summer, coming from an unexpected place. The University of California, Berkeley sought to initiate the first mass voluntary genetic testing program for the incoming freshman class of 2014.³³ The program, called "Bring Your Genes to Cal," sought to

27. Martínez-Cabrera, *supra* note 26 ("It's taking away power from consumers and putting it where it's always been" (quoting 23andMe customer CeCe Moore) (internal quotation marks omitted)).

28. *Id.*

29. Aaron Saenz, *Genetic Testing Mix-Up at 23andMe, Another Blow to the Industry*, SINGULARITY HUB (June 9, 2010), <http://singularityhub.com/2010/06/09/genetic-testing-mix-up-at-23andme-another-blow-to-the-industry/>.

30. *See generally DTC Hearing, supra* note 9.

31. *See* GREGORY KUTZ, 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 (2010) [hereinafter GAO REPORT], available at <http://www.gao.gov/new.items/d10847t.pdf> (revealing, for example, that DNA submitted by one undercover investigator to four DTC companies yielded four different risk-prediction results regarding some of the same diseases).

32. *Id.*; *see infra* Part VII.B.3.

33. *See* Victoria Colliver, *Ethics of DNA Tests for Students Questioned*, S.F. CHRON., May 21, 2010, at C1, available at 2010 WLNR 10512685. *But see* Larry Gordon, *UC Berkeley's Plan To Test DNA Sparks Debate*, L.A. TIMES, June 1, 2010, at AA1 (reporting that some dispute the voluntariness of the program because students may feel pressured to conform with peers who decide to participate and may also not want to risk alienating future professors).

educate students about the promise of personalized medicine and to help students learn more about themselves.³⁴ The program would test for three genes associated with alcohol metabolism, folate absorption, and lactose metabolism.³⁵ Even though the chosen genes were relatively “innocuous” and many supporters defended the program, outcry over privacy concerns and the fear that students would modify their behaviors negatively based on results, such as by drinking more alcohol, fueled a backlash from opposing groups.³⁶ The genes were chosen not to uncover serious health risks but with an eye toward nutritional genomics.³⁷ About 700 students voluntarily signed up for the program and submitted samples through the mail.³⁸

On June 24, 2010, California’s Senate Education Committee defeated a bill that would have expressly circumscribed all University of California and Cal State schools’ ability to seek and use students’ DNA.³⁹ However, before the students could receive their results, the California Department of Health and Public Safety prohibited the University from providing individualized results to the students, asserting that the program amounted to medical research and needed to be conducted in a licensed laboratory, not by University technicians.⁴⁰ As a result, U.C. Berkeley

34. See Victoria Colliver, *DNA Program Altered*, S.F. CHRON., Aug. 13, 2010, at C1, available at 2010 WLNR 16146856.

35. See Colliver, *supra* note 33.

36. See Tamar Lewin, *College Bound, DNA Swab in Hand*, N.Y. TIMES, May 19, 2010, at A14 (reporting that although most U.C. Berkeley professors viewed the testing as harmless, some others, such as bioethicist George Annas of Boston University, viewed all genetic testing as potentially harmful); see also Editorial, *Bonding at Berkeley via DNA*, L.A. TIMES, June 14, 2010, at A14 (reporting that U.C. Berkeley took extraordinary precautions in allowing students to opt out and taking steps to maintain confidentiality—yet still advocating that learning something potentially uncomfortable is not a reason to shield students from information about themselves).

37. Lewin, *supra* note 36. The study was aimed at encouraging students to drink less, eat more leafy greens, and, if applicable, avoid dairy consumption. *Id.*

38. See Victoria Colliver, *DNA Test Flip-Flop Stirs Debate at Cal*, S.F. CHRON., Aug. 28, 2010, at C1, available at 2010 WLNR 17137289.

39. See A.B. 70, 2009–2010 Gen. Assemb., Reg. Sess. (Cal. 2009) (introducing, at the request of Assembly member Norby, that the bill be put into effect immediately because of U.C. Berkeley’s proposed genetic testing program); Lewin, *supra* note 36.

40. Larry Gordon, *Genetic Testing of Freshmen Cut Back*, L.A. TIMES, Aug. 13, 2010, at A A1; see Colliver, *supra* note 38. U.C. Berkeley had planned to have the samples analyzed through its own laboratories. Lewin, *supra* note 36. The participating students would be assigned a barcode and receive results anonymously through a website. Gordon, *supra* note 33. The samples would be destroyed afterward. *Id.* The University also planned on offering more detailed analyses through commercial companies as prizes for participation in a personalized medicine essay contest. *Id.* Despite these seemingly

modified its program to present results only in aggregate to those students who had already submitted samples.⁴¹

This brief foray into DNA testing and education implicates the need for better guidelines on how such test results may be presented.⁴² Up until now, such DNA testing had not been introduced into the educational sphere, but it may become more of an issue as DTC genetic testing companies become more established.⁴³ Aside from the obvious privacy concerns inherent in DNA testing,⁴⁴ the most fundamental issue is exactly how professionals should present these results to consumers, students, and others. Companies and professionals must use sufficient methods to communicate results in order to ensure consumers do not conflate risk prediction with reports merely indicating the existence or nonexistence of a genetic variant.⁴⁵

benign intentions, the director of the University of Pennsylvania's Center for Bioethics, Arthur L. Caplan, said that although he supports the program, it would have been better if the results were received through one-on-one counseling rather than through a website. *Id.*

41. See Gordon, *supra* note 40.

42. Although the crossroads of DTC genetic testing and academia is not the focus of this Comment, it is important to shed light on it for a few reasons. First, it shows why a holistic and flexible approach is needed because only such an approach will enable lawmakers to meet novel problems. Second, it is important to understand, broadly, how constantly and rapidly the science is developing and how public demand for this technology is growing.

43. The kind of genetic testing that aims to teach by using students, themselves, as the subjects of genetics-based course material is distinct from the myriad of other possible uses of genetic material in an academic or research setting. See, e.g., Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1069–70 (S.D. Fla. 2003) (holding that a medical researcher who is not therapeutically treating a patient owes no duty of informed consent for commercial use of biological samples taken from patients before patenting a gene discovered to be the source of disease); Joe Fore, *Moving Beyond "Gene Doping": Preparing for Genetic Modification in Sport*, 15 VA. J.L. & TECH. 76 (2010) (discussing the problem of gene doping in sports); Debra L. Greenfield, Greenberg v. Miami Children's Hospital: *Unjust Enrichment and the Patenting of Human Genetic Material*, 15 ANNALS HEALTH L. 213 (2006) (discussing the problem and boundaries of informed consent and patenting of products of research from human genetic material); Amy Harmon, *Dispute Highlights Risks in Use of Genetic Material*, N.Y. TIMES, Apr. 22, 2010, at A17 (discussing a dispute between the Havasupai Indians and Arizona State University regarding blood samples taken and analyzed for genetic disorders without fully informed consent).

44. See generally Sara Abiola, *The Genetic Information Nondiscrimination Act of 2008: "First Major Civil Rights Bill of the Century" Bars Misuse of Genetic Test Results*, 36 J.L. MED. & ETHICS 856 (2008); Perry W. Payne, Jr., *Genetic Information Nondiscrimination Act of 2008: The Federal Answer for Genetic Discrimination*, 5 J. HEALTH & BIOMED. L. 33 (2009).

45. See generally Lucia A. Hindorff et al., *Potential Etiologic and Functional Implications of Genome-Wide Association Loci for Human Diseases and Traits*, 106 PROC. NAT'L ACAD. SCI. 9362 (2009) (discussing genome-wide association studies (GWAS) and trait-disease associations). It is important to consider the difference between using an association as an explicit predictor of disease as opposed to simply noting the association.

III. THE SPARSE LEGAL LANDSCAPE TODAY

A. *The Genetic Information Nondiscrimination Act:
The First Step*

Little legal guidance currently exists regarding the communication of genetic test results.⁴⁶ Although biotechnology and science have progressed rapidly in the recent past, the law has been slow to catch up.⁴⁷ In 2008, Congress took the first step in regulating genetic information when it passed the Genetic Information Nondiscrimination Act (GINA), cosponsored by Senators Edward Kennedy and Olympia Snowe and signed into law by former President Bush.⁴⁸ Senator Kennedy went so far as to say that “GINA is the first major new civil rights bill of the new century.”⁴⁹ The legislation is quite narrow in scope, however.⁵⁰ GINA is narrowly tailored to eliminating discrimination based on genetic information by private- and public-sector employers, employment agencies, and insurance companies.⁵¹ The legislation delineates how employers can use and store genetic information and prohibits insurance companies from basing eligibility and premium rates on test results.⁵² Highlighting the extent of GINA’s narrow scope, even within the targeted domain of insurance, GINA does not prevent discrimination in the areas of long-term medical care and disability insurance.⁵³ Specifically, GINA protects individuals

46. Lee Black et al., *Genetic Testing, Physicians and the Law: Will the Tortoise Ever Catch Up with the Hare?*, 19 ANNALS HEALTH L. 115, 118 (2010).

47. See, e.g., *id.* at 118–19.

48. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (codified as amended in scattered sections of 26, 29, and 42 U.S.C.); Kathy L. Hudson, M.K. Holohan & Francis S. Collins, *Keeping Pace with the Times—The Genetic Information Nondiscrimination Act of 2008*, 358 NEW ENG. J. MED. 2661, 2661 (2008); see also H.R. 493, 110th Cong. (2008) (enacted) (giving background information describing the legislators’ motivations).

49. Hudson et al., *supra* note 48, at 2662 (quoting U.S. Senator Edward Kennedy) (internal quotation marks omitted).

50. Lauren Elizabeth Nuffort, *The Genetic Information Nondiscrimination Act of 2008: Raising a Shield to Genetic Discrimination in Employment and Health Insurance*, HEALTH LAW., June 2009, at 1, 16 (noting that it remains to be seen whether the gap left in GINA regarding life insurance, disability insurance, and long-term care will result in discrimination).

51. Daniel Schlein, *New Frontiers for Genetic Privacy Law: The Genetic Information Nondiscrimination Act of 2008*, 19 GEO. MASON U. C.R. L.J. 311, 313 (2009).

52. *Id.*

53. Amy Foster, Comment, *Critical Dilemmas in Genetic Testing: Why Regulations To Protect the Confidentiality of Genetic Information Should Be Expanded*, 62 BAYLOR L. REV. 537, 538 (2010); see also Bruce Patsner, *New “Home Brew” Predictive Genetic*

and their medical data—which could indicate predispositions toward certain illnesses—by prohibiting discrimination through use or solicitation of such data only in the above-named few categories.⁵⁴

Aimed at protecting privacy and preventing discrimination, certainly worthy goals, the legislation left a gaping hole in regulation regarding any other use of genomic information.⁵⁵ Notably, GINA does not indicate how genetic tests such as those employed by DTC genetic testing companies should be interpreted and communicated.⁵⁶ For this reason, it is important for Congress to galvanize the industry, academics, and regulatory agencies to work together in better structuring the industry by extending the legislation GINA started. This would be a preemptive move to setting up a new legal structure and will head off the temptation to solve problems only ad hoc.⁵⁷

B. Federal Agencies and the Lack of Defined Authority

Although federal regulation and guidance seem necessary, it is unclear which agency should lead the charge.⁵⁸ Two federal agencies share jurisdiction over regulating DTC tests; however, the boundaries of each agency's purview are too ill-defined to efficiently take on this challenge.⁵⁹

Tests Present Significant Regulatory Problems, 9 HOUS. J. HEALTH L. & POL'Y 237, 263 (2009) (“GINA does not apply to life insurance, disability insurance, [and] long-term insurance Nor do GINA’s health insurance provisions apply to people who are symptomatic or to ‘non-genetic’ predictive testing and information (also known as epigenetics).” (footnote omitted) (citing 122 Stat. 881)).

54. Sagit Ziskind, *The Genetic Information Nondiscrimination Act: A New Look at an Old Problem*, 35 RUTGERS COMPUTER & TECH. L.J. 163, 163–64 (2009).

55. SACGHS REPORT, *supra* note 11, at 51 tbl.2-2.

56. Congress likely could see the potential for serious constitutional problems on the horizon—what it did not address, the courts would have to muddle through alone. See, for example, *Norman-Bloodsaw v. Lawrence Berkeley Lab*, 135 F.3d 1260, 1264–65 (9th Cir. 1998), in which several employees challenged employment preplacement exams conducted by the University of California laboratory. The preplacement exams were aimed at uncovering markers for syphilis, pregnancy, and sickle-cell anemia. *Id.* The Ninth Circuit reasoned that such tests were nonconsensual because they were required for employment and were targeted at women and African-Americans. *Id.* at 1272–73.

57. See Payne, *supra* note 44, at 58–59. GINA was in part a response to accounts of discrimination. *Id.* at 40–41. One example of such discrimination was sickle-cell anemia research conducted on African-Americans without their consent. *Id.* at 40. Employment discrimination against railroad workers, who were genetically tested without their consent, also spurred on Congress to draft GINA. *Id.* at 40–41.

58. Andrew S. Robertson, *Taking Responsibility: Regulations and Protections in Direct-to-Consumer Genetic Testing*, 24 BERKELEY TECH. L.J. 213, 221–22 (2009).

59. See *DTC Hearing*, *supra* note 9, at 14 (statement of Rep. Henry A. Waxman, Chairman, H. Subcomm. on Oversight & Investigations). Furthermore, if there is a question as to whether deliberately false or misleading claims are being made, the Federal Trade Commission would need to step in. See *infra* Part VII.B.3.

The Clinical Laboratory Improvement Act of 1988 (CLIA) endows the Centers for Medicaid or Medicare Services (CMS) with the power to regulate the laboratories conducting DTC genetic tests.⁶⁰ It is not within the purview of the CMS, however, to regulate communications DTC companies make to consumers based on such tests.⁶¹ The FDA, on the other hand, has the power to regulate diagnostic tests considered to be medical devices.⁶² Unlike the CMS, the FDA can regulate communications, for instance those made through television commercials and labeling, but it can regulate claims related to DTC tests only if they are categorized as medical devices.⁶³ Presently, it is still unclear whether these tests fall under the definition of a medical device.⁶⁴ The FDA's role is potentially further limited by the categorization of DTC genetic tests as "laboratory-developed tests" (LDT), which the FDA does not automatically have the authority to regulate.⁶⁵ CMS regulates these tests

60. 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, 173 (2010) (discussing how CLIA governs certification of laboratories but "CLIA is not considered particularly on point for genetic testing as it 'does not address clinical validity or claims made by the laboratory regarding the tests'" (quoting *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, 81 AM. J. HUM. GENETICS 635, 636 (2007))); see *DTC Hearing*, *supra* note 9, at 14 (statement of Rep. Henry A. Waxman, Chairman, H. Subcomm. on Oversight & Investigations).

61. *DTC Hearing*, *supra* note 9, at 14 (statement of Rep. Henry A. Waxman, Chairman, H. Subcomm. on Oversight & Investigations) ("Under the Clinical Laboratory Improvement Act, CLIA, the Centers for Medicare and Medicaid Services, CMS, regulates the laboratories that conduct the testing but not the health claims made by genetic testing manufacturers."); see also Novy, *supra* note 60, at 173–74 (noting that CMS had considered creating a specialty category for regulating genetic testing but abandoned the idea in 2006).

62. See 21 U.S.C. § 321(h) (2006); *DTC Hearing*, *supra* note 9, at 14 (statement of Rep. Henry A. Waxman, Chairman, H. Subcomm. on Oversight & Investigations).

63. 21 U.S.C. § 352(r) (2006).

64. See 21 U.S.C. § 321(h); *DTC Hearing*, *supra* note 9, at 14 (statement of Rep. Henry A. Waxman, Chairman, H. Subcomm. on Oversight & Investigations). For a contrary and recent statement by the FDA that these tests do qualify as medical devices, see the numerous letters sent to various DTC genetic testing companies in June 2010. See *In Vitro Diagnostics*, FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm> (last updated Jan. 25, 2012) (hosting the numerous letters sent to various DTC genetic testing companies).

65. Solberg, *supra* note 24, at 711. In contrast, "test kits" are developed independent of the laboratories that use them and are not directly available to consumers; these tests are FDA-governed. *Id.* Except for one specific kind of laboratory-developed test (LDT) meant for diagnosing, treating, or preventing a group of specific diseases that the FDA has definite authority to oversee, Robertson, *supra* note 58, at 223 n.66, the FDA has only "enforcement discretion" as to LDTs developed in-house, *id.* at 223–24.

pursuant to the CLIA.⁶⁶ This means that, in most cases, these laboratory-developed tests are not subject to premarket FDA review before reaching the public.⁶⁷

With the involvement of the GAO and FDA in the most recent 2010 congressional subcommittee hearing, Congress seemed to imply that the FDA is best suited to lead the charge.⁶⁸ However, other key players, such as the Federal Trade Commission (FTC), industry leaders, and academics, should also play a role in fashioning an appropriate response to the regulatory problem.

DTC genetic tests occupy a gray area under the purview of these regulatory agencies. For that reason, any amendment to GINA that extends its scope must both recognize the necessity of these various agencies' collective, collaborative action and fashion a new category in which some of the risk-predictive testing clearly falls under FDA and FTC authority.⁶⁹

IV. CURRENT SHORTCOMINGS IN INDUSTRY: CONSUMER INTERFACING

A. *The Government Accountability Office's Sting Operation*

No matter which agency ends up leading the charge in regulating industry standards, agency officials will find no shortage of claims made by unscrupulous companies requiring vigilant handling. The July 2010 congressional hearing on the DTC practices highlighted several of the communicative problems inherent in the industry that are potentially harmful to consumers.⁷⁰ The hearing discussed the results of a joint effort, initiated in 2009, between members of the Energy and Commerce

66. Robertson, *supra* note 58, at 221–22.

67. Patsner, *supra* note 53, at 254–55. See generally Rebecca Antar Novick, Note, *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 (2008) (discussing in detail the regulatory bodies and functions).

68. See *infra* Part IV.C.

69. See, e.g., Amy L. McGuire et al., *Regulating Direct-to-Consumer Personal Genome Testing*, 330 SCIENCE 181, 181 (2010). Companies can forgo premarket FDA review by sending their LDTs to CLIA-certified laboratories. *Id.* To circumvent FDA review, a laboratory can use its own LDTs but cannot sell them to other laboratories. *Id.* FDA premarket review requires data-driven review for most tests introduced into the market, but the business model used by these companies may preclude such review. *Id.* This prevents a baseline assurance of quality throughout the DTC genetic testing industry that other drugs and medical devices must attain. See *id.*

70. To hear recorded audio of part of the GAO's sting operation, highlighting some of the more egregious offenses, see Usgao, *GAO: Undercover Contact with Direct-to-Consumer Genetic Testing Companies*, YOUTUBE (July 22, 2010), <http://www.youtube.com/watch?v=VJpN7-x3iSM&autoplay=1&rel=0&showinfo=0>.

Committee and the GAO to investigate the practices of the genetic testing industry.⁷¹ What the GAO discovered was disturbing.

First, the GAO report revealed potential false advertising problems.⁷² Online, television, or print advertisements are usually among the first communications that DTC genetic testing companies have with members of the public, and these advertisements may have a powerful effect on consumers.⁷³ These initial communications are critical because the claims that DTC genetic testing companies make to attract customers frame and delimit the scope of their businesses.⁷⁴ Regarding fraudulent or misleading advertising, the FTC would be the appropriate agency to police the bounds of claims made by DTC companies.⁷⁵ It is within FTC purview to regulate the unfair and deceptive practices relating to commercial activity and advertising.⁷⁶ However, aside from publishing a warning pamphlet for consumers, the FTC has yet to initiate an enforcement action against any of these companies.⁷⁷

Some of the claims made by certain companies have been egregious. For example, one company claimed it would tailor a nutritional supplement based on submitted DNA that would cure arthritis and prevent high cholesterol.⁷⁸ Not only was this claim absolutely false but the representative told the customer he could eventually stop taking his physician-prescribed cholesterol medication.⁷⁹ A representative from the same company told

71. *DTC Hearing*, *supra* note 9, at 4 (statement of Rep. Bart Stupak, Chairman, H. Subcomm. on Oversight & Investigations).

72. *See, e.g.*, GAO REPORT, *supra* note 31, at 15–16 tbl.2 (giving examples of deceptive marketing, misinformation, and questionable practices).

73. *See* Mark Bartholomew, *Advertising and Social Identity*, 58 BUFF. L. REV. 931, 943 (2010) (discussing the history of critics' view of how powerful advertising works upon the consumer's mind and how it, in some ways, even may shape our identities).

74. *But see id.* at 934 (discussing how the effects of advertising are likely a combination of both the message the advertiser hopes to convey and the message that the consumer subjectively reinvents).

75. *See DTC Hearing*, *supra* note 9, at 64 (statement of Dr. Jeffrey Shuren, Director, Center for Device and Radiological Health with the Food and Drug Administration).

76. KATHERINE DRABIAK-SYED, IND. UNIV. CTR. FOR BIOETHICS, DIRECT-TO-CONSUMER GENETIC TESTING (DTC): *PREDICTER LAW AND POLICY UPDATE* (2010), available at http://bioethics.iu.edu/index.php/download_file/view/87/.

77. *Id.* *See generally* FED. TRADE COMM'N, AT-HOME GENETIC TESTS: A HEALTHY DOSE OF SKEPTICISM MAY BE THE BEST PRESCRIPTION (2006), available at <http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea02.pdf>.

78. GAO REPORT, *supra* note 31, at 15 tbl.2.

79. *Id.* at 15–16 tbl.2. Another company claimed, falsely, that its tests and related products could repair damaged DNA. *Id.* at 16 tbl.2.

another undercover customer that Michael Phelps endorsed the company's tests and that the company was in talks with Lance Armstrong because his doctors thought the tests were "the most amazing thing they [had] ever seen."⁸⁰ These claims were also absolutely false—representatives for both Phelps and Armstrong stated that they had not even heard of the company before.⁸¹ It is important here to differentiate between the bottom-feeders in the industry and those that are respected leaders.⁸² Not all DTC companies engage in this kind of blatant deception, and the kinds of claims that companies make do vary.⁸³ The purpose of regulation should be to snuff out charlatans and set a single high standard for the remainder.

Second, the investigation revealed problems about the uniformity of the results. A secret shopper submitted DNA samples to three separate companies, and the same person received three different risk predictions for prostate cancer and hypertension.⁸⁴ The standard of review and analysis of samples, the approaches, and the results are, unsurprisingly, inconsistent because the DTC industry does not have uniform regulations to follow.⁸⁵ However, if risk predictions are to survive government scrutiny, the finding highlights the need for a consistent set of standards or, at the

80. *Id.* at 15 tbl.2.

81. *Id.*

82. See, for example, Joyce Y. Tung et al., *Efficient Replication of Over 180 Genetic Associations with Self-Reported Medical Data*, PLOS ONE, at 2, 3 figs.1 & 5 (Aug. 17, 2011), <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0023473>, for a study published in a peer-reviewed scientific journal in which 23andMe researchers used customer samples, with permission, and self-reported surveys regarding disease status to effectively replicate 180 genetic associations in a genome-wide association study. In another peer-reviewed publication, 23andMe researchers teamed up with the Parkinson's Institute and presented findings from the largest GWAS for Parkinson's disease to date—using data derived from its customer base—that revealed two previously unknown genetic associations for Parkinson's. Chuong B. Do et al., *Web-Based Genome-Wide Association Study Identifies Two Novel Loci and a Substantial Genetic Component for Parkinson's Disease*, PLOS GENETICS, 1–2 (June 23, 2011), <http://www.plosgenetics.org/article/info:doi/10.1371/journal.pgen.1002141>. In effect, the DTC genetic testing 23andMe is a hybrid: it not only provides consumers with a commercial service but also conducts research with consumer data, contributing to the body of scholarly scientific literature. Hybridization of this kind provides a beneficial model for the future of the industry.

83. See GAO REPORT, *supra* note 31, at 15–16 tbl.2 (summarizing the types of claims a variety of companies made during the GAO's sting operation).

84. *DTC Hearing*, *supra* note 9, at 10 (statement of Rep. Michael C. Burgess).

85. See, e.g., *id.* at 93–94 (statement of Ashley Gould, General Counsel, 23andMe). General counsel for 23andMe, Ashley Gould, agreed that consistent standards were needed across companies and explained that the reason why different DTC companies might reach different results was because predictive models that each company used were based on different standards. *Id.* Gould further explained that companies varied regarding which single-nucleotide polymorphisms (SNPs) they look for and what weight they give to any SNPs. *Id.* Moreover, she noted there were differences regarding which variants can be tested among the technologies implemented by various companies. *Id.*

very least, transparent disclaimers and understandable information about the way in which each company comes to its conclusions.⁸⁶

B. Medical History and Risk Prediction

The 2010 congressional hearing also discussed how a person's actual medical history sometimes did not match up with the risk prediction given for a condition.⁸⁷ It is important to note that this does not necessarily indicate shoddy science or methodology—a risk prediction is not synonymous with a diagnosis.⁸⁸ However, the finding highlights the need to effectively communicate what a risk prediction does and does not tell the consumer and also to offer the consumer an opportunity to opt out of receiving certain information that may be too upsetting.⁸⁹ This would best protect against miscommunication.

86. At least one company has published online material detailing how it arrives at results. See *For Scientists: White Papers*, 23ANDME, <https://www.23andme.com/for/scientists/#whitepapers> (last visited Mar. 6, 2012). Perhaps such disclosure should be required for all companies. Federal agencies could also look to what they have done in other industries. See, e.g., 21 U.S.C. §§ 321(ff), 343 (2006); Jennifer A. Gniady, Note, *Regulating Direct-to-Consumer Genetic Testing: Protecting the Consumer Without Quashing a Medical Revolution*, 76 *FORDHAM L. REV.* 2429, 2453 (2008) (describing the FTC's decision to require disclaimers in the dietary supplement industry).

87. See *DTC Hearing*, *supra* note 9, at 6 (statement of Rep. Bart Stupak, Chairman, H. Subcomm. on Oversight & Investigations) (expressing concern regarding a report that a donor in the GAO investigation received a report for prediction of decreased risk for heart disease when in actuality, he had a pacemaker implanted fourteen years ago to treat an irregular heartbeat).

88. See Teri A. Manolio, *Genomewide Association Studies and Assessment of the Risk of Disease*, 363 *NEW ENG. J. MED.* 166, 166 (2010) (noting that the manifestation of a disease—or complex trait—is due to a number of factors, including genetic and environmental factors, and that it may well be that no single factor need be required in every manifestation). To see an example of the confusion surrounding the difference between mere presence of a variant versus a diagnosis, see GAO REPORT, *supra* note 31. The GAO wrote in its report that the sting operation participants received “disease risk predictions that conflicted with their actual medical conditions”; for instance, a donor reported that he was told he was at decreased risk for heart disease when he already had a pacemaker. *Id.* Although companies need to rethink using “risk” verbiage, it is critical to realize that mere presence of a variant *does not* automatically lead to a set-in-stone diagnosis that one *will* or *will not* get a disease or condition in the future. See *infra* Part V. Therefore, we must move away from oversimplification, and we must move toward developing appropriate verbiage to accurately communicate what these tests suggest. The easiest way to do this, of course, is to simply avoid “risk” verbiage and communicate only strict facts.

89. For a discussion on the “right not to know,” see Tamir, *supra* note 4, at 228–29. Tamir discusses how the general public is often unaware of the dangers of being exposed to genetic information that is revealing and predictive, but “probabilistic” as

Another aspect of DTC genetic testing companies is that they may implicitly appear to suggest taking or not taking particular drugs based on the presence of genetic variants that have been linked to particular favorable or unfavorable reactions to drugs.⁹⁰ Although the revolutionary frontier in terms of personalized medicine will likely have its biggest impact in the area of drug predictions to tailor medical treatment for patients, the state of the science is not ready yet.⁹¹ Thus, even though association data should be acceptable, it is problematic if a consumer could interpret the results to mean that a commercial company is suggesting taking or not taking a drug merely based on associations between genetic variants.⁹²

well. *Id.* Many companies do not offer the option to essentially opt out of knowing such information, which deprives them of the right not to know. *See id.* However, some companies such as 23andMe offer an opportunity to opt out of knowing results for certain genetic variant reports by having the user click “see report.” *See* Shwu, *Health at 23andMe: Navigating Your Health Results*, SPITTOON (Dec. 1, 2010, 3:05 PM), <http://spittoon.23andme.com/2010/12/01/health-at-23andme-navigating-your-health-results/>. Although there is no express indication that the company’s purpose in including this feature was to expressly account for a right not to know, this is likely an unintended benefit, and the “see report” feature could be more widely implemented for diseases likely to be particularly devastating to a sensitive individual. *See also* Gaia Bernstein, *Accommodating Technological Innovation: Identity, Genetic Testing and the Internet*, 57 VAND. L. REV. 965, 987 (2004) (recounting the story of such an individual). Bernstein recounts the story of a woman in her mid-twenties who got tested for carrier-status of the neurological disease spinocerebellar ataxia type I, which has a typical onset of thirty to forty years old. *Id.* (citing Howard F. Taswell & Susan K. Sholtes, *Predictive Genetic Testing: A Story of One Family*, 17 FAM. SYS. & HEALTH 111, 115 (1999)). It ran in her family. *Id.* She ended up being a carrier, and when she was told that it would result in an immense pain for a period of decades leading up to her death, it impacted her profoundly. *Id.* She fell into depression, had trouble holding down jobs, and resented others who lacked such a formidable burden. *Id.* This story shows how much of a serious impact such knowledge can bring. For this reason, creating an opt-out system would be beneficial for certain diseases.

90. *See* GAO REPORT, *supra* note 31, at 15 tbl.2. In its sting operation, the GAO discovered that one company had told an undercover customer that its nutritional supplements would cure his arthritis and prevent high cholesterol and blood pressure. *Id.* The company representative also told the undercover customer that he could stop taking his prescription medications once he began the nutritional supplement regimen. *Id.* These statements were false and dangerous. *Id.*

91. Ann K. Daly, *Pharmacogenetics and Human Genetic Polymorphisms*, 429 BIOCHEMICAL J. 435, 445 (2010).

92. *See DTC Hearing, supra* note 9, at 5 (statement of Rep. Bart Stupak, Chairman, H. Subcomm. on Oversight & Investigations) (describing one website’s suggestion for a medical team to consider using a certain cancer drug, irinotecan, when genetic markers may indicate low risk of adverse drug reaction).

*C. Inconsistent Risk-Prediction Standards and the
Need for Uniformity*

There have been problems revealed about the manner in which companies communicated results to consumers and about corresponding claims that company representatives made to the consumer regarding results. In one case, even though the company did not test for *BRCA1* or *BRCA2*, both of which are associated with breast cancer, the company's representative told a consumer over the phone that because she received an above-average risk prediction, she was "in the high risk of pretty much getting" the disease.⁹³ There are two problems with this statement. First, the prediction is indisputably inaccurate because *BRCA1* and *BRCA2*, two genes routinely associated with breast cancer, were not even tested for.⁹⁴ This belies a need for consistent standards setting forth which variants must be tested for to make related claims; otherwise consumers may receive inaccurate or incomplete information that may lead to unnecessary tests, surgeries, and life choices—not to mention a good deal of worry. Second, the representative's statement shows a clear case where the communicated result amounts to a diagnosis because she told the consumer that the risk prediction signified that the disease would surely manifest.⁹⁵ In such a case, it is necessary to take into consideration the kinds of other factors, such as family health history, best medical practice, and the best interest of the patient's needs, which a medical professional has the expertise to consider.⁹⁶ This type

93. *Id.* at 10 (statement of Rep. Bart Stupak, Chairman, H. Subcomm. on Oversight & Investigations); *Transcript of Undercover Contact with Direct-to-Consumer Genetic Testing Companies*, GOV'T ACCOUNTABILITY OFFICE (July 22, 2010), http://www.gao.gov/videofiles/gao_10_847t/gao_10_847t.txt.

94. Katherine L. Nathanson et al., *Breast Cancer Genetics: What We Know and What We Need*, 7 NATURE MED. 552, 552 (2001) ("The most widely accepted model of breast cancer susceptibility is that it is due to a small number of highly penetrant mutations (such as in *BRCA1* and *BRCA2*) and much larger number of low-penetrance variants." (footnote omitted)); see also Alan E. Gutmacher & Francis S. Collins, *Genomic Medicine—A Primer*, 347 NEW ENG. J. MED. 1512, 1518 (2002) (discussing how *BRCA1* and *BRCA2* are common genes found to increase the risk of breast cancer).

95. See *supra* note 88 and accompanying text. Mutations in some genes, however, have a strong effect on manifestation of disease or, in other words, are "highly penetrant." Gregory Katz & Stuart O. Schweitzer, *Implications of Genetic Testing for Health Policy*, 10 YALE J. HEALTH POL'Y L. & ETHICS 90, 99 (2010). Highly penetrant genetic mutations, such as the mutation that causes cystic fibrosis, ensure a high likelihood that the disease will manifest. *Id.*

96. Cynthia Marietta & Amy L. McGuire, *Direct-to-Consumer Genetic Testing: Is It the Practice of Medicine?*, 37 J.L. MED. & ETHICS 369, 370 (2009).

of activity should fall to the FDA to regulate because of its inherently medical nature.⁹⁷

Congress must ensure that the industry is subject to consistent standards, and this entails analyzing each component of the industry in detail. If Congress chooses to allow the FDA to lead the effort in standardizing the industry, which appears to be its intent,⁹⁸ then Congress should ensure that the FDA confers with experts in the scientific and medical fields as well as leaders in the industry to decide on uniform standards.⁹⁹ At a minimum, Congress should work with the FDA to determine a procedure for establishing variants that must be tested for in order to make related assertions about what the presence of these variants means to a consumer. Then, the FDA should work with industry leaders to put forth standards for how to determine what counts as a low, average, or high risk prediction.¹⁰⁰ This should include the numbers of variants tested for and how much weight will be given to each variant. The FDA should also work with these companies to determine which activities are acceptable. Although recommending that a customer cease taking medication based on test results and instead take nutritional supplements is obviously unacceptable, disease-risk and drug-response predictions

97. See SACGHS REPORT, *supra* note 11, at 28 tbl.2-1 (outlining the potential various jurisdictions for different DTC genetic testing activities). In addition, it may be prudent to allow states to play a role in the future by refining any federal standards put out by establishing specific state tort standards.

98. See *DTC Hearing*, *supra* note 9, at 11 (statement of Rep. Michael C. Burgess) (“One might argue that greater Food and Drug Administration regulation of the results is needed [T]he FDA convened a public meeting to look at the broader issues of regulating the developed tests. I do want to hear from the Food and Drug Administration about their plans.”).

99. Uniformity at the federal level is important because if standards are left *only* for states to decide, then it will be impossible to achieve any level of uniformity for an industry that is inherently an interstate enterprise. See Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 2(5), 122 Stat. 881, 882–83 (describing a relevant, parallel concern in its findings prefacing GINA legislation).

Federal law addressing genetic discrimination in health insurance and employment is incomplete in both the scope and depth of its protections. Moreover, while many States have enacted some type of genetic non-discrimination law, these laws vary widely with respect to their approach, application, and level of protection. Congress has collected substantial evidence that the American public and the medical community find the existing patchwork of State and Federal laws to be confusing and inadequate to protect them from discrimination. Therefore Federal legislation establishing a national and uniform basic standard is necessary to fully protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies.

Id.; *cf.* text accompanying notes 96–97 (discussing the importance of the states and the FDA in the rulemaking process “because of its inherently medical nature”).

100. See McGuire et al., *supra* note 69, at 182 (noting that a risk-stratification approach is not currently in place).

are not so easy to deal with because so much disagreement abounds regarding whether these activities are truly medical in nature.¹⁰¹

V. THE PROBLEM WITH INTERPRETATION OF GENOME-WIDE ASSOCIATION STUDIES

A. History of Genome-Wide Association Studies

DTC companies use genome-wide association studies (GWAS) and candidate gene studies to analyze risk of diseases and drug interactions.¹⁰² To understand the interpretive and communicative problems inherent in the DTC industry, an understanding of how the industry arrives at its results is necessary. The problems with GWAS are part of what contributes to the varying interpretations of results that different companies arrive at for any given variant.¹⁰³ Also, the vast majority of lower “confidence”¹⁰⁴

101. See generally Marietta & McGuire, *supra* note 96 (discussing whether risk prediction amounts to the practice of medicine).

102. Quanhe Yang et al., *Using Lifetime Risk Estimates in Personal Genomic Profiles: Estimation of Uncertainty*, 85 AM. J. HUM. GENETICS 786, 786 (2009).

103. See, e.g., Thomas A. Pearson & Teri A. Manolio, *How To Interpret a Genome-Wide Association Study*, 299 JAMA 1335, 1335 (2008) (discussing the danger of false-positive results).

104. For the purposes of this Comment, I use the term *confidence* in the most general way, as defined by *Merriam-Webster* to mean “the quality or state of being certain.” *Confidence Definition*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/confidence> (last visited Mar. 6, 2012). This means the degree to which scientists are certain that gene *A* really is linked to the manifestation of trait *a*. So the lower the confidence, the less certain scientists are regarding the relationship between gene *A* and trait *a*. One of the problems inherent in the industry is the nonstandardization of terms such as *confidence*. To illustrate why I have chosen to construct a very general umbrella term, consider the following definitions that are all valid to some extent. The term *confidence* in the context of *confidence intervals*, a term referenced in several scientific articles on GWAS, points to the statistical relationships—expressed and arrived at by statistical analyses of genetic information—in GWAS between a gene and a trait. See generally Hua Zhong & Ross L. Prentice, *Bias-Reduced Estimators and Confidence Intervals for Odds Ratios in Genome-Wide Association Studies*, 9 BIostatistics 621 (2008) (analyzing confidence intervals statistically). One company, 23andMe, uses the term *confidence* in yet another way. It expressly points out that it does not discuss confidence intervals in the statistical context during consumer interfacing, although it does consider confidence intervals separately as it analyzes data. Mike Macpherson et al., *White Paper 23-01: Estimating Genotype Specific Incidence for One or Several Loci*, 23ANDME, https://23andme.https.internapcdn.net/res/pdf/f6Jjz_mcXDI0BTfj-EA9tw_23-03_Vetting_Genetic_Associations_2011_08.pdf (last revised Aug. 25, 2011); see Brian Naughton & Shirley Wu, *White Paper 23-03: Guidelines on Vetting Genetic Associations*, 23ANDME, https://23andme.https.internapcdn.net/res/pdf/f6Jjz_mcXDI0BTfj-EA9tw_23-

associations between genetic variants and phenotypes (expressed traits) result from these GWAS as well.¹⁰⁵ Only after understanding the underlying nature of these tests can regulatory agencies and lawmakers arrive at the best solution to protect consumers as well as the industry.¹⁰⁶ With technological and scientific advances becoming more complex, an interdisciplinary approach may be necessary for effective and thoughtful lawmaking.¹⁰⁷ Although the DTC genetic testing companies are not operating illegally,¹⁰⁸ these companies need to standardize the way in which they present results and communicate methods for arriving at results. One way to accomplish this is for Congress to draft clear definitions that assign appropriate levels of oversight to the various activities the industry engages in.¹⁰⁹ Understanding how GWAS are used helps determine the type of information that companies should be required to disclose to the consumer.

Genome-wide association studies, built upon the foundation of genomics and genetics, have followed from major milestones like the completion of the Human Genome Project in 2003, which sequenced and assembled the entire human genome.¹¹⁰ Genomics approaches trait investigation by

03_Vetting_Genetic_Associations_2011_08.pdf (last revised Aug. 25, 2011). Rather, it gradates the term *confidence* in a scale of one-to-four “stars” indicating the following:

A report containing an association derived from a sample size of at least 750 cases is given three gray stars, 100 to 750 cases is given two gray stars, and fewer than 100 cases is given one gray star. . . . Established Research reports, which typically contain associations that have been independently replicated in large studies, are given a ranking of four gold stars.

Id. at 10. Because there are so many ways to understand the term *confidence*, the bottom line is that the layman’s understanding of terms such as *confidence* needs to be at the forefront of decisionmakers’ minds, and there is a need for standardization in what exactly this term—just one among many—should mean to consumers.

105. The limitations of GWAS include potential false-positive results, incomplete understanding of gene function, insensitivity to rare variants, requirement for large sample size, environmental factors, possible biases for case and control selection, and genotyping errors. Pearson & Manolio, *supra* note 103, at 1343.

106. See Vence L. Bonham, Foreword, *Living in the Genetic Age: New Issues, New Challenges*, 3 ST. LOUIS U. J. HEALTH L. & POL’Y 1, 9 (2009) (“Living in the genetic and genomic age clearly presents new issues and challenges for the law, and requires the legal profession to consider the intersection of law and science in new ways.”).

107. See Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342, 373 (2004) (arguing for a pluralized approach to decisionmaking that celebrates bringing in a diversity of experience and expertise).

108. See *supra* Part III.B.

109. See *infra* Part V.C.

110. *All About the Human Genome Project*, NAT’L HUM. GENOME RES. INST., <http://www.genome.gov/10001772> (last updated Dec. 13, 2010). Another important development for the growth of GWAS was the International Research Consortium’s launch of the International HapMap Project in 2002. Press Release, Nat’l Insts. of Health, Int’l Consortium Launches Genetic Variation Mapping Project (Oct. 2002), <http://www.genome.gov/10005336>. DNA was to be collected from individuals in Nigeria, Japan,

identifying gene variants and considering how they lead to variation in gene function and, ultimately, phenotype.¹¹¹ The human genome consists of all genetic material in a cell, which means twenty-three pairs of chromosomes located in the nucleus as well as a small chromosome located in each mitochondrion.¹¹² Genetics, in contrast, is the study of how single genes affect traits.¹¹³ Genome-wide association studies search for associations between hundreds or even thousands of genetic variations, usually single-nucleotide polymorphisms (SNPs), and diseases.¹¹⁴ Such studies allow screening for a number of diseases or traits all at one time, not limited to determining whether a single gene is associated with a particular disease.¹¹⁵

Genome-wide association studies have provided researchers with a powerful tool to search for the genetic influences responsible for complex diseases¹¹⁶ and genetic bases for drug reactions.¹¹⁷ Such diseases are distinct from single-gene diseases because the causal factors are often much more complicated—the causes can be linked to a combination of both environmental and genetic factors.¹¹⁸ Genome-wide association studies have revolutionized the way scientists research the causes of disease and have opened up enormous potential for finding genetic causal factors that once remained completely mysterious.¹¹⁹ Due to the increasing

China, and the United States in order to analyze associations between genetic variants and disease. *Id.* The HapMap Project was conceived as a large, population-level method of speeding discoveries in medical genetic research. The Int'l HapMap Consortium, *A Second Generation Human Haplotype Map of Over 3.1 Million SNPs*, 449 NATURE 851, 851 (2007).

111. Guttmacher & Collins, *supra* note 94, at 1512.

112. W. Gregory Feero, Alan E. Guttmacher & Francis S. Collins, *Genomic Medicine—An Updated Primer*, 362 NEW ENG. J. MED. 2001, 2004 (2010).

113. See Guttmacher & Collins, *supra* note 94, at 1512; see also Katz & Schweitzer, *supra* note 95, at 99 (distinguishing single-gene diseases as “monogenic” as opposed to diseases caused by multiple genes as “polygenic”).

114. Feero et al., *supra* note 112, at 2004–05 (defining common terms in the glossary such as SNPs, which are variations of a particular gene in a genetic sequence).

115. Manolio, *supra* note 88, at 173.

116. *Id.* at 166.

117. See Daly, *supra* note 91, at 435 (discussing how GWAS have uncovered certain genetic associations for adverse drug reactions to the liver, skin, heart, and muscle).

118. Manolio, *supra* note 88, at 166.

119. See, e.g., Douglas F. Easton et al., *Genome-Wide Association Study Identifies Novel Breast Cancer Susceptibility Loci*, 447 NATURE 1087, 1087 (2007) (describing a genome-wide association study to identify four possible causative genes that may be in part responsible for breast cancer and hypothesizing that further alleles could be found using a similar approach); Gilles Thomas et al., *Multiple Loci Identified in a Genome-Wide Association Study of Prostate Cancer*, 40 NATURE GENETICS 310, 310 (2008)

potential of GWAS, the past five years have yielded an explosion of findings linking genetic variants to over eighty diseases, including various cancers.¹²⁰

B. Limitations of Genome-Wide Association Studies

Although GWAS have aided in advancing science and ultimately, medical care, the general methodology behind such association studies also has serious limitations that must be recognized in order to fully determine what DTC genetic tests can and cannot tell consumers.

The first major limitation is the strength of the association between the genetic variants and the investigated trait. The relative strength of the association is often fairly weak.¹²¹ Many causal factors of the diseases or conditions that GWAS investigate are complex; unlike single-gene traits, the explanations for complex traits will likely involve multiple genetic loci and, perhaps, environmental factors.¹²² Because there can be such a multitude of associations, most of which may or may not be known, the relevance of any one association may be relatively small or moderate.¹²³ The lifetime risk of the incidence of a disease in a population often depends on many issues including genotype frequencies, differing genetic variants across populations, and gene-gene and gene-environment interactions.¹²⁴

(describing methods using GWAS narrowing down four-out-of-nine suggestive loci possibly linked to prostate cancer, which could be useful for risk prediction in certain individuals); Psychiatric GWAS Consortium Coordinating Comm., *Genomewide Association Studies: History, Rationale, and Prospects for Psychiatric Disorders*, 166 AM. J. PSYCHIATRY 540, 546–48 (2009) (explaining that GWAS have been helpful and will be instrumental in the future for finding genetic variants linked to psychiatric disorders such as autism, bipolar disorder, and schizophrenia).

120. See Manolio, *supra* note 88, at 166. See generally Hindorff et al., *supra* note 45 (reporting creation of an online catalog of associations based on the results of published GWAS); *A Catalog of Published Genome-Wide Association Studies*, NAT'L HUM. GENOME RES. INST., <http://www.genome.gov/26525384> (last updated Mar. 3, 2012) (cataloging published GWAS).

121. See Manolio, *supra* note 88, at 166; Feero et al., *supra* note 112, at 2003–05 (“Most SNPs associated with common diseases explain a small proportion of the observed contribution of heredity to the risk of disease—in many cases less than 5 to 10%—substantially limiting the use of these markers to predict risk.”).

122. Manolio, *supra* note 88, at 167 (explaining that a genome-wide association study led to discovering thirty variants associated with Crohn’s disease and over forty variants to date for type 1 diabetes).

123. Yang et al., *supra* note 102, at 786.

124. *Id.*

A second limitation is that researchers may obtain false-positive associations that may lead researchers to incorrectly draw associations.¹²⁵ Part of eliminating false-positive results is to look at results across pooled, various GWAS.¹²⁶ If a functional causal variant, which is actually direct proof of causality as opposed to merely an association, cannot be discerned, then the next-best alternative is to replicate the association across multiple populations.¹²⁷ An attractive, but false-positive, association can be the result of improper methodology and can sometimes be difficult to quickly catch.¹²⁸ If such mistaken associations are difficult to catch even by the well-trained eye, trusting that the public can discern the strength of associations may prove to be too optimistic. Without restructuring the way the industry is able to sell the scope of its service and results, there will be too much room for error and misrepresentation.¹²⁹

The third limitation in GWAS is that to bolster the strength of the association between genetic variants and the investigated disease or trait, such studies depend upon differences in population-dependent risk factors. In assessing lifetime risk of developing the disease trait, differences across populations and ethnicities can be important.¹³⁰ As researchers continue to generate data, most GWAS to date have been conducted across white populations.¹³¹ This neglects potentially notable risk differences in other races for particular disease incidence.¹³² Some traits, such as diabetes, are more prone to differences across populations than others.¹³³ Accordingly, when evaluating lifetime risk, it is important to

125. See Manolio, *supra* note 88, at 167 (describing a multitiered approach to narrowing down to a manageable and feasible amount the large number of SNPs tested in a genome-wide association study as useful for minimizing false-positive results).

126. *Id.*

127. *Id.*

128. See, e.g., Paola Sebastiani et al., *Genetic Signatures of Exceptional Longevity in Humans*, *SCIENCE* (July 1, 2010), <http://www.sciencemag.org/cgi/content/abstract/science.1190532v2> (finding, through improper methods, inaccurate associations between genetic variants and longevity, which prompted *Science* to issue a retraction); Tina Hesman Saey, *Critics Point to Flaws in Longevity Study*, 178 *SCI. NEWS* 10 (2010), available at http://www.sciencenews.org/view/generic/id/61050/title/Deleted_Scenes_Critics_point_to_flaws_in_longevity_study (commenting on the Sebastiani error).

129. See *infra* Part VII.B.3.

130. One research group describes its study of breast cancer where it found “3-fold differences . . . even within white populations.” Yang et al., *supra* note 102, at 791.

131. See *id.* at 791, 793.

132. *Id.* at 793.

133. *Id.* at 792.

consider and properly convey the “appropriate population incidence rates” to avoid misleading the receiver of genetic test results.¹³⁴

Already, the lack of diverse population studies has affected the DTC industry. Some consumers have requested and received refunds from companies because they received sparse results—they were members of ethnic groups not yet well studied.¹³⁵ Without full and clear disclosure before purchasing the kit and service, nonwhite consumers may be misled into purchasing a service for which they will receive few results or will receive results based on population studies not ideally applicable to them.¹³⁶ Noting that an individual does or does not have a genetic variant associated with a trait may be innocent, but simplistically assigning a risk level based on the presence or absence of a variant in the absence of diverse population studies may mislead the unwary consumer who has little background knowledge and who could be spending hundreds of dollars on a test.¹³⁷ Although addressing genetic results in terms of racial classification might bring up the old fear of reinforcing—or even reintroducing—a new kind of racial stereotyping, it not only is one valid factor to consider but will inevitably lead to improved understanding of what genetic test results ultimately reveal.¹³⁸

The foregoing limitations illustrate that determining any individual’s true risk of developing a disease may not always be so simple. Without fully informing consumers about such limitations, the DTC industry

134. *Id.*

135. *See DTC Hearing, supra* note 9, at 74 (statement of Gregory Kutz, Managing Director, Forensic Audits and Special Investigation, Government Accountability Office) (noting that two companies, deCODE and Pathway Genomics, had already given refunds for minorities who had purchased tests).

136. *See id.* at 61–62 (statement of Gregory Kutz, Managing Director, Forensic Audits and Special Investigation, Government Accountability Office).

137. *See id.* at 23 (statement of Rep. Donna M. Christensen, Member, H. Subcomm. on Oversight & Investigations)

The gross underrepresentation of African Americans and other minorities in clinical trials has impacted the kind of information we could receive from the kind of genetic testing generally offered. It is my understanding that, because of this, results may come back with no information on some of the diseases that cause some of the major health disparities. And this is after the client has paid for information that they don’t get.

Id.; *see also* Gniady, *supra* note 86, at 2444 (noting that tests can be hundreds, and even thousands, of dollars).

138. *See* Bernstein, *supra* note 89, at 991 (noting that genetic information is distinct from ordinary medical information because it “renders individuals as innately different, thereby becoming a dangerous tool in the hands of those seeking to discriminate and stigmatize”); David Wasserman, *The Justifiability of Racial Classification and Generalizations in Contemporary Clinical and Research Practice*, 9 *LAW, PROBABILITY & RISK* 215 (2010) (acknowledging the general fear of regressing to racial stereotyping but discussing the relationship between the presence of genetic markers and racial classification in terms of limitations and uses for risk assessment).

risks misleading consumers about what test results really mean.¹³⁹ Contrary to what some harsh critics say, the risk is not that the results of genetic tests are meaningless or the work of the proverbial “snake oil salesman”; to believe such accusations is to commit a grievous harm upon future generations.¹⁴⁰ The danger lies in selling the results to mean something different from what they truly reveal, not that they are all “snake oil.” These tests are meaningful in that they show curious consumers small pieces of a larger puzzle in the genetic determination of traits.¹⁴¹ It is still useful and interesting to know that one has a common genetic variant associated with a disease—it simply is not a diagnosis that one will exhibit that related complex trait.¹⁴²

139. See Feero et al., *supra* note 112, at 2009 (noting, for instance, that because in every twenty tests ordered there may be a false-positive result, it will be a challenge to “separat[e] the wheat from the chaff”).

140. Some members of Congress had a very visceral reaction to the existence of DTC genetic testing companies. The following comments illuminate the need for better understanding amongst all interested parties. See *DTC Hearing*, *supra* note 9, at 51 (statement of Rep. Parker Griffith, Member, H. Subcomm. on Oversight & Investigations).

I don’t think that the companies that are in question here would, if they disappeared tomorrow, would impact the scientific community and our desire to do research into genetics. . . . I don’t think that is really a discussion here. . . .

This is all bogus. This is nothing more than the snake oil salesman revisited again in a high-tech community and in a high-tech way.

Id. However, such fears are not new—Skloot describes how the reputation of an immortal cell line, a rare discovery, had an uphill battle with the public because the image of cell culturing in the early twentieth century was already marred from the publicity missteps made by imprudent scientists and media. See SKLOOT, *supra* note 6, at 61–62. Skloot writes, “Tissue culture was the stuff of racism, creepy science fiction, Nazis, and snake oil. It wasn’t something to be celebrated. In fact, no one paid much attention to it at all.” *Id.* at 62. It was considered “snake oil,” but today, we owe the polio vaccine, advances in chemotherapy, cloning, gene-mapping, and in vitro fertilization to that same technology. *Id.* at 2. History, pocked with scars of fear and hubris, instructs us to choose our words wisely.

141. See, e.g., FED. TRADE COMM’N, *supra* note 77, at 2 (agreeing that the presence of genetic variants is only one piece of the puzzle and stating that family background, medical history, and environment should not be discounted).

142. Manolio, *supra* note 88, at 166 (explaining that associations for complex traits may have limited effect on incidence of disease and few may be absolutely necessary to determine incidence of disease); see also MAX BLACK, “The Identity of Indiscernibles,” in METAPHYSICS: CONTEMPORARY READINGS 104–13 (Michael J. Loux ed., 2001). Black describes the problem of whether or not two things with qualitatively-the-same features share identity. *Id.* Speaking analogously, here, possession of a variant is not the same as trait expression, but the misunderstanding seems to be that they *are* the same. The key is in removing oneself from the misapplication of Black’s paradox.

C. Definitional Issues Facing Future Legislation

The passage of GINA was one small step toward developing a body of genetics law, but without more guidance, even its scope of definitions is too narrow to account for the problems that the public and the industry face.¹⁴³ For instance, Congress defined *genetic test* as merely “analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.”¹⁴⁴ This definition lacks the specificity necessary to apply it to the DTC genetic testing industry.¹⁴⁵ The most troubling word in this definition is *analysis*. Many activities could be called “analysis” by different objective observers. Actually observing the biological material could qualify as analysis, but so could inspecting the data and deriving conclusions from it. The definition, as it stands, may preclude differentiation between in-depth analysis of someone’s risk for disease as opposed to more innocent uses such as ancestry analysis. The difference has to do with a wide spectrum of activity: everything from deriving sophisticated conclusions bordering on medical diagnoses to simple observation that one has a genetic marker at all.

The definition for *genetic services* under this chapter is just as unhelpful. It defines *genetic service* as one of three things: “(A) a genetic test; (B) genetic counseling (including obtaining, interpreting, or assessing genetic information); or (C) genetic education.”¹⁴⁶ Here, it seems that if all interpretation falls under the umbrella of genetic counseling, then what the DTC companies engage in is just that, genetic counseling. But it must be remembered that these definitions were drafted for GINA’s employment discrimination chapter, and as of yet, neither GINA nor any other existing statute has a section specifically addressing the DTC industry’s activities. Thus, whether Congress really would conclude that the general definition of *genetic test* would include all analyses, even of ancestry or simple traits, and whether such activities could be called

143. See Payne, *supra* note 44, at 36 (noting that in coming up with definitions for GINA, it became clear that defining such terms as *genetic condition* and *genetic information* was quite difficult). Likely, coming up with precise definitions for the purposes of the DTC genetic testing industry will require splitting hairs as well.

144. 42 U.S.C. § 2000ff(7) (Supp. IV 2010).

145. The definition is quite general and broad, so it lacks the specificity to account for the various types of genetic test results the industry generates. See *The Genetic Information Nondiscrimination Act: Hearing on H.R. 493 Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 110th Cong. 3 (2007) (statement of Rep. Nathan Deal, Member, H. Subcomm. on Health of the H. Comm. on Energy & Commerce). Representative Deal expressed serious concern that the definition for *genetic test* was much too broad in that it may include routine tests not contemplated by the legislation. *Id.*

146. 42 U.S.C. § 2000ff(7).

“genetic counseling,” is still open to interpretation. It seems as though Congress would be not especially concerned about ancestry but very concerned about risk prediction.¹⁴⁷ This highlights the need for Congress to continue the legislation it began in GINA.

Congress should reconsider the definitions utilized within the scope of the DTC genetic testing industry.¹⁴⁸ If Congress were to draft a new chapter of GINA-like legislation, it must start from the very beginning and draft new definitions that will clearly address the complex activities of this industry.¹⁴⁹ Otherwise, Congress will be fitting the DTC industry in a Procrustean bed, running the risk of quashing this fledgling industry through too stringent and ill-fitting legislation.¹⁵⁰

One way to formulate a definition of a genetic test would be to specifically include within the legislative definition any higher level analysis that would include risk prediction or drug-reaction prediction.¹⁵¹ Another possibility would be to categorize and define all risk-predictive tests as necessarily “medical,” thereby immediately giving the FDA direct purview over these tests.¹⁵² The former option is preferable because it addresses the specific differences of the varied activities that

147. See Arthur L. Beaudet, *Which Way for Genetic Test Regulation? Leave Test Interpretation to Specialists*, 466 NATURE 816, 817 (2010). This is because the risk involved in allowing activities such as ancestry services based on genetic tests is relatively low—people are unlikely to make severely life-changing decisions based on such information.

148. See generally 42 U.S.C. § 2000ff (Supp. IV 2010) (listing definitions in the context of genetic information and employment discrimination).

149. See David Castle, *Genomic Nutritional Profiling: Innovation and Regulation in Nutrigenomics*, 9 MINN. J.L. SCI. & TECH. 37, 38 (2008), for a reason to resist the temptation to apply old law to new technologies. Castle discusses the regulatory issues of nutrigenomics, which is an offshoot of the genetic testing technology at issue in this Comment. *Id.* Castle worries that “in light of the evolution of the science and commercial developments, regulators must cope with the problem of fitting existing regulations and regulatory practices to nutrigenomics even though these regulations existed prior to the advent of this field.” *Id.* at 39. This worry, which is pertinent to the umbrella issue of DTC genetic testing regulation, is one main reason why the solution must encompass a holistic approach, not a single regulatory scheme. See *infra* Part VIII. Because technology in this area changes so quickly, lawmakers need a novel *modus operandi*, not an ad hoc regulation of the particular technology in question. *Id.*

150. See Gail Javitt, *Which Way for Genetic Test Regulation? Assign Regulation Appropriate to the Level of Risk*, 466 NATURE 817, 818 (2010) (“In such a fast-changing landscape, striking the right balance between protecting the public and promoting innovation is crucial.”).

151. McGuire et al., *supra* note 69, at 182 (calling this approach risk-stratification).

152. James P. Evans & Robert C. Green, *Direct to Consumer Genetic Testing: Avoiding a Culture War*, 11 GENETICS MED. 568, 569 (2009).

the DTC industry engages in. It would help to conceptually differentiate the activities and direct the appropriate amount of oversight to each activity. The latter option is a one-size-fits-all approach that may not adequately address the idea that risk-predictive tests can be presented upon a wide spectrum—as merely educational or as equivalent to medical diagnoses.¹⁵³

VI. MEDICAL DEVICE OR EDUCATION AND INFORMATION: HAVING YOUR CAKE AND EATING IT TOO

A. *The Purpose of Genetic Tests and Regulatory Scope*

One of the issues surrounding how the industry should be regulated is determining whether the purpose of genetic tests is medical or purely educational and informational.¹⁵⁴ Most of the DTC companies post disclaimers stating that they do not purport to give medical advice.¹⁵⁵ In the past, these companies have adamantly maintained that what they offer is a service not intended for diagnosis or treatment and that this precludes classification as a medical device.¹⁵⁶ However, these companies are communicating mixed signals to consumers. One company tells consumers to “take charge of your health and wellness today”¹⁵⁷ while another company tells consumers they can “learn if certain medications work with your genetic makeup”¹⁵⁸ and that results “can help point you toward better health and well-being.”¹⁵⁹ Based on these companies’ own claims, the FDA had determined that these tests qualify as medical devices under the Food, Drug, and Cosmetic Act (FDCA).¹⁶⁰

153. See Lobel, *supra* note 107, at 379–80 (describing a one-size-fits-all approach as a negative feature of a traditional form of governing).

154. *DTC Hearing*, *supra* note 9, at 131–32 (statements of Rep. Bart Stupak, Chairman, H. Subcomm. on Oversight & Investigations, and Ashley Gould, General Counsel, 23andMe).

155. See, e.g., *Frequently Asked Questions*, DECODEME, <http://www.decodeme.com/faq#interpreting3> (last visited Mar. 6, 2012) (“[I]t is not a medical test, and it is by no means a substitute for professional medical advice, genetic counseling, diagnosis, or treatment.”).

156. *DTC Hearing*, *supra* note 9, at 77 (statement of Dr. James Evans, Editor-in-Chief, *Genetics in Medicine*).

157. 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/> (quoting message from 23andMe’s website to consumers).

158. NAVIGENICS, http://www.navigenics.com/visitor/genetics_and_health/ (last visited Mar. 6, 2012).

159. *Id.*

160. *DTC Hearing*, *supra* note 9, at 14 (statement of Rep. Bart Stupak, Chairman, H. Subcomm. on Oversight & Investigations).

*B. FDA Definition of a Medical Device and the Need for
Line-Drawing*

The FDCA, in relevant part, defines *medical device* as follows:

[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which 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 intended to affect the structure or any function of the body of man or other animals . . .¹⁶¹

It is possible for DTC companies to avoid being classified as *medical* and continue marketing their products as purely educational, and this would not be entirely undesirable—after all, access to such information can improve the general scientific education of lay people.¹⁶² However, if industry members chose to do this, they would need to rethink risk prediction and drug-response prediction activities or be subject to FDA oversight for these particular activities.¹⁶³ As one company maintains, it is possible that the sole purpose of these tests could be for educational and informational purposes.¹⁶⁴ If that is the case, however, then no claims about changing a consumer’s health habits or choices should be made; otherwise these tests appear to fall squarely within the purview of the FDA definition.¹⁶⁵ Instead of reducing an individual’s genomic data for any given variant down to muddied classifications such as higher, average, and decreased risk, these companies should simply state that any given variant has been associated with a phenotypic trait, or condition, based

161. Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h) (2006) (emphasis added).

162. *Contra* Tamir, *supra* note 4, at 219 (stating that despite the possible educational benefit to the public, DTC genetic tests should not be offered to an ill-prepared and genetically illiterate public). One wonders if the genetic illiteracy of the general public is overstated given both the self-selecting group of consumers who seek out DTC tests and their desire to learn and understand the meaning of the tests.

163. *See* Solberg, *supra* 24, at 718–19. The FDA has asserted before that it is within its statutory right to regulate DTC genetic tests, but it had declined to try to do so until the summer of 2010. *Id.*

164. *DTC Hearing*, *supra* note 9, at 95 (statement of Ashley Gould, General Counsel, 23andMe); *see* Carlson, *supra* note 16, at 39. Carlson warns that it is “both shallow and short sighted” to merely deem the DTC genetic testing technology as a “leviathan of biotechnology.” *Id.* It seems like a tautology to say that the DTC genetic testing technology can be used to teach the public about genetic testing technology, but because it is so poorly understood, this is a necessary reality if lawmakers and the public desire meaningful progress. *See id.*

165. 21 U.S.C. § 321(h).

on the current state of science.¹⁶⁶ It is key to distinguish the foregoing risk and prediction results from other kinds of results these companies present, such as those having to do with ancestry, which can clearly be for educational purposes and remain relatively uncontroversial.¹⁶⁷ From the DTC companies' perspective, avoiding being classified as medical is imperative if they want to keep touting the educational benefits of their services.¹⁶⁸ From the consumers' perspective, avoiding these classifications preserves consumers' ability to learn about their own biological information in the context of current science. This is an educational benefit, perhaps even a right, worth protecting.¹⁶⁹

Despite the optimistic message most of the DTC industry sends to consumers regarding the usefulness of its tests for improving their health, the scope of what these tests reveal should be more accurately conveyed. Although it is clear that advances in genomics will offer medical professionals new clinical tools via genetic test results, the industry is still in the "Stone Age of genomic medicine."¹⁷⁰ Accordingly, most test results are of little to no *clinical* use currently.¹⁷¹ Even with high hopes for the field of personalized medicine of tomorrow, it may still be

166. See Guttmacher et al., *supra* note 112, at 1518. The authors discuss how a person who has certain mutational variants, such as *MODY 1*, *MODY 2*, or *MODY 3*, which increase risk for diabetes, has a high likelihood of disease. *Id.* However, they also characterize the relationship between variant and disease as an *association*, an association that when viewed on a population-scale level, may have a one-in-one-thousand prevalence of actually manifesting. *Id.*

167. See Marietta & McGuire, *supra* note 96, at 369–70 (noting how it seems clear that ancestry and simple-trait analysis, such as for bitter taste perception, are not medical).

168. See *infra* Part VIII.D.

169. *Id.* Indeed, many customers of DTC companies seem to be satisfied with the *type* of services they receive, which may indicate that many consumers do not expect medical services. Keyan Salari, *The Dawning Era of Personalized Medicine Exposes a Gap in Medical Education*, 6 PLOS MED. 1, 1 (Aug. 25, 2009), <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000138>. This indicates that despite the naysayers, educational benefit is perceived by consumers as an actual benefit worthy of protection. In order to protect this benefit, the DTC industry needs to steer clear of any possibility of supplanting traditional medical care. Reframing the way the industry communicates with consumers is a key way to do this. See *supra* notes 154–59 and accompanying text.

170. Barbara J. Evans, *Seven Pillars of a New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era*, 85 NOTRE DAME L. REV. 419, 461–62 (2010).

171. Manolio, *supra* note 88, at 173; see Gniady, *supra* note 86, at 2431 (“In most scenarios, the results are even less useful than having a cholesterol-level reading taken, where there are a variety of options for treatment of dangerously high cholesterol levels, such as exercise, diet changes, prescription medicine, or even surgical intervention when necessary.”).

apt to say genomic information is an end in itself rather than a means to better healthcare.¹⁷²

VII. THE PROPER INTERPRETERS AND BEARING THE RISK OF LIABILITY

A. *Insufficient Genetics Expertise Amongst Today's Physicians*

Despite the interpretation issues with DTC tests and the lack of clarity regarding whether they are or should be labeled medical devices, critics have called for the necessary inclusion of a physician for interpretation of genetic test results.¹⁷³ It is not clear, however, that currently limiting the gatekeepers of this information to physicians or other healthcare professionals would serve a beneficial purpose.¹⁷⁴ Although likely to change, the majority of the medical profession is currently ill-equipped to accurately interpret genomic sequencing results.¹⁷⁵ As more and more patients begin bringing in their test results from DTC companies, several studies have highlighted the limitations posed by insufficient knowledge of this developing field.¹⁷⁶ In one survey conducted on nearly 6000 people, 64% of respondents reported receiving no educational material

172. See Tamir, *supra* note 4, at 214 (noting that some additional limitations keeping DTC tests from being of more clinical utility is the fact that many markers are yet undiscovered, their contributions to disease and interactions yet unknown). *But see* Evans, *supra* note 170, at 461 (stating that knowing genomic information “as an endpoint” purely for its own sake is a thing of the past (quoting Wylie Burke, *Integrating Genetic Technology into a Health Care System*, in *DIFFUSION AND USE OF GENOMIC INNOVATIONS IN HEALTH AND MEDICINE: WORKSHOP SUMMARY* 33, 33 (Lyla M. Hernandez rapporteur, Nat'l Academies Press 2008))).

173. See, e.g., Marietta & McGuire, *supra* note 96, at 372 (calling for the inclusion of licensed healthcare providers).

174. *Compare DTC Hearing*, *supra* note 9, at 65 (statement by Jeffrey Shuren, Director, Center for Devices and Radiological Health at the Food and Drug Administration) (agreeing that consumers would be better off if a physician or equivalent medical professional were involved in the process), *with* Salari, *supra* note 169, at 1 (“While some physicians are equipped to interpret such reports, evidence indicates that the majority of physicians are poorly prepared to deal with issues related to genetics and genomics, and that such patients are likely to be disappointed and misinformed.”).

175. Salari, *supra* note 169, at 1; *see* Gniady, *supra* note 86, at 2443. In the 1990s, there was great concern over the inability of physicians to analyze earlier versions of genetic tests and a substituted reliance on commercial laboratories to interpret them. *Id.* With the increase in the genetic testing industry, this concern comes up once again in the context of more complex technology. *Id.*

176. Salari, *supra* note 169, at 1.

on genetics from the healthcare provider they relied on most.¹⁷⁷ In another study, one third of physicians failed to correctly interpret the results of single-gene tests conducted for colorectal cancer.¹⁷⁸ Given that a single-gene test is an older technology than the GWAS, which are more advanced cutting-edge tools, and that over 30% of physicians still have trouble even with single-gene tests, the prospect of handing over the mantle of responsibility solely to this group is troubling.¹⁷⁹ Another study showed that over half of physicians surveyed answered basic genetic testing questions incorrectly even after a genetic testing company sent out educational mailers.¹⁸⁰ Despite this educational gap present across physicians, it is important to note that 68% of physicians surveyed expressed a desire to become better versed in the interpretation of genetic testing.¹⁸¹ Regardless, these surveys show that limiting interpretation to physicians is not the answer and, in fact, oversimplifies the problem.¹⁸² The assumption that only physicians are equipped in terms of both knowledge and ability to interpret and communicate these results may lead to the same dangers of misinformation, misrepresentation, and even fraud, which the industry is struggling to ward off.¹⁸³

This lack of qualified professionals in the medical field to offer medical advice based on such test results is compounded by the fact that

177. *Id.*

178. *Id.*

179. See Tamir, *supra* note 4, at 220 (“[R]egrettably, healthcare professionals themselves often lack familiarity with the basic principles of genetics, thereby hindering the application of genomic advances into routine patient care.”); see also Rucinski, *supra* note 13, at 822. The lack of medical know-how regarding genetic tests is troubling considering “[d]octors have both ‘ethical and legal obligations to stay abreast of the latest research in their fields.’” *Id.* (quoting Lars Noah, *Medicine’s Epistemology: Mapping the Haphazard Diffusion in the Biomedical Community*, 44 ARIZ. L. REV. 373, 404 (2002)).

180. Salari, *supra* note 169, at 1.

181. *Id.*

182. Genetics-savvy physicians are not the only professionals in short supply—so too are other genetics professionals who could help communicate what results mean to consumers seeking more pointed medical advice. *Id.* at 2 (noting only 3300 genetics professionals are licensed in the United States by the American Board of Medical Genetics or the American Board of Genetic Counseling); see also Tamir, *supra* note 4, at 220 (“[T]here is a perceptible lack of physicians and genetic [counselors] trained in the field of genetics.”). Furthermore, although the GAO argues these tests may not be of any substantial benefit to the consumer, note that even the GAO acknowledged the comments made by the SACGHS regarding the current state of the medical field: “[Practitioners] cannot keep up with the pace of development of genetic tests. . . . [and] are not adequately prepared to use test information to treat patients appropriately. . . .” SACGHS REPORT, *supra* note 11, at 72, 187; GAO REPORT, *supra* note 31, at 16 tbl.2.

183. See *DTC Hearing*, *supra* note 9, at 22–23 (statement of Rep. Donna M. Christensen, Member, H. Subcomm. on Oversight & Investigations). While admitting bias because, as a physician, Christensen has always disliked DTC advertising, she expressed that a healthcare professional is needed for analysis and guidance in order to ward off “wrong assumptions and wrong decisions.” *Id.*

several DTC companies explicitly claim that they are not providing medical advice and instead suggest taking the results to a physician for advice.¹⁸⁴ This places a heavy burden on the medical profession. It potentially shifts the burden of liability for faulty interpretation from the companies to doctors, who may be ill-equipped to interpret the results.¹⁸⁵

B. Learned Intermediary Doctrine and Standard of Care in a Novel Arena

1. A Parallel Problem

Although the medical profession is currently ill-equipped to consistently and reliably interpret DTC genetic tests for its patients, critics of the DTC genetic testing industry are calling for the profession's involvement.¹⁸⁶ However, the consequences of this could be catastrophic. Under the "learned intermediary doctrine," involvement of doctors in this way may

184. See, e.g., *Terms of Service*, 23ANDME, <https://www.23andme.com/about/tos/> (last visited Mar. 6, 2012); *Frequently Asked Questions*, *supra* note 155; *Terms and Conditions*, NAVIGENICS, http://www.navigenics.com/visitor/what_we_offer/our_policies/terms_conditions/ (last visited Mar. 6, 2012).

185. See Rucinski, *supra* note 13, at 797–98. This kind of burden shifting would impact the degree of liability exposure a doctor would face, especially as to the scope of duty imposed on doctors to sufficiently inform their patients as to medical decisions. See JUDICIAL COUNCIL OF CAL., CIVIL JURY INSTRUCTIONS: CACI (2012) [hereinafter CACI], available at http://www.courts.ca.gov/partners/documents/caci_2012_edtion.pdf (giving jury instructions for litigation in California medical malpractice cases). CACI lays out the jury instruction for standard of care of health professionals in California as follows:

[A/An] [*insert type of medical practitioner*] is negligent if [he/she] fails to use the level of skill, knowledge, and care in diagnosis and treatment that other reasonably careful [*insert type of medical practitioners*] would use in the same or similar circumstances. This level of skill, knowledge, and care is sometimes referred to as "the standard of care."

[You must determine the level of skill, knowledge, and care that other reasonably careful [*insert type of medical practitioners*] would use in the same or similar circumstances]

Id. § 501, at 408 (alterations in original) (giving the jury instruction for "standard of care for health care professionals"); see also *id.* § 502, at 411 (giving the jury instruction for medical specialists). The standard of care in California gives deference to what another medical practitioner would have done in a similar situation. This does allow doctors some leeway. However, given that commercial genetic testing is so new, it would be difficult to determine what is and is not appropriate for doctors to do when a patient brings an outside test to them. If they choose to interpret the test, interpret it incorrectly, and it is shown in court that the doctor's "skill, knowledge, and care" in handling this situation was not on a par with that of others in a similar situation, this may mean trouble.

186. See generally Marietta & McGuire, *supra* note 96.

serve to shield the DTC companies from liability and shift it to physicians.¹⁸⁷

Traditionally, the learned intermediary doctrine shifts the burden of informing patients about the risks of prescription drugs from pharmaceutical companies to physicians.¹⁸⁸ Under this doctrine, physicians are held liable for informing patients about potential adverse effects of drugs because physicians are in a position to determine whether a drug or treatment will be right for an individual patient.¹⁸⁹ Pharmaceutical drug and medical device manufacturers, in contrast, satisfy their duty to patients by properly warning prescribing physicians.¹⁹⁰

In a suit based on DTC genetic tests, this learned intermediary defense could be applicable,¹⁹¹ potentially implicating any number of players as

187. This assumes, of course, that the status of the DTC genetic tests could be covered under the learned intermediary doctrine. Normally, courts have declined to extend the learned intermediary doctrine to drugs or medical devices available to the public without a prescription. DRUG AND MEDICAL DEVICE LIABILITY DESKBOOK § 2.03[3] (2006). This stems both from the idea that the manufacturer has an actual and intended direct manufacturer-consumer relationship and from the lack of a physician's involvement. *Id.* (citing *Torsiello v. Whithall Labs., Div. of Home Prods. Corp.*, 398 A.2d 132, 138 (N.J. Super. Ct. App. Div. 1979)). In the DTC genetic test situation, however, if physicians are to play a greater role as the FDA and Congress would prefer, then the requirement to adequately warn physicians and to impute liability to those physicians may be appropriate.

188. Robertson, *supra* note 58, at 232.

189. *Id.* ("Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. . . . The choice he makes is an informed one. . . . Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a 'learned intermediary' between manufacturer and consumer." (quoting *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974))).

190. *Id.*

191. *Id.* at 233. The *Restatement* sets out the learned intermediary doctrine as follows:

- (a) A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect. A prescription drug or medical device is one that may be legally sold or otherwise distributed only pursuant to a health-care provider's prescription.
- (b) For purposes of liability under Subsection (a), a prescription drug or medical device is defective if at the time of sale or other distribution the drug or medical device:
 - (1) contains a manufacturing defect as defined in § 2(a); or
 - (2) is not reasonably safe due to defective design as defined in Subsection (c); or
 - (3) is not reasonably safe due to inadequate instructions or warnings as defined in Subsection (d).
- (c) A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks

the learned intermediary.¹⁹² This learned intermediary could be the consulted doctor or the DTC company providing the information, or perhaps even the consumer could be considered the sole learned interpreter.¹⁹³

2. Genetic Tests: A Service or Product

To begin a discussion of the learned intermediary doctrine¹⁹⁴ as applied to DTC genetic testing, one preliminary question to address is whether DTC tests are services or products. The categorization of these tests impacts the degree of liability that involved parties may face.¹⁹⁵ The DTC genetic testing industry characterizes itself as a service, and not as a products manufacturer.¹⁹⁶ If it were characterized as a product manufacturer, it would be subject to strict products liability for any faulty

and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

- (d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
 - (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
 - (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.
- (e) A retail seller or other distributor of a prescription drug or medical device is subject to liability for harm caused by the drug or device if:
 - (1) at the time of sale or other distribution the drug or medical device contains a manufacturing defect as defined in § 2(a); or
 - (2) at or before the time of sale or other distribution of the drug or medical device the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons.

RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (1998).

192. See Randy J. Prebula, Note, *The Promise of Personalized Medicine: Regulatory Controls and Tort Influences in the Context of Personalized Risks and Benefits*, 26 J. CONTEMP. HEALTH L. & POL'Y 343, 368 (2010).

193. *Id.*

194. For a general discussion on the learned intermediary doctrine, see *infra* Part VII.B.

195. See, e.g., Prebula, *supra* note 192, at 370 (“Because clinical laboratories have historically been viewed by FDA and CMS as service providers, any basis for liability on the part of the laboratory would likely need to be established, for example, by negligence in the reasonable provision of medical services.”).

196. *DTC Hearing*, *supra* note 9, at 81 (statement of Ashley Gould, General Counsel, 23andMe); *contra* Patsner, *supra* note 53, at 238–39 (discussing DTC genetic tests as medical products).

products.¹⁹⁷ Thus, the manufacturer of a test that yields faulty results, which in turn could cause a doctor to misdiagnose a patient, would be subject to strict products liability.¹⁹⁸ However, if DTC genetic testing companies are viewed only as service providers, simply offering to conduct a test and provide results would not yield strict liability, and instead, some negligence of a duty of reasonable care would need to be shown.¹⁹⁹

Even viewing the genetic tests as products, rather than services, another consequence of the DTC marketing is that it may weaken the availability of the learned intermediary defense for manufacturers because it prevents physicians from readily standing between consumers and manufacturers.²⁰⁰ If physicians are expected to be involved, however, this is more problematic than easily imputing a doctor as the undisputed learned intermediary.²⁰¹ Much more than in previous generations, consumers now have ample access to medical and scientific information due to the advent of the Internet, so that consumers can be viewed as better informed.²⁰² If the product itself is questionable, however, in many cases even an informed consumer would depend on a physician or someone with more expertise to assess the risks and benefits of a medical course of action, and in turn this intermediary would bear the risk of liability for unreasonable uses of the tests.²⁰³

3. *Direct-to-Consumer Advertising and Interpretation*

A readily available industry watchdog—whether it is the FDA, the FTC, or physicians—is needed to protect against consumer fraud. This

197. Prebula, *supra* note 192, at 370. Subjecting DTC providers to strict products liability would mean that the manufacturer would be liable without any finding of fault. *See id.*

198. *Id.*

199. *See id.* (“This could be demonstrated by evidence that the laboratory mishandled or misidentified specimens in a way that could lead to inaccurate test results being reported to doctors and patients.”).

200. *See id.* at 368. It is the actual and intended direct relationship, without a physician’s involvement, that has traditionally excluded the learned intermediary defense for manufacturers in nonprescription situations after all. *See supra* note 187 and accompanying text.

201. *See id.*

202. Rucinski, *supra* note 13, at 797. *Contra* Marietta & McGuire, *supra* note 96, at 373 (noting that although “[c]onsumers should be free to purchase information,” it is likely that consumers will misinterpret information given to them).

203. Prebula, *supra* note 192, at 368. The rise of the Internet has also facilitated online communities where consumers can share and compare personal genomic data with others. *See* Sandra Soo-Jin Lee, *Social Networking in the Age of Personal Genomics*, 3 ST. LOUIS U. J. HEALTH L. & POL’Y 41, 48 (2009). 23andMe, for instance, allows members to post comments, share stories, and get in touch with relatives to discuss and compare genetic findings. *See* 23ANDME, <https://www.23andme.com/> (last visited Mar. 6, 2012).

is especially true because of the prevalence of DTC advertising that targets the consumer directly with the goal of enticing business.²⁰⁴ When consumers see a business's claims and advertisements, they receive only filtered information.²⁰⁵ The FTC has authority to guard against this type of false and misleading advertising.²⁰⁶ It has yet to institute any enforcement actions against DTC companies, however, only issuing a consumer warning pamphlet in 2006.²⁰⁷ According to the FTC, a false advertisement is misleading in a material respect "[if] it either inaccurately represents the product or fails to disclose material facts."²⁰⁸ The FTC also states that if a claim relates to public health or safety, such a claim is presumptively material.²⁰⁹ Even with such a presumption, and with monetary, health, and safety damages in the balance, the FTC has yet to apply this presumption to DTC genetic tests.²¹⁰ As a result, although some companies have taken the initiative to educate their customers,²¹¹ DTC

204. Gniady, *supra* note 86, at 2444. Most objections focus on heavy marketing campaigns targeted at drawing in business without regard to the efficacy or necessity of marketed genetic tests. *Id.*

205. *See id.* at 2443–44 (explaining that DTC advertising for genetic tests is very similar to the DTC advertising drug companies employ by transmitting their messages by newspaper, magazine, and television); *see also* Blumer v. Acu-Gen Biolabs, Inc., 638 F. Supp. 2d 81 (D. Mass. 2009) (discussing the Baby Gender Mentor class action based on false advertising of prenatal genetic tests). In *Blumer*, Acu-Gen Biolabs marketed the Baby Gender Mentor Kit as a test to discern the gender of a fetus by detecting gender-specific fetal blood in the mother's blood. *Id.* at 84. It was falsely advertised as "99.9% accurate" and "infallibly accurate in foretelling the gender of a healthy baby." *Id.* (internal quotation marks omitted). When confronted by the consumers about inaccurate results, the CEO of the company gave a variety of disconcerting reasons for the inaccuracies including fetus chromosomal abnormalities, vanishing twin syndrome, and infant deformities. *Id.* The women feared they had gotten unnecessary and dangerous procedures, including multiple ultrasounds, amniocentesis, and chromosomal testing, as a result of the testing and results. *Id.* Because many of the procedures were not covered by insurance, the women shouldered the costs themselves. *Id.*

206. Gniady, *supra* note 86, at 2453.

207. 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) (citing FED. TRADE COMM'N, *supra* note 77).

208. *Id.* at 76 (citing 15 U.S.C. § 55(a)(1) (2006)).

209. *Id.* at 84.

210. *Id.*

211. *See, e.g., Health Reports: Complete List*, 23ANDME, <https://www.23andme.com/health/all/> (last visited Mar. 6, 2012) (describing in detail scientific information about diseases and including citations); *For Scientists: White Papers*, *supra* note 86 (describing 23andMe's methodology for arriving at results).

genetic testing companies are not required to disclose the scientific bases of their tests.²¹²

The nature of DTC advertising affects the learned intermediary doctrine and the degree to which the defense should be available to DTC companies. Courts may be less willing to allow DTC companies the advantage of a learned intermediary defense because these companies directly market to and manage test results for the consumer without requiring any intermediary.²¹³ Furthermore, because of the demonstrated deficit in genetics expertise of the medical profession, it is likely inadequate to depend solely on traditional intermediaries, such as physicians, to clear up advertising confusion.²¹⁴ These companies possess the best knowledge about their own tests, methods, and results, so it would be fair for liability to be imputed back to them—as opposed to consulted doctors—unless they reframe their advertising and results.²¹⁵ In fact, over the years, the growth of DTC advertising has weakened the learned intermediary defense, and courts have supported shifting the burden back to manufacturers.²¹⁶

Although a governmental entity is not the traditional archetype of a learned intermediary, one can think of a governmental entity, such as the FTC, as a potential type of watchdog *proxy* for a traditional intermediary in order to force companies to stay honest. Because genetic tests are highly technical, consumers would benefit from a governmental entity, which has the means to assemble experts and promulgate uniform guidelines to ensure the accuracy of advertising claims and prevent puffery.²¹⁷ In other industries, such as the dietary supplement industry, the FTC requires disclaimers stating that the supplement is not FDA-

212. Drabiak-Syed, *supra* note 207, at 84.

213. See Gniady, *supra* note 86, at 2444 (noting that in light of recent successful attempts to deregulate drug advertisements and in light of recent free speech trends, objections to DTC advertising would likely be unavailing). Furthermore, even if physicians were involved and the manufacturer adequately warned the physician about the product, aggressive promotion—“overpromotion”—could undercut the warnings, making the manufacturer liable. *Love v. Wolf*, 38 Cal. Rptr. 183 (Ct. App. 1964); DRUG AND MEDICAL DEVICE LIABILITY DESKBOOK, *supra* note 187, § 2.06.

214. See *supra* Part VII.A.

215. See Prebula, *supra* note 192, at 368 (discussing the policy rationale for traditional application of the learned intermediary defense). But see Marietta & McGuire, *supra* note 96, at 372–73, for an interesting discussion about company-employed physicians and genetic counselors with regard to whether such a relationship triggers the traditional doctor-patient relationship.

216. See Robertson, *supra* note 58, at 233 (citing *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245 (N.J. 1999)). *Perez* held that because Wyeth engaged in a nationwide campaign to directly market its drug to consumer women, not physicians, it had a duty to sufficiently warn the women about potential side effects. *Perez*, 734 A.2d 1245.

217. See Gniady, *supra* note 86, at 2453–54 (discussing how the FTC does have authority to regulate false and misleading advertising).

approved and “not intended to diagnose, treat, cure, or prevent any disease.”²¹⁸ Perhaps one place to start improving advertising is to require a similar disclaimer to be prominently displayed on DTC genetic testing industry websites and advertisements. Some companies have disclaimers posted on their website,²¹⁹ but they are often buried in the fine print of their terms-and-conditions page.²²⁰ If advertising is vague, however, it is unclear “how learned any learned intermediary can be,” when labeling by the manufacturer is insufficient, the disclaimer too difficult to find, or the test too complex.²²¹ The inherent complexity of the industry defies traditional intermediaries and traditional solutions—this is why governmental agencies are well positioned to craft uniform guidelines for companies to follow from the very outset.

4. Applying the Learned Intermediary Doctrine and Weighing Responsibility

The reason why governmental agencies need to step in becomes clear with the following example that considers a scenario in which a DTC genetic test customer engages a physician to play the role of a learned intermediary in interpreting test results. A consumer brings in results of a DTC genetic test to a private physician’s office. The consumer who purchased a DTC test gets back the results showing higher risk of negative response to a drug *X*, and then the concerned consumer takes this information to the physician for further information. The physician knows the patient has a heart condition and has been in the process of coming up with a treatment regimen. Given current medical standards, drug *X* is known to be one of the most effective drugs for the condition.

218. *Id.* at 2453 (quoting Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1001 (Jan. 6, 2000) (to be codified at 21 C.F.R. pt. 101)) (internal quotation marks omitted).

219. *See, e.g., Terms of Service, supra* note 184 (“23andMe Services are for research, informational, and educational use only. We do not provide medical advice. . . . 23andMe does not recommend or endorse any specific course of action, resources, tests, physician or other health care providers, drugs, biologics, medical devices or other products, procedures, opinions, or other information that may be mentioned on our website.”).

220. *See, e.g., DeCODEme Genetic Scan Service Agreement and Informed Consent, DECODEME*, <http://www.decodeme.com/service-agreement> (last visited Mar. 6, 2012). The problem with deCODE’s service agreement, and ones like it, is that one must read through long, dense disclaimers searching for the most important ones of benefit to the consumer. *See id.*

221. *Prebula, supra* note 192, at 368.

The doctor must decide whether to prescribe or not to prescribe the drug.²²² The physician, who lacks expertise in interpreting genetic results and who is unfamiliar with DTC company methods for interpreting risk, is thus forced to make a choice that could result in litigation for improper treatment no matter which choice the physician makes.²²³

The current state of the law gives scant concrete guidance in the above *specific* scenario, but one court says of the medical professional standard of negligence:

Each physician may with reason and fairness be expected to possess or have reasonable access to such medical knowledge as is commonly possessed or reasonably available to minimally competent physicians in the same specialty or general field of practice throughout the United States, to have a realistic understanding of the limitations on his or her knowledge or competence, and, in general, to exercise minimally adequate medical judgment. . . .

In the care and treatment of each patient, each physician has a non-delegable duty to render professional services consistent with that objectively ascertained minimally acceptable level of competence he may be expected to apply given

222. Presented with this information from the DTC company, however, inaction or action may lead to a lawsuit against the doctor. See Black et al., *supra* note 46, at 117–18. The Judicial Council of California Jury Instructions, CACI, also sheds some light on the problem, at least in California, through its jury instruction for “alternative methods of care.” See CACI, *supra* note 185, § 506, at 442 (“[A/An] [*insert type of medical practitioner*] is not necessarily negligent just because [he/she] chooses one medically accepted method of treatment or diagnosis and it turns out that another medically accepted method would have been a better choice.” (alterations in original)); *Clemens v. Regents of Univ. of Cal.*, 87 Cal. Rptr. 108, 116–17 (Ct. App. 1970). CACI § 506 is interesting because it allows physicians the breathing room they need to make independent medical decisions without fearing litigation anytime it turns out later that another medical route would have ended up more favorable to the patient. See *Barton v. Owen*, 139 Cal. Rptr. 494, 503–04 (Ct. App. 1977) (allowing for “professional judgment”). In other words, it precludes “but for” reasoning. See *Meier v. Ross Gen. Hosp.*, 445 P.2d 519, 530 (Cal. 1968). In the DTC context, it may be that interpreting the results and giving or not giving the drug based on that information may have been better than ignoring them and having the patient undergo a treatment regimen based on independent expertise. Or it may not. The decision must simply have been a “medically accepted method of treatment or diagnosis”—one out of potentially many. Yet how could a physician truly ignore a test result if it indicates presence of markers strongly associated with serious conditions simply because that physician may feel ill-equipped to deal with the results? See also *infra* note 226 and accompanying text (discussing CACI § 508 regarding duty to refer to a specialist).

223. See *Marietta & McGuire*, *supra* note 96, at 371 (noting that whether an activity counts as the practice of medicine is usually a state matter that is defined in state regulations and that the definitions usually include some combination of the following words: *diagnosis, treatment, cure, disease, disorder, and injury*). One problem is that when a physician must interpret the DTC company’s interpretations of results, the boundaries of what counts as the practice of medicine are blurred. The second problem is that if it is left up to the states to apply their own definitions, there will be little uniformity in regulating an industry that ubiquitously reaches out to many states through the Internet.

the qualifications and level of expertise he holds himself out as possessing and given the circumstances of the particular case.²²⁴

In the hypothetical scenario above, it is unclear what should be expected from physicians.²²⁵ If a patient goes to see a cardiologist, a gastroenterologist, or even simply an internist, a patient could reasonably think the physician should know something about genetic variants pertinent to his or her area of practice. If so, then the patient may assume such a physician should be able to interpret genetic tests giving results for those variants. It is quite unclear what the scope of the doctor's duty is to the patient in this regard as well as what would constitute a breach.²²⁶ The threshold

224. *Hall v. Hilbun*, 466 So.2d 856, 871 (Miss. 1985) (discussing, in a case where a sponge was left in a patient's stomach, versions of the *professional* standard of care with regard to medical malpractice); *see also* *Hinlicky v. Dreyfuss*, 848 N.E.2d 1285 (N.Y. 2006) (discussing the role reliance on medical practice guidelines plays in standard of care). *But see* *Helling v. Carey*, 519 P.2d 981, 983 (Wash. 1974) (moving away from a view of liability based on custom in the medical community when it held that a physician was negligent because "timely giving of [a] simple, harmless pressure test to th[e] plaintiff . . . proximately resulted in the [plaintiff's] blindness" even though the physician followed the custom in the medical community in treating glaucoma patients). Compare the *Hall* professional standard with the basic *Restatement* standard of the reasonable person:

Negligent conduct may be either:

- (a) an act which the actor as a reasonable man should recognize as involving an unreasonable risk of causing an invasion of an interest of another, or
- (b) a failure to do an act which is necessary for the protection or assistance of another and which the actor is under a duty to do.

RESTATEMENT (SECOND) TORTS § 284 (1965).

225. *See, e.g., Patsner, supra* note 53, at 260–63 (describing how the nature of the DTC genetic testing industry's shift to a commercial, purely nonmedical venture brings up concerns about the qualifications of scientists employed at these companies as well as general quality control of equipment and methods). Reasonableness is also the standard that the FTC uses to determine whether a representation that a company makes is misleading; it is whether a consumer's reaction is a reasonable one. *Drabiak-Syed, supra* note 207, at 76.

226. *See, e.g., Foster, supra* note 53, at 555 (citing *Safer v. Estate of Pack*, 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1996) (holding that a physician had a duty "to warn of the avertable risk from genetic causes, by definition a matter of familial concern" where a daughter developed cancerous blockage and multiple polyptosis and the doctor, who had treated her father for the same condition, did not tell her of the genetic risk)).

One option for the treating physician is to refer the patient to specialist qualified to interpret the genetic test. *See CACI, supra* note 185, § 508, at 426. CACI § 508 lays out the jury instruction for the duty to refer to a specialist as follows:

If a reasonably careful [insert type of medical practitioner] in the same situation would have referred [name of patient] to a [insert type of medical specialist], then [name of defendant] was negligent if [he/she] did not do so.

question is whether the doctor in such a scenario should have known to prescribe or not to prescribe drug X given the presence of the DTC results. Or, if a drug is prescribed, there is a question of whether the physician properly obtained informed consent from the patient.²²⁷ The ability to obtain meaningful consent is dubious considering it is far from certain that the average physician would have a meaningful understanding of the tests.²²⁸ Clear guidelines are needed to delineate, for the present and future, what each party's responsibilities are in the interpretation and communication of results.²²⁹

In general, doctors should be held responsible only to a limited extent for failing to heed genetic tests brought in by patients where the patient later develops a disease associated with a detected genetic variant.²³⁰ Where a doctor has not independently decided that a genetic test is

However, if [name of defendant] treated [name of patient] with as much skill and care as a reasonable [insert type of medical specialist] would have, then [name of defendant] was not negligent.

Id.: Simone v. Sabo, 231 P.2d 19, 25 (Cal. 1951). Thus, it may be that treating physicians may simply fulfill their duty to the patient and avoid liability by referring the patient to someone else. The trouble here is that because DTC tests are new there is little legal guidance to tell us what the level of skill and care of a reasonable physician in this scenario really would be.

227. See Rucinski, *supra* note 13, at 797–802 (discussing how informed consent requires “capacity, disclosure, and voluntariness,” but that, today, what is considered the “reasonable patient” regarding the degree of informed consent needed for medical treatments must take into account the “informed consumer” because of increasing Internet access to medical information and news before the patient ever steps into the doctor’s office (quoting Douglas Andrew Grimm, *Informed Consent for All! No Exceptions*, 37 N.M.L. REV. 39, 40 (2009)) (internal quotation marks omitted)).

228. See Salari, *supra* note 169, at 1.

229. See Prebula, *supra* note 192, at 371 (noting that courts have held physicians liable for negligently prescribing drugs, even in cases having to do with insufficient testing for prescribing the best drug for an individual patient). See also Kirsten Rabe Smolensky, *Creating Children with Disabilities: Parental Tort Liability for Liability for Preimplantation Genetic Interventions*, 60 HASTINGS L.J. 299 (2008), for a discussion on parental tort liability for preimplantation genetic screenings and interventions. Although it is outside the scope of this Comment, an interesting question is what rights and responsibilities children of parents who bring genetic test results to private physicians would have. See *id.* Although scholars have generally said that children born as a result of preimplantation genetic intervention cannot sue their parents, *id.* at 299, it would be interesting to know what liability the other players, companies, and physicians may have in the future.

230. See Black et al., *supra* note 46, at 117. Black notes that under the current state of the law, doctors could certainly face liability. *Id.*; see *supra* note 224 and accompanying text. However, the current state of law does not clearly define the boundaries of such liability. It is also interesting to consider *Helling v. Carey*, 519 P.2d 981, 983 (Wash. 1974), in its move away from medical custom in imputing liability here, however. Although interpreting genetic tests is not as easy as the “simple, harmless pressure test” the court ruled the physician should have given in *Helling*, merely observing from the test results that a person has a variant or not is simple. See *id.* Perhaps courts seeking to evolve away from the custom standard would be more willing to impose liability to some extent.

necessary, subsequently ordered it, and had it analyzed by a qualified employee at the medical facility, holding a doctor responsible for ignoring an outside genetic test would be too strict.²³¹ A physician should not be forced to take on an expertise that was never claimed.²³² This being said, because the law does not define a physician's scope of duty in the context of DTC tests, it is quite likely that legal action could result from action or inaction regarding these tests.²³³ A physician's failure to act, after all, can be just as harmful an action if a physician downplays potential genetic risk.²³⁴

When a physician affirmatively does decide to undertake a particular course of treatment based on outside genetic tests, this may yield a different result in liability.²³⁵ In such a case, use of the test constitutes

231. *Hall v. Hilbun*, 466 So.2d 856, 871 (Miss. 1985) (discussing standard of care and following customary practice in the medical community as a benchmark for liability); cf. Rucinski, *supra* note 13, at 822 (noting that doctors have a duty to stay abreast of all new medical developments in their field and that limiting the scope of informed consent as to treatments ensures that patients are not misled by the wealth of information accessible to the lay person).

232. This is, of course, assuming that such a physician does not claim expertise to interpret results. If a physician does, it may open him or her up to liability. See *Hall*, 466 So.2d at 871 (imposing a standard of care that "may be expected to apply given the qualifications and level of expertise [a physician] holds himself out as possessing and given the circumstances of the particular case").

Consider also the *Restatement*: it addresses the scope of the learned intermediary doctrine in traditional scenarios only to deal with "drug[s] or medical device[s]" that are prescribed by physicians. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (1998). Yet when a physician does not ignore test results but instead adopts them, one might ask whether there is any real difference between prescribing a test and adopting test results if the net outcome in each is that the doctor relies on these tests in making medical decisions. When a physician adopts results in making medical decisions, there is an argument for suggesting that physician should come to share in responsibility for consequences. Nevertheless, when a physician ignores test results, the *Restatement* itself suggests support for denying liability for physicians because they have not even prescribed the tests. See *id.*

233. Black et al., *supra* note 46, at 116–18.

234. *Id.* ("[P]laying down potential and unknown genetic risk in response to a negative test, especially for patients with a strong family history of breast cancer, could cause inattentiveness to other warning signs. Physicians could certainly be faced with liability in these circumstances under current law.").

235. See Rucinski, *supra* note 13, at 797–99 (discussing the scope of necessary informed consent in the digital age). The doctrine of informed consent, for instance, requires that doctors obtain informed consent from patients so that patients can make educated decisions about their own medical treatment. *Id.* at 797–98. The *Acuna v. Turkish* court brings up an analogously relevant point regarding the scope of informed consent. There, the court said that although a doctor must provide "medically material" information regarding abortion procedures, a physician is not required to discuss all the possible available medical information. *Id.* at 798–99 (citing *Acuna v. Turkish*, 930

both a claim of expertise in interpreting the test and an agreement to take on the risk of using such results.²³⁶ Here, there is greater reason to impute liability for any medical missteps to the physician for recommended courses of action because the physician has affirmatively chosen to *adopt* and *integrate* the results in the patient's treatment plan.²³⁷ The vast difference in liability risk gives physicians convincing incentive to ignore the results of outside genetic tests in formulating treatment plans. For now, this is the preferable course of action in order to minimize medical malpractice.

The foregoing problems are distinct from the learned intermediary doctrine as traditionally applied to the relationships between doctors, patients, and pharmaceutical companies.²³⁸ Presumably, it is the doctor who independently decides to undertake courses of treatment, so it makes sense to impute responsibility to the doctor for giving warnings.²³⁹ The physician is an active decisionmaker in introducing the drug to the patient, and the physician usually has expert knowledge about the treatment's appropriateness and any side effects.²⁴⁰ However, a commercial genetic test is outside the decisionmaking sphere.²⁴¹ Accordingly, physicians should face only limited liability in certain circumstances and face *no* liability when DTC companies have essentially punted responsibility to them by telling consumers to speak with medical providers for further information. It would undermine the relationship between doctor and

A.2d 416 (N.J. 2007)). However, what counts as “medically material” regarding DTC genetic tests is unclear because there is much disagreement about the degree of information that physicians can impute to patients.

236. See, e.g., Richard Tutton et al., *Genotyping the Future: Scientists' Expectations About Race/Ethnicity After BiDil*, 36 J.L. MED. & ETHICS 464, 464 (2008) (discussing the sociological effects of the FDA-approved drug BiDil, made specifically for African-Americans and available for physicians to prescribe based on an individual's genetic makeup). BiDil was the first drug tailored for a specific racial group, but one can easily imagine an increase in other such treatments based on genetic makeup. *Id.*

237. Black et al., *supra* note 46, at 117 (noting that prophylactic mastectomies would be one example of a plausible drastic step that could occur as a result of miscalculated information given by the doctor based on genetic tests). *But see* CACI, *supra* note 185, § 506, at 442 (noting that, in California, instead of a but-for standard, physicians must have undertaken only a medically acceptable treatment).

238. See Robertson, *supra* note 58, at 232 (discussing the learned intermediary doctrine).

239. See Prebula, *supra* note 192, at 368.

240. *Id.*

241. When consumer-patients bring outside DTC tests—along with the advertising claims touted by the company—*inside* the decisionmaking sphere, the influence of the test results on the physician may weaken the physician-patient fiduciary relationship by influencing the independent judgment of the physician. See Heather Harrell, *Direct-to-Consumer Advertising of Prescription Pharmaceuticals, the Learned Intermediary Doctrine, and Fiduciary Duties*, 8 IND. HEALTH L. REV. 69, 78–83 (2011) (discussing the psychological effect that DTC advertising for traditional pharmaceuticals has upon the physician-patient fiduciary relationship in the context of the learned intermediary doctrine).

patient by creating a fear of liability, prevent the free flow of unbiased communication, and weaken the fiduciary relationship.²⁴² If, however, physicians actively decide to incorporate consideration of results into their treatment plans, then some limited liability should apply.²⁴³

VIII. RECOMMENDATION: A HOLISTIC APPROACH TO IMPROVING THE DTC GENETIC TESTING INDUSTRY

The most important and effective change is to extend GINA by better defining key terms and to clearly define which agencies and parties have regulatory power over the industry. This is necessary to address the unique issues cropping up as a result of the DTC genetic testing industry. It is key, however, to emphasize the importance of a holistic approach because it will not only encourage active problem solving between all interested parties but also best foster a long-term solution.²⁴⁴ The DTC

242. The discussion that some scholars engage in regarding the effect DTC advertising has on medical treatment and traditional prescription pharmaceuticals is instructive and relevant for the novel situation in which DTC tests are brought in to physicians' offices. *See, e.g., id.* at 80–83.

Exceptions to the LID are based mostly on a weak or nonexistent patient-physician encounter. DTC advertising erodes the patient-physician relationship by altering expectations of the relationship, shaping discussions during patient encounters, and affecting prescribing practices, among other influences. In the presence of DTC promotion, physicians may no longer meet the criteria of a “learned intermediary,” since they are not the sole source of information for the patient, and their judgment may be affected by such advertising. Changes to the health care system independent of DTC advertising weaken the reasoning for application of the LID and increase the potential influence of DTC advertising. These changes also make it more difficult for physicians to be true “learned intermediaries.” When deciding how DTC advertising should affect liability of the manufacturer, all of these issues should be considered.

Id. at 83. The general concern—that DTC advertising brought in to the physicians' sphere of expertise weakens their role as learned intermediaries—finds a cogent, parallel application in the context of outside DTC tests brought in by a consumer who also brings in an outside perspective of what test results are supposed to mean. *See id.* at 82 (“DTC advertising changes the information the patient has with respect to treatment and condition, alters views on proper physician roles, influences the content of discussion, and can affect treatment decisions.”).

243. *See supra* note 232 and accompanying text.

244. *See* Gary E. Marchant, Foreword, *Law and the New Era of Personalized Medicine*, 48 JURIMETRICS J. 131, 134 (2008) (discussing Sharon Lewis, *The Tissue Issue: A Wicked Problem*, 48 JURIMETRICS J. 193 (2008)). In the context of tissue collection, author Sharon Lewis stated that a “wicked problem” is one that is “so complex and intractable that it cannot be resolved by any one solution.” *Id.* “At best, such a problem can be managed, but always imperfectly.” *Id.* The DTC genetic testing industry may be viewed as a type of wicked problem because of the various interests pulling in different directions.

companies engage in a variety of activities including ancestry reports, simple-trait analysis, disease-risk prediction, drug-response prediction, and even research.²⁴⁵ Each of these activities should be examined and addressed separately to appropriately tailor regulation. This is so that resources go to the most controversial activities, such as risk prediction and drug-response prediction.²⁴⁶ Employing multiple approaches changes the dynamic of problem solving to one that is collaborative in nature, allowing for diversity of thought and maximum utility of expertise.²⁴⁷

A. Meeting the Challenge of Emerging Technologies with a Combination of Solutions

DTC genetic testing and individual decisionmaking should not replace practitioners in a traditional model of medicine who offer knowledge and experience.²⁴⁸ Nevertheless, new emerging technologies can and do supplement such traditional models.²⁴⁹ The goal is to provide enough oversight and regulation to ensure that these new emerging technologies provide accurate and reliable information to today's consumer and to be utilized by tomorrow's medical professionals.²⁵⁰ This requires that DTC companies start by effectively communicating risk assessments to consumers.²⁵¹ Whether the industry uses qualified physicians, scientists, or genetic counselors as communication filters, or forgoes risk predictions altogether, the industry must improve communication regarding its results.²⁵²

For such a new industry that trades in novel and evolving technology, a holistic approach is necessary to protect the interests of the consumer, the industry, and scientific and medical progress.²⁵³ An overly paternalistic

A holistic and flexible approach is critical in meeting these different interests. For an analogous solution, see Tamir, *supra* note 4, at 213. Based on the variety of legal and ethical issues surrounding DTC genetic tests, Tamir suggests a “harmonised” approach to regulation. *Id.*

245. See, e.g., 23ANDME, *supra* note 203.

246. See McGuire et al., *supra* note 69, at 182 (pointing out that there is a lack of a risk-stratification approach and that it would be useful to come up with one).

247. See Lobel, *supra* note 107, at 379–80.

248. See Braverman, *supra* note 8, at 495–96.

249. *Id.* at 496.

250. *Id.* at 495–96.

251. Black et al., *supra* note 46, at 117.

252. *Id.*

253. For an example of an alternative approach employed by Germany, see Tamir, *supra* note 4, at 236 (citing Gendiagnostikgesetz [GenDG] [Genetic Diagnosis Act], July 31, 2009, BUNDESGESETZBLATT, Teil I [BGBl. I] at 2009 2529 (Ger.), available at http://www2.bgbl.de/Xaver/media.xav?SID=anonymous3307876363287&toctf=Bundesanzeiger_BGBL_tocFrame&tf=Bundesanzeiger_BGBL_mainFrame&qmf=Bundesanzeiger_BGBL_mainFrame&hlf=Bundesanzeiger_BGBL_mainFrame&bk=Bundesanzeiger_BGBL&name=bgbl%2FBundesgesetzblatt%20Teil%20I%2F2009%2FNr.%2050%20vom%2004.08.2009%2Fbgbl109s2529.pdf), which discusses how Germany has enacted the

approach or continued regulatory uncertainty is unreasonable and likely to obliterate the industry,²⁵⁴ as at least one country has shown.²⁵⁵ The better, holistic approach would encompass regulatory, legislative, self-regulatory, and educational solutions that flexibly work in tandem—this type of approach would promote both a “rich definition of democracy” and “facilitate wider imaginative horizons.”²⁵⁶

One approach to narrowly addressing the activities of the DTC industry is to use a risk-stratification approach in which the more controversial activities, such as risk prediction, are regulated more heavily than the less controversial components, such as the ancestry and simple-trait results.²⁵⁷ This is desirable because it helps to funnel resources and effort to the activities that most need attention. It also helps to organize

Human Genetic Examination Act, a strict law that went into effect in February 2010. To read an English translation, see BUNDESRAT DRUCKSACHEN [BR] 374/09 (Ger.), available at <http://www.genomicslawreport.com/wp-content/uploads/2010/11/German-Act-Translation.pdf>. The Act essentially bans DTC genetic testing by implementing rigorous requirements. Tamir, *supra* note 4, at 236; BUNDESRAT DRUCKSACHEN [BR] 374/09. The general opinion on Germany’s approach seems to be that it is too strict and that it is an example of both genetic exceptionalism and paternalism. See Tamir, *supra* note 4, at 236.

254. Potential consequences of regulatory uncertainty include reduced access to capital for new or additional investments, fewer new innovative products, fewer startups, litigation risks, reduced access to technology due to scaring off collaborators, and encouraging overseas development. 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>.

255. Germany enacted the Genetic Diagnosis Act, an overly strict law that inhibits innovation and has all but stopped the industry in its tracks. See *supra* note 253 and accompanying text. However, it is also important to consider that the regulatory frameworks and approaches across European countries vary widely. Katz & Schweitzer, *supra* note 95, at 127. For example, some regulatory bodies might view clinical validity, how accurately a test recognizes a marker, as the most important aspect. *Id.* Others may view analytical validity, how accurately it predicts disease, as the most pressing concern. *Id.* Because of these differences, there is little uniformity even on the international level as to what consumers should expect. See *id.* at 129. While a Global Harmonization Task Force, including the United States, European Union, Canada, Australia, and Japan, is working to develop uniform regulation, *id.* (citing GLOBAL HARMONISATION TASK FORCE, <http://ghf.org/> (last visited Mar. 7, 2012)), the fact that there is disagreement within the individual countries indicates that it is a long road to a global solution. *Id.*

256. Lobel, *supra* note 107, at 442–43 (discussing the possibility of a “third way” of governance that facilitates plural solutions as opposed to the traditional dichotomy between “state-based, top-down regulation and a single-minded reliance on market-based norms”).

257. See Javitt, *supra* note 150, at 817–18 (“Agencies should next assign regulation to each test according to its level of risk.”); McGuire, *supra* note 69, at 181–82 (noting the current lack of a risk-stratification approach and advocating its creation).

the efforts for regulation in what likely will be a comprehensive overhaul of the industry.²⁵⁸ However, this is only one starting point, and it is necessary to include other approaches as part of a long-term solution.

The approach suggested in this Comment is similar to the risk-stratification approach but encompasses a larger scale as a holistic, solution-stratification approach.²⁵⁹ Implementing a variety of solutions will increase the likelihood of addressing the variety of weaknesses in the industry and provide the necessary flexibility to manage a technology that is likely to evolve over time.²⁶⁰ Employing a wide variety of solution strategies starts with small steps.²⁶¹

*B. A Legislative and Regulatory Approach To Extending GINA:
Reining In Advertising and Creating Uniform
Standards for Interpretation*

Although heavily regulating the industry as a whole may be undesirable, some regulation may be necessary in order to offer guidance to the industry, courts, and consumers to navigate this complex and ever-evolving field.²⁶² In particular, the most sensible approach would be for Congress to start by extending GINA-like legislation to cover the activities of the DTC industry, instead of covering only employment discrimination, insurance discrimination, and privacy issues.²⁶³ Defining terms to adequately cover the DTC industry as to communication and interpretation and delineating

258. See Gniady, *supra* note 86, at 2436 (noting that although there has been a lack of regulation, this will likely not last long because of the growing public and business interest in developing the genetic test industry).

259. See McGuire, *supra* note 69, at 181–82. McGuire notes that there is currently not a risk-stratification approach regarding risk prediction. Javitt suggests such an approach is necessary, pointing to the idea that disease risk prediction and drug-reaction prediction pose more of a problem by potentially affecting how a consumer might make healthcare choices, while ancestry and simple-trait analysis pose little such danger. Javitt, *supra* note 150, at 817–18.

260. This is the best way to wrangle such a “wicked problem.” See Marchant, *supra* note 244, at 134 (discussing Lewis, *supra* note 244).

261. Javitt, *supra* note 150, at 817–18.

262. See *supra* note 254 and accompanying text. *But see* Pauline T. Kim, *Regulating the Use of Genetic Information: Perspectives from the U.S. Experience*, 31 *COMP. LAB. L. & POL’Y J.* 693, 699 (2010). Kim notes that the purpose of enacting the GINA legislation was to prevent discrimination and inequality specifically to “promote the use of genetic technologies.” *Id.* at 698. So, any further extension of this legislation might proceed under such a policy purpose as well—at least on paper, that is.

263. See Payne, *supra* note 44, at 58. GINA is quite limited, and it does not even offer protection against genetic discrimination in life insurance, disability insurance, long-term care insurance, and Medicare and Medicaid. *Id.*

the scope of the FDA, CMS, and FTC power would be one step toward allowing those agencies to craft a better-suited regulatory scheme.²⁶⁴

Because communication and interpretation can easily become a subjective jungle,²⁶⁵ one way to consider how to regulate the industry's communicative and interpretive activities is to begin drawing boundaries by looking to what the reasonable consumer would think. Reasonableness is worth considering because the state of science does not offer clear-cut answers for how genomic data should be conveyed.²⁶⁶ Section 285 of the *Restatement (Second) of Torts* indicates that reasonable conduct can be established by legislative enactment or administrative regulation, by judicial decision, or by the factfinder's application of the facts to the case if there is no enactment, regulation, or decision.²⁶⁷ The standard for communication with consumers is not obvious, as evidenced by DTC genetic testing companies' use of various standards of interpretation, and because reasonable minds can differ in the absence of regulatory, legislative, or judicial guidance, the FDA should lead an effort to establish uniform standards to which industry members must adhere.²⁶⁸ Therefore, it is crucial for Congress to define the scope of the FDA's role so that the FDA and other agencies such as the FTC may act with clear authority to set industry standards and draw the boundaries around what should be considered "reasonable."²⁶⁹ Furthermore, waiting for the courts to come

264. To see an interesting and, perhaps, promising set of guidelines the United Kingdom has promulgated, see the Human Genetics Commission's guidelines published in August 2010. HUMAN GENETICS COMM'N, A COMMON FRAMEWORK OF PRINCIPLES FOR DIRECT-TO-CONSUMER GENETIC TESTING SERVICES (2010) (U.K.), available at <http://www.hgc.gov.uk/UploadDocs/DocPub/Document/HGC%20Principles%20for%20DTC%20genetic%20tests%20-%20final.pdf>. It covers various aspects of DTC genetic testing such as advertising and marketing, genetic counseling, consent, interpretation of tests results, and provision of test results. *Id.* at 6–13.

265. To consider how the average consumer may be misled, see *supra* text accompanying note 105.

266. See generally Pearson & Manolio, *supra* note 103 (discussing an approach for interpretation of GWAS results by experts, yet not addressing how such complex information could be conveyed to the lay consumer).

267. RESTATEMENT (SECOND) OF TORTS § 285 (1965).

268. See, e.g., *DTC Hearing*, *supra* note 9, at 20 (statement of Rep. Diana DeGette, Member, H. Subcomm. on Oversight & Investigations).

269. For now, there is much regulatory uncertainty. Vorhaus et al., *supra* note 254. The Department of Health and Human Services (DHHS) and the FDA posted a formal notice in the Federal Register to open up the issue of regulating the industry to public comment before holding an advisory meeting to discuss regulatory issues. Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee, 76 Fed. Reg. 25, 6623 (Feb. 7, 2011). This indicates an intention to regulate, but as of this writing, the

up with a solution is undesirable.²⁷⁰ The courts need guidance for any decision on this topic, and allowing courts to fashion a standard will likely only frustrate judges and yield unsatisfying solutions begotten of necessity, and not workability—they cannot be expected to be experts after all.²⁷¹ Additionally, having Congress and the regulatory agencies work through a solution before most problems reach the courts would allow the industry time to implement necessary changes.²⁷²

The FTC should also enact strict regulation for the advertising component of the industry. Strictly regulating advertising minimizes industry intrusion and a government takeover because it will eliminate false advertising

FDA has yet to propose any concrete language, including any draft language. The DHHS and FDA convened a two-day meeting to discuss a number of issues including: (1) the risks and benefits of permitting a consumer to have “direct access” to “clinical” genetic tests without the involvement of a genetic professional; (2) the risks involved in and possible solutions for “incorrect, miscommunicated, or misunderstood test results for clinical genetic tests”; and (3) “[t]he level and type of scientific evidence appropriate for supporting direct-to-consumer genetic testing claims including whether it should be different than that required to support similar claims for prescription use clinical genetic tests.” *Id.* at 6624. The notice defines the scope of the term *clinical genetic test* to include (1) genetic tests determining carrier status for hereditary conditions; (2) genetic tests predicting disease risk in currently asymptomatic individuals; and (3) genetic tests indicating drug response. *Id.*

270. See Gniady, *supra* note 86, at 2437. Gniady notes that as of 2008, there were over 1000 largely unregulated genetic tests available on the market. *Id.* at 2436. She also notes that the lack of regulation is unlikely to last because of growing public and business interest. *Id.* The combination of growing interest and a lack of regulation increases the likelihood that courts might need to resolve potential problems without the tools they need to analyze them.

271. See generally Sebastiani et al., *supra* note 128, for a real-world methodology and interpretation flub by *experts*, which does not bode well for courts wading through technical issues without any helpful guidance. See also *Calling GWAS Longevity Calls into Question*, GENOMEWEB (July 06, 2010), <http://www.genomeweb.com/blog/calling-gwas-longevity-calls-question> (discussing the flub). A research group at Boston University managed to publish an article in one of the top science journals, *Science*, and described gene variants it found that were related to life longevity. See generally Sebastiani et al., *supra* note 128. The problem is that these results could not be recreated by other researchers who read the paper. See *Calling GWAS Longevity Calls into Question*, *supra*. It turns out that because of a technical flaw, the results were compromised. Hesman Saey, *supra* note 128. The moral of this story is quite related to the DTC story. If a faulty research paper could make it into one of the world’s preeminent scientific journals, passing rigorous peer review, then surely lay people, Congress, and even scientific or medical peers could be misled about DTC genetic results based on other GWAS. This tells us that the problem of misleading consumers must be carefully thought out before courts are deluged with a problem they are not equipped to handle. This is not a “solution in search of a problem,” as some had said of GINA legislation that preempted major court involvement. 110 Cong. Rec. E120–21 (Jan. 16, 2007) (statement of Hon. Louise M. Slaughter). The same reasons for Congress to move quickly to speak with one voice are relevant here—bolstering the confidence of the general public and promoting progress in genetics research.

272. See generally HUMAN GENETICS COMM’N, *supra* note 264. Such guidelines, although not fully comprehensive, would be a good starting point for the United States to fashion similar guidelines or regulation. *Id.*

claims from the very outset.²⁷³ However, the protections offered to the consumer would be even more substantial if advertising regulation works in tandem with clear and uniform guidelines for the delivery of genetic testing results. The very first communication a DTC company has with a consumer is its advertising, and this frames what the consumer will expect from the company. Preventing companies from making false or misleading claims at the front end of the transaction prevents a further string of problems as the transaction continues.²⁷⁴ Consumers can then make fully informed choices regarding the product or service they hope to receive. This forces companies to be honest about their services instead of playing to consumers' fears, preexisting beliefs, and speculation.²⁷⁵ A preference for heavy advertising regulation—as opposed to heavy regulation of the industry's business model, which is to offer consumers a nonmedical service to enable review of their genetic data—preserves consumers' desire to maintain consumer autonomy while ensuring consumer protection.²⁷⁶ Regulating claims made on company websites or through other advertisements, including slogans, promises, and descriptions, encourages honesty from the first contact companies make with consumers and prevents potential harm in the form of injury or liability.²⁷⁷

The current state of the law provides companies with wide latitude to make claims that have a high potential of misleading the average consumer.²⁷⁸ If the FTC deems advertising false or misleading, it can

273. See *DTC Hearing*, *supra* note 9, at 22 (statement of Rep. Diana DeGette, Member, H. Subcomm. on Oversight & Investigations) (“The rapidly growing field of genetic testing symbolizes the entrepreneurial spirit and innovation that makes America great. The possibility of excessive government regulations, which would and could effectively put an end to an increasing technology, should not be our goal.”).

274. See, e.g., *Blumer v. Acu-Gen Biolabs, Inc.*, 638 F. Supp. 2d 81, 84 (D. Mass. 2009) (discussing how female consumers undertook dangerous and unnecessary procedures, often at their own expense without insurance coverage, as a result of receiving faulty test results from false advertising of prenatal genetic tests).

275. See *Tamir*, *supra* note 4, at 232 (describing how the way DTC genetic test advertisers word their advertisements often overstates the efficacy or merits of the tests, while also downplaying the weaknesses).

276. See *Martinez-Cabrera*, *supra* note 26.

277. See *Gniady*, *supra* note 86, at 2452–53 (noting that although the FTC has the authority to regulate false and misleading advertising claims, it is a limited avenue of regulation for widespread consumer protection).

278. See, e.g., *About Gene Partner*, GENEPARTNER, <http://www.genepartner.com/index.php/aboutgenepartner> (last visited Mar. 7, 2012) (“The probability for successful and long-lasting romantic relationships is greatest in couples with high genetic compatibility. . . . With genetically highly compatible people we feel that rare sensation of perfect chemistry. This is the body’s receptive and welcoming response when immune systems harmonize

issue a cease-and-desist enforcement action and require the offending company to pull or change the ads.²⁷⁹ The FTC should be encouraged to take a more active role by issuing such enforcement actions to incentivize companies to engage in ethical advertising.²⁸⁰ Descriptions of what results will tell consumers and promises made as to what the company offers should be objective, absolutely accurate, and regularly screened by a panel of experts assigned by the FDA or FTC to prevent misleading or exaggerated statements.²⁸¹ Heavy regulation and screening in this area should be implemented because of the high risk of consumer fraud stemming from the technical nature of the tests.

Congress and federal agencies should focus on creating uniform standards for interpretation, including requirements for clear company communications regarding methods and limits, and making relied-upon resources easily available.²⁸² To give a concrete example of how many

and fit well together.”). Furthermore, the FTC has not aggressively instituted enforcement actions. Drabiak-Syed, *supra* note 207, at 77.

279. Drabiak-Syed, *supra* note 207, at 76.

280. *Id.* at 77.

281. *But see* Brienne Taylor Greiner, Note, *A Tough Pill To Swallow: Does the First Amendment Prohibit WV from Regulating Pharmaceutical Companies’ Advertising Expenses To Lower the Cost of Prescription Drugs?*, 109 W. VA. L. REV. 107, 120 (2006) (“The commercial speech doctrine protects communication made for the sole purpose of selling products or services. While commercial speech does not receive the strongest degree of protection that the First Amendment can give, it does receive a heightened level of scrutiny.” (footnotes omitted)). One wonders if the DTC genetic industry may raise a First Amendment defense.

282. The need to address the regulatory and legislative gap for genetic tests has not gone unnoticed, and lawmakers and administrative agencies are taking slow steps to address the problem. *See, e.g.*, Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 27, 125 Stat. 284, 338–39 (2011) (to be codified at 35 U.S.C.); *see also* Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee, 76 Fed. Reg. 6623 (Feb. 7, 2011) (opening up to public comment the issues surrounding regulation of DTC testing); Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee, 76 Fed. Reg. 18227 (Apr. 1, 2011) (extending the comment period through May 2, 2011). The Leahy-Smith America Invents Act, enacted in 2011, is one very recent example where Congress has taken another step toward acknowledging and providing guidance, albeit minor, to the thorny problem of ensuring quality, beneficial access to genetic tests. Leahy-Smith America Invents Act § 27. In the context of patent reform, section 27 gives authority to the United State Patent Office (USPTO) “to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist.” *Id.* § 27(a). In effectuating this goal, section 27 raises familiar criteria for examination including investigating quality level due to lack of second opinion testing; harm to innovative activity; impact that exclusive licensing has on the medical profession, noting particularly the “interpretation of testing results and performance of testing procedures”; and impact on cost. *Id.* § 27(b). Although newly enacted section 27 deals very specifically with patents and clarifies little more at this point than giving an entity authority to investigate a solution further and requiring the director of the USPTO to report to the House of Representatives on the findings, it is one more much-needed step in the right direction. *See* Request for Comments and Notice of Public Hearings on Genetic Diagnostic Testing, 77 Fed. Reg. 3748, 3748–49 (Jan. 25,

variables are at play in delineating uniform standards for interpretation such as methodology, consider the current debate on gene patents.²⁸³ Patents play a role in regulating standards of result analysis accurately communicating the scope of DTC testing services.²⁸⁴ It may be possible for a laboratory to exclusively hold a gene-testing patent and to become the sole provider of such genetic testing.²⁸⁵ This would limit the accuracy and analysis of the laboratory's own results as well as those of other labs that may not be able to license the use of the patented genetic testing.²⁸⁶ Although companies must disclose the limits of their testing, there is a public health problem in allowing the possibility of holdouts at the expense of offering the most accurate picture of an individual's genetic

2012) (announcing two public hearings to gather information for preparing reports, one in Alexandria, Virginia, and the second at the University of San Diego).

283. See generally *Assoc. for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 237 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 635 F.3d 1329 (Fed. Cir. 2011).

284. See generally Eileen M. Kane, *Patent-Mediated Standards in Genetic Testing*, 2008 UTAH L. REV. 835, 835 (2008) (discussing the problem patenting can pose in regulating genetic testing).

285. *Id.* at 847–48.

286. *Id.* For instance, Myriad Genetics, based in Salt Lake City, Utah, patented its sequencing test to detect *BRCA1* and *BRCA2*, genetic variants associated with breast and ovarian cancer. *Id.* at 848. The unrelated King laboratory published a paper finding that its test, called multiplex ligation probe amplification, detected genomic rearrangements in the *BRCA1* and *BRCA2* genes, such as large deletions and mutations, in women who tested negatively under the Myriad test. *Id.* at 850–51. The King researchers noted that “genetic testing, as currently carried out in the United States, does not provide all available information to” patients. *Id.* at 851 (quoting Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 JAMA 1379, 1386 (2006)) (internal quotation marks omitted). Use of patent rights can set a “de facto clinical standard” by limiting the testing options available. *Id.* at 852; see also Wendy S. Rubenstein, *Inherited Breast Cancer*, in *MOLECULAR PATHOLOGY IN CLINICAL PRACTICE* 207, 208 (Debra G.B. Leonard et al. eds., 2007) (noting that the technique or set of techniques chosen for mutation detection in *BRCA1* and *BRCA2* “must be comprehensive in order to provide an accurate clinical result”). This is a problem for the scientific community because it limits peer review and compensatory research. Kane, *supra* note 284, at 852. It is also a problem for patients and physicians because it prevents comprehensive testing that can lead to the most accurate results possible, and this limitation can impact medical and personal choices. See Gaia Bernstein, *In the Shadow of Innovation*, 31 CARDOZO L. REV. 2257, 2296 (2010) (discussing how physicians often charged patients exorbitant prices for the test because Myriad essentially forced anyone testing for *BRCA1* and *BRCA2* to have the testing processed through its facility in Salt Lake City, Utah, regardless of where the patient was in the world); Kane, *supra* note 284, at 851–52 (“[S]cientific literature has consistently noted that the ongoing *BRCA1* and *BRCA2* patent issues must be factored into any assessment of progress in the field of genetic testing for inherited breast and ovarian cancer.”).

makeup.²⁸⁷ Only one district court has recently tried to draw a line as to what kind of genetic testing and material is patentable.²⁸⁸ Some have argued for a statutory research and innovation exemption,²⁸⁹ but in light of the burgeoning DTC genetic testing field, it may be more prudent to offer a statutory exemption that facilitates using patented materials whenever a DTC company or physician will be offering higher level analysis to a consumer, such as disease-risk prediction or drug-response prediction.²⁹⁰ This would improve quality for consumer-patients who would be unaware that their results could be inadequate based on patent monopolies happening behind the scenes.²⁹¹

C. Self-Regulatory Approach: The Carrot, Not the Stick

Because commercial genetic testing is relatively new, some amount of trial and error will be inevitable. It may even be desirable because it will allow companies to freely experiment with innovative ideas. To allow room for growth, Congress and regulatory agencies must draft solutions flexible enough to allow companies to implement their own solutions and remedies where possible. Encouraging such self-regulation means decisionmakers should include industry leaders and better differentiate between those more reputable companies and the bottom-feeders.²⁹² To do so, industry leaders should continue to be encouraged in the crafting of uniform standards, and those who cooperate with Congress and governmental agencies should be rewarded.²⁹³ For instance, some

287. See Kane, *supra* note 284, at 851–52.

288. *Assoc. for Molecular Pathology*, 702 F. Supp. 2d at 237 (holding that Myriad’s method of identifying potential cancer therapeutics by utilizing cells injected with altered breast cancer susceptibility genes was not patentable because Myriad’s claimed process was simply the scientific method), *aff’d in part, rev’d in part*, 635 F.3d 1329. The Federal Circuit overturned this result in part, bringing back the status quo to gene-testing patents. It remains to be seen whether or not the case will be taken up by the Supreme Court.

289. See Bernstein, *supra* note 286, at 2298–99 (discussing suggestions by academics and legislators for an exemption to facilitate research and innovation); Kane, *supra* note 284, at 852–53.

290. See, e.g., Bernstein, *supra* note 286, at 2299 (suggesting a healthcare provider exemption and noting that this aspect had been largely neglected by academics and legislators with the exception of the rejected Genomic Research and Diagnostic Accessibility Act of 2002, which included an ancillary exemption for healthcare providers (citing Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002))).

291. See *id.* at 2300–01 (noting a health provider exemption would clear up legal uncertainty).

292. See GAO REPORT, *supra* note 31, at 15–16 tbl.2 (describing the GAO’s findings of widespread deceptive marketing, misinformation, and questionable practices among several companies).

293. See, e.g., Robertson, *supra* note 58, at 242–43 (discussing how in 2008, Navigenics announced it would develop a set of industry standards and that it would consult stakeholders involved). During the 2009 DTC hearing, general counsel for 23andMe

companies have independently addressed the need for an opt-out option to preserve the “right not to know” about potentially harmful genetic information.²⁹⁴ Without recognizing such self-regulating efforts and remaining flexible, federal regulation could be much too stringent, stifling the growth and creativity that could have led to otherwise fast advances in the field’s technology.²⁹⁵ Instead, decisionmakers should reward responsible behavior, such as by quickly admitting and rectifying mistakes or by improving practices, by maintaining a certain amount of breathing room free of government intrusion.²⁹⁶ To give another example, in response to worries that most of the genomic data pools consisted of white populations, one company included an informational page on its website with a chart detailing which population datasets are represented for tested diseases.²⁹⁷ Another company increased the availability of genetic counselors to help consumers interpret its results.²⁹⁸

Another approach would be to leave it up to the free market to take care of the problem of faulty interpretive and communicative results—in this way, customers will naturally weed out companies that deceive and do not deliver as promised. Because the Internet is still somewhat of a legal hinterland, it lends itself to this kind of individualist ideal.²⁹⁹ Although in some industries such a laissez-faire approach may be more

stated it supported Congress and the FDA in creating an improved regulatory framework and that the company had already been working with the FDA, NIH, and others since 2007. *DTC Hearing*, *supra* note 9, at 81 (statement of Ashley Gould, General Counsel, 23andMe). Gould noted 23andMe would be presenting its regulatory proposal the following day to the FDA. *Id.*

294. Tamir, *supra* note 4, at 215–18 tbl.1, 228–29.

295. See Lobel, *supra* note 107, at 379–80. Lobel describes the traditional, predominantly regulatory approach as “one-size-fits-all.” *Id.* at 379. Lobel argues for an alternative, legally sustainable model that “encompass[es] a multitude of values and account[s] for conflict and compromise.” *Id.* at 380. Such an approach “acknowledge[s] the diversity and changing interests of many stakeholders.” *Id.*

296. See, e.g., Martinez-Cabrera, *supra* note 26 (reporting that when personal genomics company 23andMe mixed up ninety-six customers’ DNA results, the company quickly responded and many customers defended the company despite the mix-up).

297. See, e.g., *Health Reports: By Ethnicity*, 23ANDME, <https://www.23andme.com/health/ethnicity/> (last visited Mar. 7, 2012).

298. See, e.g., *Our Experts*, PATHWAY GENOMICS, <https://www.pathway.com/about-us/our-experts> (last visited Mar. 7, 2012).

299. See Lobel, *supra* note 107, at 436 (noting that some have declared the Internet a “government-free zone” and that the 1996 Declaration of the Independence of Cyberspace declared “governments of the industrial world . . . you of the past . . . leave us alone” (quoting John Perry Barlow, *A Declaration of the Independence of Cyberspace*, ELEC. FRONTIER FOUND. (Feb. 8, 1996), <https://projects.eff.org/~barlow/Declaration-Final.html>) (internal quotation marks omitted)).

workable, it should not be solely relied upon when the subject matter is technical enough to risk confusing the consumer and obfuscating problems inherent in industry techniques, methods, and claims. Because of the undeveloped regulatory structure of the industry, this laissez-faire approach is in place by default, yet as the GAO reports reveal, it is too easy to deceive the average lay consumer for this to be an adequate sole method of market control.

D. Educational Improvements

Regulatory agencies should also encourage educational avenues of improving oversight of this industry. The most important group to educate is the public, which also might be the most difficult group to educate effectively because of its size and varying levels of knowledge bases.³⁰⁰ However, involving industry leaders, qualified physicians, and regulatory agencies in this education movement could not only lead to educating the interested consumer but also help to improve industry standards.³⁰¹ For these reasons, leaders should support grant funding or public campaigns to educate the public.³⁰²

If physicians or other professionals are to play increasingly significant roles in the communication of genetic information, better education in the science of genetics and genomics will be necessary.³⁰³ This will allow professionals who become involved to properly communicate what the genomic data means and the strength of any risk assessments made as a result.³⁰⁴ Medical professionals' vast deficit in knowledge of genetic and genomic analysis has not gone unnoticed by members of the medical and scientific community.³⁰⁵

300. See, e.g., Payne, *supra* note 44, at 63. Educating the public is an old problem in genetic issues—Payne notes the importance of “[e]ducating the public about GINA’s limitations and the limitations of state laws . . . for those seeking to prevent genetic discrimination.” *Id.*; see also Lobel, *supra* note 107, at 454–55 (discussing how the public’s ability to process increasingly ubiquitous and complex information becomes more of a problem because of the “[a]symmetry of resources among private groups and differences in the organization of knowledge communities”).

301. See, e.g., Lobel, *supra* note 107, at 457 (discussing how, in the context of workforce development and vocational training, encouraging ongoing training and government support best combines “participatory decision making and professionalism”).

302. Novick, *supra* note 67, at 649.

303. Black et al., *supra* note 46, at 119; see also Tamir, *supra* note 4, at 220 (“It . . . seems advisable to invest in the education of healthcare professionals so that more of them will become proficient in the ‘language of genetics.’”).

304. Black et al., *supra* note 46, at 119.

305. See, e.g., Susan Ipaktchian, *Medical School To Offer Course That Gives Students Option of Studying Their Own Genotype Data*, STAN. SCH. MED. (June 7, 2010), <http://med.stanford.edu/ism/2010/june/genotype.html>.

Some institutions have initiated efforts to educate the physicians of tomorrow to be better prepared for major technological advances such as personalized-medicine approaches to healthcare.³⁰⁶ For instance, Stanford Medical School started a “Genomics and Personalized Medicine” class that began in autumn 2010, in which students would discuss their personal genotyping results received through commercial testing.³⁰⁷ Just as in the U.C. Berkeley genetic testing program, opponents voiced privacy concerns regarding data handling as well as concerns over how well equipped students would be to receive and interpret their test results.³⁰⁸ However, Stanford went through extensive planning to address ethical pitfalls, and the educational value was deemed strong enough to give the innovative approach a try.³⁰⁹ Such initiatives should be encouraged as one step toward educating individuals about what a genetic test can tell someone.

The FDA and FTC have the potential unique role as facilitators to bring interested parties together.³¹⁰ This is also a way in which older or established physicians could be offered opportunities to become better acquainted with the new emerging science.³¹¹ Because many physicians show a desire to learn more about genetic testing and because of the cutting-edge nature of the technology and ethical problems surrounding genetic testing, the government is in a unique position to bring together regulatory agencies, congressional members, attorneys, healthcare providers, and DTC industry members in colloquia or symposia to discuss and learn about emerging genetic testing issues.³¹² Additionally, because

306. Gregorio M. Garcia, *The FDA and Regulation of Genetic Tests: Building Confidence and Promoting Safety*, 48 JURIMETRICS J. 217, 233–34 (2008) (discussing the paradigm shift from one-size-fits-all healthcare to targeted treatments based on unique genetic profiles and citing two reports supporting the topic).

307. Ipaktchian, *supra* note 305.

308. Ferris Jabr, *Exposing the Student Body: Stanford Joins U.C. Berkeley in Controversial Genetic Testing of Students*, SCI. AM. (July 6, 2010), <http://www.scientificamerican.com/article.cfm?id=exposing-the-student-body>.

309. *Id.* (describing the differences in level of planning and implemented safeguards between the U.C. Berkeley incoming freshmen genetic testing program and the Stanford genetic testing class regarding what made the latter more acceptable than the former).

310. See Lobel, *supra* note 107, at 373 (arguing for a “new governance model” that includes multiple actors at various stages of the legal process and “shifting citizens from passive to active roles”).

311. Black et al., *supra* note 46, at 119.

312. See, e.g., Gaia Bernstein, Introduction, *Toward a General Theory of Law and Technology*, 8 MINN. J. L. SCI. & TECH. 441, 441–42 (2007) (summarizing a symposium organized to address the issue of whether it would be best to address new technologies by regulating them in isolation or by developing a new general theory of law and

those in the DTC industry and medical field may not fully understand regulations put forth by the FDA or Congress, putting together colloquia, symposia, or other education materials is a necessary step for the implementation of any new regulation or legislation.³¹³

It is also necessary for legislators, judges, and attorneys to become better educated about genetics and legal implications before making decisions in this area.³¹⁴ The speed with which science has advanced, and the speed with which it will continue to develop, necessitates a new approach—lawmakers must adequately understand the science underlying these new technologies, and only then will they be able to fashion prospective laws with clear foresight rather than reacting to problems post hoc.³¹⁵ All parties involved—the consumer-patient, physicians, industry members, Congress, and regulatory agencies, attorneys, and judges—need to understand one another and the issues in a meaningful way.³¹⁶ One way to do this is for the government to assemble diverse committees composed of appropriate, unbiased experts that would deal specifically with emerging scientific or medical technologies impacting the consumer marketplace.³¹⁷ Even if all parties cannot come to speak the same language, whether it is the language of the lawyer, FDA official,

technology). Perhaps similar symposia would be beneficial where parties of varied backgrounds meet and present works.

313. See FED. DRUG ADMIN. & U.S. DEP'T OF HEALTH & HUMAN SERVS., PUBLIC MEETING ON OVERSIGHT OF LABORATORY DEVELOPED TESTS 171–72 (2010) (statement of Dr. Gail Vance, American College of Pathologists).

FDA-speak is foreign to laboratories. We know CLIA We report to CLIA . . . [B]ut we don't have a clue, and I'm just speaking for myself, about FDA.

I mean, . . . QSR, Labeling, really these are terms that you guys use, or many of you, may use every day, but we don't. So there is an educational problem here. There is a chasm here that I think we have to be well-aware of and it's going to take education, education and more education to bridge that.

Id. at 171.

314. See *id.* at 171–72.

315. Black et al., *supra* note 46, at 120.

316. See, e.g., FED. DRUG ADMIN. & U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 313.

317. See Christine Dugas, *Warren Begins Shaping Agency: She Says New Consumer Protection Bureau Will Level Playing Field with Big Banks*, USA TODAY, Dec. 29, 2010, at 3B. The Obama administration has been more active than previous presidential administrations, extending consumer protection by creating the Consumer Financial Protection Bureau, implemented by special advisor and Harvard professor Elizabeth Warren. *Id.* This may indicate a more active role in shaping consumer protection laws and regulations in general. See also Laboratory Test Improvement Act, S. 736, 110th Cong. §§ 1–9 (2007) (introduced by then-Senators Barack Obama and Edward Kennedy). Senate Bill 736 suggested extending FDA jurisdiction to cover DTC genetic testing activities, but it never went anywhere. Patsner, *supra* note 53, at 277.

scientist, physician, or layperson, efforts should be made to understand these different languages and mindsets.³¹⁸

IX. CONCLUSION

The advancements in the DTC genetic testing industry offer consumers a new opportunity to learn about themselves. These advancements promise a revolution in personalized medicine for tomorrow. Thus, it is imperative for Congress and the FDA to exercise restraint and continue to work together with all stakeholders to “spur the industry” to address problems.³¹⁹

The passage of GINA was one critical step toward an evolving body of law in this area, but as the science in this area continues to progress, it is only the first step.³²⁰ A more robust body of law governing genetic information is needed to help guide the public, the industry, and courts before litigation occurs.³²¹

A holistic approach would best ensure the success of a long-term solution.³²² Congress and regulatory agencies must start at the ground level by establishing a framework of definitions that accounts for the various activities of the DTC industry, such as ancestry, disease-risk prediction, drug-response prediction, and simple-trait analysis. Roles and responsibilities between all parties should be defined. This will help create consistent standards to which the DTC industry must adhere. Self-regulation should also be encouraged to allow industry members to take responsibility and pride in evolving the industry. To foster this, the government should not be overly paternalistic by essentially taking over these companies³²³ or, worse, by stamping them out.³²⁴ Finally, new

318. See Patsner, *supra* note 53, at 277.

319. *DTC Hearing*, *supra* note 9, at 22 (statement of Rep. Robert Latta, Member, H. Subcomm. on Oversight & Investigations).

320. *Id.*; see also Abiola, *supra* note 44, at 858 (discussing the limitations on private causes of action in GINA).

321. See, e.g., *Blumer v. Acu-Gen Biolabs, Inc.*, 638 F. Supp. 2d 81 (D. Mass. 2009) (adjudicating a class action litigation based on false advertising of the accuracy of prenatal genetic tests). *Blumer* is an example of what could be avoided by creating an effective regulatory framework now.

322. See, e.g., Lobel, *supra* note 107, at 385 (discussing how a holistic approach to problem solving avoids a fragmentary approach, while taking into account multiple, interconnected issues).

323. See Evans & Green, *supra* note 152, at 569. Evans and Green discuss the need for simple transparency, that open labeling and honestly telling consumers how tests are conducted can avoid paternalism. *Id.* In fact, the authors note that many leading companies

approaches to educating future generations of consumers, patients, researchers, and doctors should be encouraged. Access to our genetic information empowers us, and we are on the cusp of a revolutionary paradigm shift in how medical professionals, researchers, and the general public view individual genetic information. In the wake of this new horizon, the approach we take today will shape the world of tomorrow; it is time to embrace a new, holistic approach that nurtures limitless possibility.

have already taken laudable steps toward improving the industry by publishing how they arrive at risk estimates on their websites. *Id.* Such efforts should be rewarded by decisionmakers.

324. *See* Novick, *supra* note 67, at 647. Novick argues the solution is not to stamp out the industry through state or federal regulation. *Id.* Even if this were the goal, as we have seen through the proliferation and availability of prescription drugs via the Internet, the market will likely defeat complete obliteration. *See id.*