

RISK AND RESPONSIBILITY: STATE REGULATION AND ENFORCEMENT OF THE DIRECT-TO-CONSUMER GENETIC TESTING INDUSTRY

I. INTRODUCTION

Does your DNA hold evidence of Native American ancestry? Are you likely to experience muscle pain while taking cholesterol-lowering drugs? Are you at an increased risk for developing Parkinson's disease? Do you produce wet or dry earwax? Advances in genetic and medical science have led to the rise of the direct-to-consumer (DTC) genetic testing industry, allowing people to discover answers to hundreds of such questions from the comfort of their homes. At a federal level, this industry remains largely unregulated, although there have been recent movements toward the imposition of new standards. In the meantime, states have been left to decide how to individually manage these new companies. Some states have no laws on this subject, permitting all kinds of DTC genetic testing, while others have effectively banned the DTC testing industry by imposing physician prescription requirements, laboratory licensing, informed consent requirements, and strict interpretations of the definition of "the practice of medicine." DTC genetic test companies have taken varying approaches to this tangle of regulations, some changing their business models and others trying to find ways to circumvent these standards.

Through enforcement actions consisting of cease and desist letters, grants of state licenses, threats of civil fines, and public awareness campaigns, states such as New York, Maryland, and California have been able to bring most DTC genetic testing companies into compliance with state laws and regulations. However, it appears some DTC testing companies are still not complying with laws in states that prohibit DTC testing "on the books" but have yet to undertake enforcement actions. Due to the lack of scientific understanding in the general public and the risks involved with sensitive medical information, some form of consumer protection is needed. In order to effectively regulate this industry, active enforcement mechanisms are necessary to help companies understand regulations and promote compliance.

Part II of this paper describes the history and the present state of the DTC genetic testing industry, and lays out the advantages and disadvantages of this new technology. This section will also give a brief

overview of the current state of federal regulation.¹ Part III will examine the various approaches states have taken in regard to this regulation problem. It will consider states that allow the DTC genetic testing industry to operate unregulated, as well as those states that impose restrictions such as physician prescribing, laboratory licensing, informed consent, and strict interpretations of the practice of medicine.² Part IV will investigate those actions taken by states when DTC genetic test companies fail to comply with their laws.³ Part V will explore industry reaction to these enforcement actions.⁴ Finally, the analysis in Part VI will address what lessons can be learned from state attempts at regulation and what concepts should be included in the forthcoming implementation of federal regulations.⁵

II. BACKGROUND

In the nearly 60 years since Watson and Crick discovered the structure of DNA, the science of genetics has advanced rapidly.⁶ However, it is only within the past decade that it has become practical to apply this newfound knowledge towards improvements in human health.⁷ With the completion of the Human Genome Project's mapping of the genome in 2003,⁸ scientists have begun to unlock the relationships between the deviations in genetic sequences and disease.⁹ Variations in single base pairs, known as single nucleotide polymorphisms (SNPs or snips), can be correlated with risks of certain diseases.¹⁰ While the conventional medical community has been slow to incorporate these discoveries into ordinary primary care, some entrepreneurs have decided to take advantage of this technology.¹¹ They have bypassed physicians and marketed genetic tests to consumers over the

1. See *infra* Part II.

2. See *infra* Part III.

3. See *infra* Part IV.

4. See *infra* Part V.

5. See *infra* Part VI.

6. *Genetics and Genomics Timeline*, GENOME NEWS NETWORK (2004), http://www.genomenewsnetwork.org/resources/timeline/1953_Crick_Watson.php.

7. *Direct-to-Consumer Genetic Testing and the Consequences to the Public: Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 111th Cong. 2 (2010) [hereinafter *Shuren Statement*] (statement of Jeffrey Shuren, Director, Center for Devices and Radiological Health, Food and Drug Administration).

8. *Human Genome Project Information*, U.S. DEP'T OF ENERGY, OFFICE OF SCI. (July 31, 2012), http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml.

9. See *Shuren Statement*, *supra* note 7, at 2.

10. *SNP Fact Sheet*, U.S. DEP'T OF ENERGY, OFFICE OF SCI. (Sept. 19, 2008), http://www.ornl.gov/sci/techresources/Human_Genome/faq/snps.shtml.

11. See Pascal Borry et al., *Where Are You Going, Where Have You Been: A Recent History of the Direct-to-Consumer Genetic Testing Market*, 1 J. COMMUNITY GENETICS 101, 102 (2010).

internet.¹² These DTC genetic tests have taken a number of forms, including tests that evaluate monogenic diseases, complex disease susceptibility, reactions to pharmaceuticals, nutrition, and ancestry.¹³ This market expanded rapidly, and by 2009 over 30 different DTC genetic test companies were in operation.¹⁴ Initially, it appeared the public was infatuated with the idea of taking control of its own health and unlocking the information contained within each genetic code.¹⁵ For example, the DTC genetic test company 23andMe was named the 2008 Time Invention of the Year.¹⁶

However, scientists and regulators have begun to voice some concerns about the accuracy, public perception, and value of these tests.¹⁷ Most diseases are multifactorial, resulting from a combination of multiple genes and environmental factors rather than from a single mutation in a single gene.¹⁸ DTC genetic tests often report back with a category of risk of contracting a disease.¹⁹ However, risk is often defined in different ways, and such genetic tests are rarely conclusive.²⁰ In 2006, the Federal Trade Commission noted that "having a particular gene doesn't necessarily mean that a disease will develop; not having a particular gene doesn't necessarily mean that the disease will not,"²¹ and warned consumers to interpret these tests with "a healthy dose of skepticism."²² As Jessica Stransky of the genetic counseling program at the University of Maryland said, "That kind of information is pretty hard for the average person to interpret. . . . It gets more complicated with genetic traits that aren't highly linked to certain conditions."²³ Additionally, these tests estimate risk based on genetic factors

12. See *id.*

13. *Id.*

14. *Id.*

15. See Timothy Caulfield & Amy L. McGuire, *Direct-to-Consumer Genetic Testing: Perceptions, Problems and Policy Responses*, 63 ANN. REV. MED. 23, 26 (2012).

16. Anita Hamilton, *Best Inventions of 2008, The Retail DNA Test*, TIME (Oct. 29, 2008), http://www.time.com/time/specials/packages/article/0,28804,1852747_1854493_1854113,00.html.

17. Caulfield & McGuire, *supra* note 15.

18. Jeanne Erdmann, *Home Genetics Tests Are Called Unreliable*, STL TODAY, March 23, 2011, http://www.stltoday.com/lifestyles/health-med-fit/medical/home-genetics-tests-are-called-unreliable/article_cee6a092-0dc7-565e-b159-b53215f42ba1.html.

19. *Id.*

20. *Id.*

21. Jane E. Brody, *Buyer Beware of at-Home Genetic Tests*, N.Y. TIMES, Sept. 1, 2009, at D6.

22. Caulfield & McGuire, *supra* note 15, at 27.

23. Lisa Cleary, *Direct-to-Consumer Genetic Testing Debate*, NBC WASH., Aug. 14, 2011, <http://www.nbcwashington.com/news/health/Direct-to-Consumer-Genetic-Testing-Debate-112986579.html>.

alone, ignoring the impact of environment, lifestyle, and family history.²⁴ The American Medical Association (AMA) has warned that without the guidance of a physician or genetic counselor, test results could lead to misinterpretation, miscalculation of risks, and unwarranted lifestyle changes, or at the very least, money could be needlessly wasted on tests with little scientific value.²⁵

A 2010 report by the Government Accountability Office (GAO) studied four major DTC genetic test companies and came to the conclusion that the tests are “misleading and of little or no practical use.”²⁶ After submitting samples from the same donors to different companies, the investigators found a single person could be told he was at below average, average, and above average risk for a single disease, depending on which company was used.²⁷ Another blow to the industry’s credibility occurred in June 2010, when a sample swap at 23andMe resulted in 96 customers receiving data that did not belong to them, leading to confusion, distress, and privacy concerns.²⁸ In May 2010, Walgreens dropped its plan to sell Pathway Genomics over-the-counter kits in its stores upon investigative action by the FDA.²⁹ These incidents have led to questions about the adequacy of the regulation of this industry.³⁰

Most of the calls for increased regulations come from those concerned about protecting consumers.³¹ Many commentators have been concerned that the results of DTC genetic tests can cause anxiety or lead to harmful behavior changes.³² Commentators are concerned consumers will either

24. Felix W. Frueh et al., *The Future of Direct-to-Consumer Clinical Genetic Tests*, 12 NATURE REV. GENETICS 511, 511 (2011).

25. Letter from Michael D. Maves, Exec. Vice President, Chief Exec. Officer, Am. Med. Ass’n to U.S. Food & Drug Admin. (Feb. 23, 2011) (on file with Am. Med. Ass’n), available at <http://www.ama-assn.org/ama1/pub/upload/mm/399/consumer-genetic-testing-letter.pdf>.

26. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-10-847T, DIRECT TO CONSUMER GENETIC TESTS: MISLEADING TEST RESULTS ARE FURTHER COMPLICATED BY DECEPTIVE MARKETING AND OTHER QUESTIONABLE PRACTICES 1 (2010).

27. *Id.* at i.

28. Daniel MacArthur, *Sample Swaps at 23andMe: A Cautionary Tale*, WIRED SCIENCE (June 7, 2010, 6:00 AM), <http://www.wired.com/wiredscience/2010/06/Sample-swaps-at-23andMe:-a-cautionary-tale>.

29. Sherry Jacobson, *Walgreens’ Dropping of Genetic Test Kits’ Relieves Experts*, STL TODAY (May 17, 2010), http://www.stltoday.com/lifestyles/health-med-fit/medical/walgreens-dropping-of-genetic-test-kits-relievesexperts/article_d75a363a-6aa5-59ab-815b-a24a12ba6002.html.

30. Caulfield & McGuire, *supra* note 15, at 27.

31. *Id.*; Maves, *supra* note 25.

32. Caulfield & McGuire, *supra* note 15, at 27. However, recent studies have suggested these concerns about stress and psychological harm from DTC genetic test results may have been over-stated. See Cinnamon Bloss et al., *Effect of Direct-to-Consumer Genomewide Profiling to Assess Disease Risk*, 364 NEW ENG. J. MED. 524, 529 (2011).

overreact to an increased risk of disease or gain a false sense of security from a report of a lowered risk.³³ There is the potential danger of creating a population of the “worried well” who spend time and resources to deal with the results of their tests, which may only be grounded in weak science.³⁴ Adding to this confusion is the marketing strategies of many of these companies, which suggest that customers will be empowered to make informed and personalized healthcare and lifestyle decisions, implying more control over many of these diseases than science currently holds.³⁵ There are also concerns that the results of these tests will spur people to make unnecessary appointments with physicians, increasing the burden of an already overworked healthcare system and exposing patients to the risk of iatrogenic harm.³⁶ Finally, observers are also concerned about privacy risks and the uncontrolled disclosure of genetic information, given that neither traditional physician-patient confidentiality nor HIPAA standards necessarily apply.³⁷

The tort system seems incapable of effectively regulating this industry. This incapability is evidenced by only one major attempt at bringing a class-action lawsuit against a DTC genetic test company. In *Blumer v. Acu-Gen Biolabs*, the plaintiffs brought a products liability action against the manufacturer of the Baby Gender Mentor Kit, which was advertised to determine the gender of a fetus through genetic analysis of maternal blood samples with a 99% degree of accuracy.³⁸ The plaintiffs brought claims under false advertising, consequential damages, failure to provide the guaranteed refund, and infliction of emotional distress.³⁹ However, when Acu-Gen was dissolved in 2010, the case was no longer financially viable and the plaintiffs filed a motion to dismiss without prejudice.⁴⁰ This has left the legal community with doubts as to the viability of using lawsuits to keep the DTC genetic test industry in check. The ability to bring lawsuits in the first place can be dubious, due to the cost, time, and effort needed. Additionally, any lawsuit in this highly technical area is likely to come down to a “battle of the experts” and potentially result in a Daubert hearing over the validity of

33. Caulfield & McGuire, *supra* note 15, at 27.

34. Frueh et al., *supra* note 24, at 511.

35. See Caulfield & McGuire, *supra* note 15, at 24.

36. *Id.* at 29. Iatrogenic harm is defined as “injury caused by doctors and health care institutions.” BARRY FURROW ET AL., *HEALTH LAW: CASES, MATERIALS, AND PROBLEMS* 41 (6th ed. 2008).

37. Caulfield & McGuire, *supra* note 15, at 29.

38. *Blumer v. Acu-Gen Biolabs, Inc.*, 638 F. Supp. 2d 81, 83, 84 (D. Mass. 2009).

39. *Id.* at 83.

40. Annmarie Giblin, *Direct to Consumer Genetic Testing: A Pandora’s Box of Potential Litigation*, DRI TODAY, Sept. 5, 2011, <http://dritoday.org/feature.aspx?id=67>.

the mostly unsettled science behind the genetic tests.⁴¹ Finally, in cases such as Blumer where no final resolution is reached, no rule of law emerges by which others in the industry can be regulated.

Some may argue that if these tests are truly without credibility, they will go the way of “snake oil” treatments of the past, and disappear due to market forces.⁴² While this may be the eventual outcome for the more shady and unreliable members of this industry, they should not be permitted to mislead and harm uninformed consumers in the meantime. Others may claim that the responsibility should fall to consumers to be adequately informed before ordering a test kit, and that the customers should shoulder the risk of being misled. However, this industry is vastly different from traditional consumer purchasing agreements of the past, presenting new challenges.⁴³ This is a highly technical field relying almost entirely on cutting-edge science.⁴⁴ As a result of the young age of this science, many of those who are purchasing DTC genetic tests likely received very little education in genetics. There is a gross imbalance between the level of understanding of the general public and those who are marketing genetic tests with all kinds of hopeful promises.⁴⁵ As a result, consumers are placing a large amount of trust in the results they receive from their genetic tests. Some form of government regulation is needed to help stabilize this imbalance in knowledge and understanding.

It has been difficult to “determine the most appropriate way to regulate a product that has multiple purposes, that is sold to consumers internationally and over the internet, and that has been found by federal investigation to have questionable validity and unproven utility.”⁴⁶ Currently, DTC genetic tests fall within a grey area of federal regulation.⁴⁷ Both the Centers for Medicare and Medicaid Services (CMS) and the Federal Food

41. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). A Daubert challenge is a hearing held before the beginning of trial at which the admissibility of expert testimony is decided. *Id.* at 582. Courts look to a number of factors, including whether the scientific theory has been tested, if it has been subjected to peer review and publication, its error rate, standards controlling its application, and its general acceptance in the scientific community. *Id.* at 593-94. Since the algorithms used to test SNPs are rapidly evolving, it is unlikely there would be a consensus in the scientific community, leading to protracted battles at trial between experts with opposing opinions. See *Shuren Statement*, *supra* note 7, at 7-8.

42. See PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 47, 98-112 (1982).

43. See Caulfield & McGuire, *supra* note 15, at 30.

44. See *id.* at 27.

45. See Kishore, *Test at Your Own Risk: Your Genetic Report Card and the Direct-to-Consumer Duty to Secure Informed Consent*, 59 EMORY L.J. 1553, 1588 (2010).

46. Caulfield & McGuire, *supra* note 15, at 24.

47. Meredith Wadman, *Gene-Testing Firms Face Legal Battle*, 453 NATURE 1148, 1148 (2008).

and Drug Administration (FDA) share in responsibility for regulating this industry.⁴⁸ CMS is responsible for overseeing all tests developed and performed in-house, known as laboratory developed tests (LDTs).⁴⁹ The FDA regulates tests that are marketed as medical devices.⁵⁰ Under § 201(h) of the Federal Food and Drug Cosmetic Act, a device is defined as any instrument that is “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.”⁵¹ Typically, a test kit that bundles components and is labeled for a particular use is referred to as an in vitro diagnostic test (IVD), which is a medical device that cannot be marketed without FDA approval.⁵² However, most genetic tests are not sold as kits, but rather the tests are performed in-house on samples sent in by mail.⁵³ As a result, they are classified as LDTs that are not subject to FDA oversight or even strict scrutiny by CMS.⁵⁴ As long as a laboratory meets minimum quality controls under Clinical Laboratory Improvement Amendments (CLIA), there are no accuracy reviews and no mandatory proficiency testing.⁵⁵

However, there has been a lot of movement towards increasing federal oversight of this industry. In 2008, the FDA published guidelines on regulating medical devices known as In Vitro Diagnostic Multivariate Assays (IVDMIA), a particular class of LDTs, which encompasses some genetic tests.⁵⁶ The FDA intends to begin regulating this particular class of tests because they are more intricate and carry greater risks than other more traditional LDTs.⁵⁷ On July 22, 2010, the House of Representatives’ Subcommittee on the Oversight and Investigations on Energy and Commerce held a public hearing entitled “Direct-to-Consumer Genetic Testing and the Consequences to the Public Health.”⁵⁸ In March 2011, the FDA’s molecular and genetics group held a meeting to discuss DTC genetic

48. Dianne Bourque et al., *Issues and Trends in the Regulation of Genetic Testing*, LEXISNEXIS EMERGING ISSUES ANALYSIS, Apr. 2009, at 3, available at 2009 Emerging Issues 3537.

49. *Id.*

50. *Id.*

51. 21 U.S.C. § 321(h)(2) (2006).

52. Bourque et al., *supra* note 48, at 6.

53. *Id.* at 4.

54. *Id.* at 4, 8.

55. *Id.* at 4.

56. *Id.* at 8.

57. Bourque et al., *supra* note 48, at 8.

58. Giblin, *supra* note 40. The hearing examined the sale of DTC personal genetic tests and included testimony from the GAO, FDA, academia, and industry. *Direct-to-Consumer Genetic Testing and the Consequences to the Public: Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 111th Cong. (2010).

testing.⁵⁹ Between May 10, 2010 and May 11, 2011, the FDA sent letters to manufacturers of DTC genetic tests, advising them they appeared to be selling medical devices and therefore needed FDA clearance.⁶⁰ As a result, many testing companies are left confused by this tangle of federal regulations, unsure of whether their test requires CLIA certification under CMS, FDA approval, or both, and are left trying to anticipate what future federal regulations may require of them.⁶¹

In the meantime, the responsibility of regulation has fallen to the states. They have been left to their own devices in deciding how to manage this new industry. The director of the Genetics and Public Policy Center stated, "In the absence of federal leadership on genetic testing oversight, it is not surprising that the states are stepping in."⁶² The result is a complex and diverse set of regulations that vary widely between states.⁶³ While trying to serve their national customer base, DTC genetic test companies are faced with the task of complying with unique regulations and requirements in each state in order to avoid penalties.

III. STATE LAWS

Through CLIA, all states have the authority to regulate genetic testing laboratories.⁶⁴ CLIA designates that patient tests must be requested by an authorized person, and an "[a]uthorized person means an individual authorized under State law to order tests or receive test results, or both."⁶⁵ Therefore, the definition of an authorized person varies between states. As a result, the law "is very inconsistent from state to state at a time when the risks to consumers do not vary state to state — and when we have businesses that are certainly operating state to state."⁶⁶ Twenty-three states do not have any statutes addressing DTC testing, meaning there is no

59. Giblin, *supra* note 40. This was a non-voting panel meeting held to discuss and make recommendations on scientific issues concerning DTC genetic tests that make medical claims. *Summary from the Molecular & Clinical Genetics Panel Meeting – March 8 & 9, 2011*, DEP'T OF HEALTH & HUMAN SERVS., <http://www.genomicslawreport.com/wp-content/uploads/2011/03/FDA-DTC-Advisory-Panel-Meeting-Summary.pdf>.

60. Giblin, *supra* note 40.

61. *See id.*

62. Turna Ray, *Will Other States Follow NY, Calif., in Taking on DTC Genetic-Testing Firms?*, GENOMEWEB, PHARMACOGENOMICS REPORTER (June 25, 2008), <http://www.genomeweb.com/dxpgx/will-other-states-follow-ny-calif-taking-dtc-genetic-testing-firms-0>.

63. *See generally* GENETICS & PUB. POLICY CTR., JOHNS HOPKINS UNIV., SURVEY OF DIRECT-TO-CONSUMER TESTING STATUTES AND REGULATIONS, BERMAN INSTITUTE OF BIOETHICS (2007) (demonstrating the variety of direct to consumer regulations among the states).

64. Borque et al., *supra* note 48, at 9-10.

65. 42 C.F.R. § 493.2 (2011).

66. Wadman, *supra* note 47, at 1149.

regulation or limitations on the industry's ability to market their product to consumers.⁶⁷ Fifteen states have statutes that effectively ban the DTC genetic test industry, through the use of a variety of physician ordering requirements, laboratory licensing, informed consent, and scope of the definition of "the practice of medicine."⁶⁸ Other states are situated between these extremes, limiting the types of DTC tests available or specifying certifications that must be obtained before tests can be marketed to consumers.⁶⁹ This results in a highly fragmented and complex regulatory picture for any DTC genetic test company hoping to market its services nationwide.

A. States Actively Permitting DTC Genetic Tests

A small number of states have statutes or regulations permitting DTC genetic testing, meaning they are direct-access states.⁷⁰ For example, Virginia state law not only allows patients to order tests and receive results, it also provides some protection for physicians who fail to act on the results of a test that they themselves did not order, or results of a test that were not brought to them for consultation.⁷¹ Virginia law also provides that when a test is requested without the authorization of a physician, the results shall be reported to the person who was the subject of the test.⁷² The results need to include a statement in bold type that it is the responsibility of the test subject to "arrange with his physician for consultation and interpretation of the results."⁷³ Virginia not only allows direct-to-consumer genetic tests, but has also taken steps to ensure that physicians and healthcare providers are not harmed by the existence of the industry. Rather than trying to restrict the industry, Virginia has taken action to accommodate it.

B. States that are Silent

Twenty-three states are simply silent on the issue, having no statutes or regulations addressing the permissibility of patient-ordered genetic tests.⁷⁴ These are also typically direct-access states.⁷⁵ Silence by state legislatures allows DTC testing companies to directly market genetic tests to consumers

67. GENETICS & PUB. POLICY CTR., *supra* note 63, at 1-2, 4-5, 7, 9-13.

68. *Id.* at 1-9, 11-12, 14.

69. *Id.* at 1, 3-4, 6, 8-10.

70. *Id.* at 2, 8, 10, 13.

71. VA. CODE ANN. § 8.01-581.18 (2006).

72. *Id.*

73. *Id.*

74. GENETICS & PUB. POLICY CTR., *supra* note 63, at 1-2, 4-5, 7-13. These states are Alaska, Arkansas, Delaware, Indiana, Iowa, Kansas, Louisiana, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, Vermont, and West Virginia. *Id.*

75. *Id.*

without the need for an order by a physician or any other learned intermediary.⁷⁶ Also, these states do not impose strict state laboratory licensing or informed consent requirements.⁷⁷ Through their silence, these states imply that DTC genetic tests do not fall within their state definitions of the unlawful practice of medicine. However, in the absence of legislation, these states could still choose to begin regulating the DTC industry through changes in common law, agency policy, or through a different interpretation of their definition of the practice of medicine.

States such as Montana, Missouri, Vermont, and West Virginia have no laws relating to authorization to order genetic tests.⁷⁸ Nebraska law is silent on authority to order genetic tests, however it attempts to impose a written informed consent requirement on those who order predictive genetic tests through a physician.⁷⁹ Yet, if a patient directly orders the test himself, informed consent is not required.⁸⁰

Some states authorize the DTC genetic testing industry implicitly by not including these tests within their definition of the "practice of medicine."⁸¹ Under Colorado law, the practice of medicine does not include provision of laboratory tests to patients in a CLIA certified laboratory.⁸² Therefore Colorado imposes no licensing requirements and permits DTC genetic testing.⁸³ In Utah, the practice of medicine is defined as "to diagnose, treat, correct, administer anesthesia, or prescribe . . . by an individual in Utah or outside the state upon or for any human within the state."⁸⁴ However, DTC genetic tests are not viewed as being diagnostic, as an internal legal opinion from the Utah Department of Health holds that ordering a test, performing the test, and delivering the results does not constitute the "practice of medicine."⁸⁵

Through passive silence, these direct access states provide minimal regulation of the DTC genetic testing industry. This wide latitude given to the industry provides for freedom to access genetic information, but does not offer consumers any protection against potentially misleading results. These states place the responsibility of being actively informed participants upon

76. "Learned intermediary" is defined as a person in the chain of distribution between the manufacturer and consumer, who is aware of the risks of the product and has the responsibility to inform the end-user. BLACK'S LAW DICTIONARY 890, 970 (9th ed. 2009).

77. GENETICS & PUB. POLICY CTR., *supra* note 63, at 1-2, 4-5, 7-13.

78. *Id.* at 7, 12, 13.

79. NEB. REV. STAT. § 71-551 (2011).

80. GENETICS & PUB. POLICY CTR., *supra* note 63, at 8.

81. *See id.* at 1-2, 12.

82. COLO. REV. STAT. § 12-36-106(3)(u) (2011).

83. GENETICS & PUB. POLICY CTR., *supra* note 63, at 2.

84. UTAH CODE § 58-67-102 (2012).

85. GENETICS & PUB. POLICY CTR., *supra* note 63, at 12.

the shoulders of consumers who wish to know more about their genetic makeup.

C. States Prohibiting DTC Genetic Tests

Fifteen states have statutes and regulations in place that effectively ban the DTC genetic testing industry.⁸⁶ These states prohibit DTC genetic testing in a variety of ways, such as limiting the authorization to order medical tests and receive results, laboratory licensing, imposing informed consent requirements, and the scope of definition of the practice of medicine.⁸⁷

1. Authorization to Order Medical Tests

The simplest way to regulate the DTC testing industry is through statutes or regulations controlling the authority to request clinical laboratory tests. By altering the definition of an authorized person, states can effectively prevent companies from providing services to consumers without the participation of a physician or other qualified personnel.

California law spells out specific tests that may be requested by any person without the need of a physician.⁸⁸ These include “pregnancy, glucose level, cholesterol, occult blood, and any other for which there is a test for a particular analyte approved by the FDA for sale to the public without a prescription, in the form of an over-the-counter test kit.”⁸⁹ This list does not include genetics tests, meaning any orders from a DTC genetic testing company in California must go through a physician.⁹⁰

New York also prohibits marketing genetic tests directly to consumers.⁹¹ New York regulations state “a clinical laboratory shall examine specimens only at the request of licensed physicians or other persons authorized by law to use the findings of laboratory examinations in their practice or the performance of their official duties.”⁹² Other authorized persons who can request examination of specimens include dentists, podiatrists, chiropractors, physician’s assistants, licensed midwives, nurse practitioners, police officers, and judges.⁹³ Additionally, New York prohibits laboratories from reporting the results directly to the patient:

86. *Id.* at 1-9, 11-12, 14. These states are Alabama, California, Connecticut, Georgia, Hawaii, Idaho, Kentucky, Maryland, Michigan, New Hampshire, New York, Pennsylvania, Rhode Island, Tennessee, and Wyoming. *Id.*

87. See Ray, *Will Other States Follow NY, Calif., in Taking on DTC Genetic-Testing Firms?*, *supra* note 62.

88. CAL. BUS. & PROF. CODE § 1246.5 (West 2012).

89. *Id.*

90. *Id.*

91. GENETICS & PUB. POLICY CTR., *supra* note 63, at 9-10.

92. N.Y. COMP. CODES R. & REGS. tit. 10, § 58-1.7(b) (2012).

93. *Id.* § 58-1.7(b)(2).

No person shall report the result of any test, examination or analysis of a specimen submitted for evidence of human disease or medical condition except to a physician, his agent, or other person authorized by law to employ the results thereof in the conduct of his practice or in the fulfillment of his official duties. Reports shall not be issued to the patients concerned except with the written consent of the physician or other authorized person.⁹⁴

Maryland has also limited the use of DTC genetic tests, despite claiming to be “the state for progressive bioscience development.”⁹⁵ State regulations provide that a laboratory may not perform a test without authorization from a court of law, doctor, or other authorized person such as a midwife, nurse practitioner, physician’s assistant, chiropractor, or employer requesting a job-related drug or alcohol test.⁹⁶ Further, a laboratory may not release the test results to patients, nor to anyone other than the authorized person.⁹⁷ There is an exception for certain health awareness tests, approved by the Secretary of Health and Mental Hygiene and performed at a temporary laboratory, which may be provided directly to consumers.⁹⁸ However, genetic tests do not qualify under this exception.⁹⁹

Massachusetts law restricts the ordering of medical tests and receipt of results to doctors and other authorized people; however, there is a large exception for those tests that promote “health awareness and education among the general public by early detection of disease and/or associated risk factors.”¹⁰⁰ These tests that fall under the exemption are not going to be used “for the purpose of providing clinical diagnosis or treatment to patients.”¹⁰¹ As a result direct-to-consumer marketing is permitted for eight types of tests including pregnancy and cholesterol, but not genetics.¹⁰²

2. Laboratory Licensing

Through their police power, states have the authority to license the healthcare industry.¹⁰³ Licenses are used to enforce disciplinary actions,

94. *Id.* § 58-1.8.

95. *Bio in Maryland*, MD. BIOTECHNOLOGY CTR., <http://marylandbiocenter.org/Bio%20science%20of%20Maryland/Pages/Home.aspx> (last visited Sep. 29, 2012).

96. MD. CODE REGS. 10.10.06.02 (2011).

97. *Id.* 10.10.06.04.

98. *Id.* 10.10.01.03; GENETICS & PUB. POLICY CTR., *supra* note 63, at 6.

99. MD. CODE REGS. 10.10.03.02B; GENETICS & PUB. POLICY CTR., *supra* note 63, at 6.

100. GENETICS & PUB. POLICY CTR., *supra* note 63, at 6-7.

101. 105 MASS. CODE REGS. 180.010 (2012).

102. GENETICS & PUB. POLICY CTR., *supra* note 63, at 7; *Health Promotion Screening Program Approval*, MASS. DEP’T OF PUB. HEALTH CLINICAL LAB. PROGRAM, http://webcache.googleusercontent.com/search?q=cache:_ur3q7Hs8cUJ:www.mass.gov/eohhs/docs/dph/cllnicallab/health-promo-screening-general-info.rtf+&cd=1&hl=en&ct=clnk&gl=us (last visited Sep. 29, 2012).

103. FURROW ET AL., *supra* note 36, at 117.

regulate the scope of services, and prevent unqualified people from attempting to provide services to the public.¹⁰⁴

California law requires all laboratories performing these genetic tests to undergo evaluation of accuracy and medical utility,¹⁰⁵ and also imposes licensing requirements upon the scientists performing the tests.¹⁰⁶ California regulations state that “[a] clinical laboratory performing clinical laboratory tests or examinations classified as of moderate or of high complexity under CLIA¹⁰⁷ shall obtain a clinical laboratory license.”¹⁰⁸ Also, “it is unlawful for any person to own, operate, maintain, direct or engage in the business of operating a clinical laboratory . . . unless he or she possesses a valid clinical laboratory license issued by the department,”¹⁰⁹ and

no person may solicit or accept any biological specimen for clinical laboratory testing or examination unless there is in effect for the clinical laboratory where the test or examination is to be performed a license . . . , and the person performing the test or examination is authorized to perform the test or examination.¹¹⁰

There is also a provision that allows the Department of Public Health to retain the ability to

not issue a license or registration until it is satisfied that the clinical laboratory will be operated within the spirit and intent of this chapter, that the owners and laboratory directors are each of good moral character, and that the granting of the license will not be in conflict with the interests of public health.¹¹¹

This adds a subjective element to the California licensing scheme, which encourages DTC genetic testing companies to make good faith efforts to comply with state laws, or risk not being granted a license in the future.

104. *Id.*

105. Robert Langreth, *California orders stop to gene testing*, FORBES (June 14, 2008), http://www.forbes.com/2008/06/14/stop-gene-testing-biz-healthcare-cz_rl_0614gene_test.html.

106. CAL. BUS. & PROF. CODE § 1288.5 (West 2012).

107. CLIA assigns a level of complexity of 1, 2 or 3 to seven criteria of each laboratory test system. *CLIA Categorization Criteria*, U.S. FOOD & DRUG ADMIN., (Mar. 20, 2009), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124208.htm>. A score of 1 indicates low complexity, while a score of 3 indicates high complexity. *Id.* A test with a total score of 12 or more is categorized as high complexity. *Id.* The seven categories are knowledge, training and experience, reagents and materials preparations, characteristics of operational steps, calibration, quality control and interpretation and judgment. *Id.*

108. CAL. BUS. & PROF. CODE § 1265(a)(1) (West 2012).

109. *Id.* § 1281.

110. *Id.* § 1288.5.

111. *Id.* § 1265(c).

New York's Clinical Laboratory Evaluation Program (CLEP) is at least as stringent as CLIA, imposing stricter requirements on laboratories operating within the state, and giving New York CLIA-exempt status.¹¹² New York requires evidence of both the analytical and clinical validity of all tests, approval of all tests before they can be marketed (including ones not subject to FDA approval), and biennial laboratory inspections.¹¹³ New York regulations also require a clinical laboratory to have a permit before it can solicit and accept specimens for the purpose of diagnosis, prevention, or treatment of a disease, or the assessment of a health condition.¹¹⁴ As a result of the requirement that all laboratories soliciting samples from New York residents are required to obtain this license, nearly 75% of all cytogenetic and genetic tests in the United States are subject to CLEP.¹¹⁵

Maryland regulations also establish quality assurance standards for licensed laboratories, including criteria such as effective supervision, quality control, and safety procedures.¹¹⁶ Additionally, Maryland prohibits physicians from sending specimens to laboratories that are not licensed within the state.¹¹⁷ Specifically, genetic testing laboratories must provide written verification from the laboratory director that direct-to-consumer specimens will not be accepted from Maryland, nor will testing be performed on such specimens.¹¹⁸

3. Informed Consent Requirements

In addition to physician ordering and laboratory licensing, states can also regulate the genetic testing industry by implementing conditions of informed consent. These regulations can easily be tailored to meet the concerns of individual states, and are directly aimed at ensuring each individual consumer has a meaningful understanding of the risks and benefits of the test.

New York law specifies informed consent requirements for genetic tests.¹¹⁹ The laboratory must provide a statement of the purpose of the test,

112. Borque et al., *supra* note 48, at 10.

113. *Id.* Analytical validity involves correctly detecting the appropriate genetic variation, and clinical validity involves the relationship between the variation and the associated health condition. Frueh et al., *supra* note 24, at 513.

114. N.Y. COMP. CODES R. & REGS. tit. 10, § 58-1.7 (2012).

115. Borque et al., *supra* note 48, at 10.

116. MD. CODE REGS. 10.10.06.02 (2011).

117. Ray, *Will Other States Follow NY, Calif., in Taking on DTC Genetic-Testing Firms?*, *supra* note 62.

118. MD. DEP'T OF HEALTH & MENTAL HYGIENE, REQUIRED DOCUMENTATION 1 (Jan. 5, 2012), available at <http://dhmh.maryland.gov/ohcq/Labs/docs/LabsApps/Required%20Documentation%20Grid.pdf>.

119. Borque et al., *supra* note 48, at 12.

a description of the disease or condition being tested for, the level of certainty that a positive result serves as a predictor for the disease, and the name of persons to whom the results can be disclosed.¹²⁰ However, most often laboratories simply enclose a consent form with the kit.¹²¹ This usually fails to satisfy the legally-sufficient requirement of a meaningful discussion between provider and patient, and exposes the offending company to risk of a civil fine.¹²²

Michigan also imposes informed consent requirements for genetic tests.¹²³ The law requires that “a physician or an individual to whom the physician has delegated authority . . . shall not order a presymptomatic or predictive genetic test without first obtaining the written, informed consent of the test subject.”¹²⁴ This is another way to ensure that ordering of a genetic test occurs through a physician and that the subject is aware of the potential benefits and harms of undergoing the test.

4. The Practice of Medicine

Even without laws specifically authorizing persons to order clinical tests, states can regulate the DTC industry through their interpretation of the definition of the practice of medicine. Traditionally, states have regulated the practice of medicine through their police power, and no one seriously questions their ability to promote regulations for the protection of the public health.¹²⁵ State medical practice acts prohibit anyone but licensed professionals from engaging in the practice of medicine.¹²⁶ The state medical board has primary responsibility for preventing the unauthorized practice of medicine by imposing criminal sanctions and revoking the licenses of any physicians who aid the unlicensed practitioner.¹²⁷ Definitions of the practice of medicine vary from state to state, but most include diagnosis, prescribing, and surgical interventions.¹²⁸ These variations reflect historical and political factors, as well as differences in attitudes and ideologies.¹²⁹

120. *Id.* at 12.

121. *Id.* at 14.

122. N.Y. CIV. RIGHTS LAW § 79-l(5)(a) (McKinney 2012); Borque et al., *supra* note 48, at 14-15.

123. GENETICS & PUB. POLICY CTR., *supra* note 63, at 7.

124. MICH. COMP. LAWS § 333.17020 (2012).

125. Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 159 (2004).

126. FURROW ET AL., *supra* note 36, at 140.

127. *Id.*

128. Noah, *supra* note 125, at 162.

129. *Id.* at 165.

Some DTC genetic test companies claim that they only provide information on health-related predispositions, and are not involved in diagnosis, giving medical advice, or the practice of medicine. For example, Mari Baker, the chief executive of Navigenics stated that the test “‘doesn’t say you have a disease,’ . . . ‘it says you carry a genetic predisposition for the disease and should talk with a health care professional.’”¹³⁰ However, some disagree. They see the provision of information regarding probabilities of severe disease or other health conditions as the practice of medicine. Moreover, they point out that some DTC genetic test company advertisements claim to empower customers to make informed decisions about their health, seemingly emphasizing the medical purpose of the tests.¹³¹ The AMA is of the position that results that are presented as an increase or decrease in risk of a condition are diagnostic, and should be prohibited as the unauthorized practice of medicine.¹³²

Deciding whether or not DTC genetic tests are the practice of medicine has proved to be difficult. For example, most agree that tests for ancestry do not constitute the practice of medicine, while single-gene determinative tests such as those for Huntington’s disease do.¹³³ However, many traits that are screened for in these tests involve multiple genes and environmental factors, and result in only increased or decreased probabilities of susceptibility.¹³⁴ The difficulty lies in determining where along this spectrum DTC genetic testing companies cross over into the unauthorized practice of medicine. In June 2008, California, along with New York and Maryland, determined that use of genetic tests in performing risk assessments fell within the scope of state regulation.¹³⁵

In New York, the practice of medicine is defined as “diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition.”¹³⁶ In regards to DTC genetic tests, a director from the New York State Department of Health stated, “We think if you’re telling people you have increased risk of adverse health effects, that’s

130. Andrew Pollack, *Gene Testing Questioned by Regulators*, N.Y. TIMES, June 26, 2008, at C2.

131. Kishore, *supra* note 45, at 1566. For example, 23andMe’s website encourages visitors to, “Take a more active role in managing your health.” *Taking a more active role in managing your health*, 23ANDME, <https://www.23andme.com/health/> (last visited Sept. 26, 2012).

132. Maves, *supra* note 25, at 3.

133. Kishore, *supra* note 45, at 1565-66.

134. *Id.* at 1566.

135. CLINICAL LAB. TECH. ADVISORY COMM., CA. DEP’T OF PUB. HEALTH, MINUTES OF THE JUNE 25, 2010 MEETING 5 (2010), available at <http://www.cdph.ca.gov/programs/lfs/Documents/CLTAC-minutes-25Jun10.pdf>.

136. N.Y. EDUC. LAW § 6521 (McKinney 2012).

medical advice.”¹³⁷ In California, the unlawful practice of medicine involves any unlicensed person who practices “any system or mode of treating the sick or afflicted in this state, or who diagnoses, treats, operates for or prescribes for any ailment, blemish, deformity, disease, disfigurement, disorder, injury, or other physical or mental condition of any person.”¹³⁸ It appears that like New York, California believes that DTC genetic tests diagnose disorders or physical conditions. In Maryland the “practice of medicine” means “to engage, with or without compensation, in medical diagnosis, healing, treatment, or surgery” and includes “diagnosing, healing, treating, preventing, prescribing for, or removing any physical, mental, emotional ailment or supposed ailment of an individual by . . . appliance, test, drug, operation or treatment.”¹³⁹ This definition specifically includes the uses of tests within the practice of medicine, seemingly encompassing DTC genetic tests. Massachusetts’ most recent proposed regulations provide that the practice of medicine involves:

conduct, the purpose or reasonably foreseeable effect of which is to encourage the reliance of another person upon an individual’s knowledge or skill in the maintenance of human health by the prevention, alleviation or cure of disease . . . or reasonably thought to involve an assumption of responsibility for the other person’s physical or mental well being: diagnosis, treatment, use of instruments or other devices¹⁴⁰

This definition is different from the others in that it focuses on the relationship between patient and practitioner. This kind of reliance is readily apparent in the DTC genetic testing model. Michigan directly bans DTC genetic tests through its definition of the practice of medicine,¹⁴¹ which means the “diagnosis, treatment, prevention, cure or relieving of a human disease, . . . by . . . device, diagnostic test, or other means, or offering, undertaking attempting to do, or holding oneself out as able to do, any of these acts.”¹⁴² According to an official with the Michigan Department of Community Health, ordering and receiving tests is considered the practice of medicine, and therefore DTC genetic testing is banned.¹⁴³

Even though some of these definitions do not appear to be obviously different from those in direct access states, they serve as one of the available tools states can use to impose regulations on the DTC genetic testing industry. In general, it appears the distinction can be found in whether or

137. Pollack, *Gene Testing Questioned by Regulators*, *supra* note 130.

138. CAL. BUS. & PROF. CODE § 2052 (West 2012).

139. MD. CODE ANN., HEALTH OCC. § 14-101(n) (West 2012).

140. 243 MASS. CODE REGS. 2.01 (2012).

141. GENETICS & PUB. POLICY CTR., *supra* note 63, at 7.

142. MICH. COMP. LAWS § 333.17001(1)(f) (2012).

143. GENETICS & PUB. POLICY CTR., *supra* note 63, at 7.

not states view DTC genetic tests as involved in diagnosis, and therefore are included within the definition of the unlawful practice of medicine.

IV. STATE ACTIONS

Despite all of the laws and regulations outlined above, many DTC genetic testing companies initially offered their services in every state, without physician prescriptions, state laboratory licenses, or proper informed consent.¹⁴⁴ It took the rapid growth of the industry and a number of consumer complaints to draw attention to the violations.¹⁴⁵ In the absence of federal regulations, the states took action. In 2008, some of the states that had decided to ban DTC genetic testing began to investigate the compliance of online companies with their laws and regulations.¹⁴⁶ When they found companies in violation of their statutes and regulations, these states took steps to bring the industry into compliance, including sending cease and desist letters, threatening civil fines, and raising public awareness of the violations.¹⁴⁷ They also began the process of issuing state laboratory licenses to those able to meet applicable standards.¹⁴⁸ States such as New York and California have been fairly successful in bringing most personal genomics services into line.¹⁴⁹ In the three years following this flurry of enforcement by the states, there have been few major actions undertaken in furtherance of the regulation of the DTC genetic testing industry.¹⁵⁰

A. Cease and Desist Letters

In June 2008, the California Department of Public Health sent cease and desist letters to 16 genetic testing companies, including industry leaders 23andMe, deCODEme and Navigenics, notifying them of violations of state laws and ordering them to stop testing until they provided proof of compliance.¹⁵¹ These letters were sent as a result of an investigation prompted by a number of consumer complaints about the accuracy and

144. See, e.g., Ray, *Will Other States Follow NY, Calif., in Taking on DTC Genetic-Testing Firms?*, *supra* note 62 (Navigenics, 23andMe, and deCODEme operated in all 50 states as of publication of this news article on July 02, 2008).

145. Wadman, *supra* note 47, at 1148.

146. *Id.*

147. *Id.*

148. See Pollack, *Gene Testing Questioned by Regulators*, *supra* note 130.

149. See *infra* Part V.

150. LEACHMAN ET AL., AM. SOC'Y OF CLINICAL ONCOLOGY, DIRECT-TO-CONSUMER GENETIC TESTING: PERSONALIZED MEDICINE IN EVOLUTION 38 (2011), available at <http://www.asco.org/ASCOv2/Home/Education%20&%20Training/Educational%20Book/PDF%20Files/2011/zds00111000034.PDF>.

151. Bourque et al., *supra* note 48, at 11.

affordability of the tests.¹⁵² California's chief of Laboratory Field Services, Karen Nickel, stated, "We [are] no longer tolerating direct-to-consumer genetic testing in California."¹⁵³ She said, "These businesses are apparently operating without a clinical laboratory license in California. The genetic tests have not been validated for clinical utility and accuracy, and they are scaring a lot of people to death."¹⁵⁴ The letters pointed out defects of both failing to have a license to conduct laboratory testing in the state and offering genetic tests to California residents without a physician's order.¹⁵⁵ The targeted companies were given two weeks to submit a plan of how they intended to "prevent further violation of California state laboratory law."¹⁵⁶

At the June 23, 2008 deadline, only one company had announced it would stop marketing its services in California and direct its customers to order the genetic tests through a physician.¹⁵⁷ 23andMe and Navigenics both stated that they believed they were already complying with all California laws and would not change their operations.¹⁵⁸ At the time, both companies sub-contracted with California-certified laboratories to perform the genome scans,¹⁵⁹ however, the companies performed their own analysis of the genetic data without state licenses.¹⁶⁰ Also, both companies employed California-licensed physicians to order the genetic tests on behalf of customers, apparently satisfying California's physician prescription requirements.¹⁶¹ However, as pointed out by Dr. Kathy Hudson of Johns Hopkins University, the personal physician relationship called for by state regulations is vastly different from a prescription ordered by "some doc on the payroll at Genes R Us."¹⁶² Although California has questioned the extent of physician involvement in ordering, it appears that at least for the moment, a staff physician is sufficient.¹⁶³

152. Langreth, *supra* note 105.

153. Wadman, *supra* note 47, at 1148.

154. Langreth, *supra* note 105.

155. Wadman, *supra* note 47, at 1148.

156. Ray, *Will Other States Follow NY, Calif., in Taking on DTC Genetic-Testing Firms?*, *supra* note 62.

157. *Id.*

158. *Id.*

159. *Id.*

160. Andrew Pollack, *California Licenses 2 Companies to Offer Gene Services*, N.Y. TIMES, Aug. 20, 2008, at C3.

161. Ray, *Will Other States Follow NY, Calif., in Taking on DTC Genetic-Testing Firms?*, *supra* note 62.

162. Pollack, *Gene Testing Questioned by Regulators*, *supra* note 138.

163. Turna Ray, *In Calif., Outsourcing Genotyping Services to Licensed Lab May Not Equal Compliance*, GENOMEWEB, PHARMACOGENETICS REPORTER (June 25, 2008), <http://www.genomeweb.com/dxpgx/calif-outsourcing-genotyping-services-licensed-lab-may-not-equal-compliance>.

deCODEme's response was to suggest that California sent them a cease and desist letter in error because they did not market directly to Californian consumers.¹⁶⁴ deCODEme's Chief Scientific Officer stated that the company would not offer its tests to California residents until it received a state license, and even then, the tests would only be offered through physicians.¹⁶⁵ However, deCODEme continued to offer its ancestry services in every state including California, since they believed this type of test was not included in the definition of diagnostic testing.¹⁶⁶

The New York State Department of Health sent similar cease and desist letters to 26 companies between November 2007 and June 2008.¹⁶⁷ Navigenics placed its New York customers on a waiting list until its sub-contracted laboratory Affymetrix received a New York license.¹⁶⁸ Both Navigenics' and 23andMe's sub-contracted laboratories also received warning letters from New York.¹⁶⁹ These letters were effective, as evidenced by the very few personal genomics companies currently operating within the state.¹⁷⁰

B. Licensing

Licensing of laboratories is another tool states can use to encourage compliance. It can be used as a stick to impose sanctions on companies who refuse to cooperate, but can also be a carrot used to entice companies to comply. Earning a state license can serve as proof of the legitimacy and quality of a company's business and scientific claims, and offer a competitive advantage over others in the industry.

In order to earn a California license, a laboratory must address the intended use and purpose of the test, the patient population, and provide methodology and samples that can be used to validate their procedures.¹⁷¹ In particular, the accuracy and precision of the algorithm needs to be validated by the Department of Public Health.¹⁷² In August 2008, California granted Navigenics and 23andMe laboratory licenses after a review found

164. Ray, *Will Other States Follow NY, Calif., in Taking on DTC Genetic-Testing Firms?*, *supra* note 62.

165. *Id.*

166. *Id.*

167. Wadman, *supra* note 47, at 1149.

168. Ray, *Will Other States Follow NY, Calif., in Taking on DTC Genetic-Testing Firms?*, *supra* note 62.

169. *Id.*

170. *See infra* Part V.

171. CLINICAL LAB. TECH. ADVISORY COMM., CA. DEP'T OF PUB. HEALTH, MINUTES OF THE SEPTEMBER 5, 2008 MEETING 5 (2008), available at <http://www.cdph.ca.gov/programs/lfs/Documents/CLTAC%20minutes%2005Sep08.pdf>.

172. *Id.*

their genetic analysis procedures were based on valid, current scientific literature.¹⁷³ As of June 2010, 15 laboratories using DTC genetic algorithms were licensed to operate in California.¹⁷⁴

An application for a New York Laboratory Permit involves disclosure of materials and methods, interpretation of results, and validation studies.¹⁷⁵ The application form also states that consent forms must comply with the Genetic Testing Confidentiality Law Art. 7, § 79-l.¹⁷⁶ Each consent form must be disease-specific, and laboratories should have a policy in place to ensure the patient agrees to each test requested.¹⁷⁷ In 2010, Navigenics became the first personal genomics service to receive a state laboratory license from New York, and because their business model already required physician ordering, they are one of the few companies legally able to offer their genetic testing services in that state.¹⁷⁸

C. Civil Fines

Accompanying California's cease and desist letters were threats of civil and criminal sanctions.¹⁷⁹ Under California law, each company in question was facing fines of up to \$3,000 per day or per violation if there was no immediate jeopardy to California residents, and fines from \$3,050 to \$10,000 per day or per violation if immediate jeopardy was present.¹⁸⁰ Additionally, California had the possibility of imposing onsite monitoring as defined under CLIA,¹⁸¹ as well as imposing the cost of the onsite monitoring on the offending company.¹⁸² In New York, a violation of owning or operating a clinical laboratory without a valid permit can result in a civil

173. Pollack, *California Licenses 2 Companies to Offer Gene Services*, *supra* note 160.

174. CLINICAL LAB. TECH. ADVISORY COMM., CA. DEP'T OF PUB. HEALTH, MINUTES OF THE JUNE 25, 2010 MEETING 5, *supra* note 135.

175. STATE OF N.Y. DEP'T OF HEALTH, ASSAY APPROVAL IN GENETIC TESTING – MOLECULAR 2-4 (2011), available at http://www.wadsworth.org/labcert/TestApproval/forms/Genetic_Testing_Molecular_Checklist.pdf.

176. N.Y. CIV. RIGHTS LAW § 97-L (McKinney 2012); STATE OF N.Y. DEP'T OF HEALTH, *supra* note 175, at 4.

177. STATE OF N.Y. DEP'T OF HEALTH, *supra* note 175, at 4.

178. *The Navigator, Working Closely With Regulators – A Navigenics Core Principle*, NAVIGENICS (May 13, 2010), http://blog.navigenics.com/articles/comments/working_closely_with_regulators_a_navigenics_core_principle/ (on file with author).

179. Wadman, *supra* note 47, at 1148.

180. CAL. BUS. & PROF. CODE § 1310(b) (West 2012).

181. 42 C.F.R. § 493.1836 (2011). "CMS may require continuous or intermittent monitoring of a plan of correction by the State survey agency to ensure the laboratory makes the improvements necessary to bring it into compliance with the condition level requirements." *Id.*

182. CAL. BUS. & PROF. CODE § 1310(e) (West 2012).

penalty of up to \$2,000 per day.¹⁸³ Apparently the threat of substantial monetary sanctions was significant enough to quickly bring most of the targeted companies into compliance with state laws.

The use of company-employed physicians to rubber stamp consumer orders is another area where civil fines could play a role in enforcement. If states are unhappy with the practice of using company physicians to satisfy the physician prescription requirement, they may take actions similar to those in enforcement regarding telemedicine. Like DTC genetic tests, the telemedicine industry does not easily recognize state boundaries.¹⁸⁴ As a result, many states adopted specific statutes relating to the practice of telemedicine.¹⁸⁵ For example, a California statute imposes a fine of up to \$25,000 against the physicians themselves for each episode of prescribing dangerous drugs without an appropriate prior examination and medical indication.¹⁸⁶ States who would like to prohibit a DTC genetic company from employing its own physicians in order to more fully satisfy the physician-prescription requirements may choose to enact similar statutes to penalize those physicians who order genetic tests without a good faith examination or a true face to face doctor-patient relationship.

D. Public Awareness

Public awareness about the DTC genetic testing industry has grown immensely in recent years, and is another available tool states can use to pressure companies into compliance. For example, the distribution of the cease and desist letters by both California and New York were widely publicized in the media.¹⁸⁷ In March 2011, Maryland's Attorney General posted an online letter entitled "At-Home Genetic Tests: Proceed with Caution."¹⁸⁸ It warned Maryland residents to consult their physician before and after a test, and that "no at-home genetic test has been reviewed or has had their claims evaluated for accuracy by the FDA."¹⁸⁹ If the residents of a state are aware a DTC genetic testing company is continuing to flirt with violations of state law, customers will become wary and business in that state will surely decline.

183. N.Y. PUB. HEALTH LAW § 577(5) (McKinney 2012).

184. FURROW ET AL., *supra* note 36, at 130.

185. *Id.*

186. CAL. BUS. & PROF. CODE § 2242.1 (West 2012).

187. See, e.g., Pollack, *Gene Testing Questioned by Regulators*, *supra* note 130; Brody, *supra* note 21; Langreth, *supra* note 105.

188. *At-Home Genetic Tests: Proceed with Caution*, MD. ATT'Y GEN. (March 2011), <http://www.oag.state.md.us/consumer/geneticTesting.htm>.

189. *Id.*

V. INDUSTRY REACTION AND CURRENT PRACTICE

DTC genetic testing companies have had varying reactions to the implementation and enforcement of state regulations. Some have altered their national business models to ensure compliance in the most stringent states, some have varied their practices between states, and others have forged ahead, only nominally claiming to adhere to the applicable standards.

A. *Navigenics*¹⁹⁰

On July 27, 2010, California-based Navigenics issued a press release in response to federal regulatory meetings indicating a willingness to work with authorities.¹⁹¹ Navigenics' CEO testified at the House of Representatives' hearing on "Direct-To-Consumer Genetic Testing and the Consequences to the Public Health."¹⁹² The statement recognized the variation in practice between genetic testing companies, claiming that Navigenics has taken a very conservative approach and has been in constant contact with the FDA.¹⁹³ In addition, Navigenics received a state license from the State of California's Department of Public Health in 2008,¹⁹⁴ a clinical laboratory permit from the New York State Department of Health in January 2010,¹⁹⁵ and is the only personal genomics company with approval to operate in all 50 states.¹⁹⁶

190. Subsequent to the submission of this article, Navigenics underwent a significant change. Their homepage currently reads: "Navigenics was recently acquired by Life Technologies, a global biotechnology company dedicated to innovation and improving life in meaningful ways. . . . We are no longer accepting orders or samples for the Navigenics Health Compass service." *Our acquisition by Life Technologies*, NAVIGENICS (2012), <http://www.navigenics.com/>. The Frequently Asked Questions Page states "[a]s of August 3, 2012, we will not be accepting new orders going forward." *Your questions answered*, NAVIGENICS (2012), http://www.navigenics.com/visitor/about_us/acquisition_faqs/. As a result, many of the following citations no longer exist on the Navigenics website; however they remain on file with the author as noted.

191. Press Release, Navigenics Statement, NAVIGENICS (July 27, 2010), available at http://www.navigenics.com/visitor/about_us/press/releases/statement_072710/ (on file with author).

192. *Direct-to-Consumer Genetic Testing and the Consequences to the Public: Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 111th Cong. (2010) [hereinafter Vanier Testimony] (testimony of Vance Vanier, Chief Executive Officer, Navigenics, Inc.).

193. *Id.* at 3-4.

194. NAVIGENICS, *The Navigator, Working Closely with Regulators – A Navigenics Core Principle*, *supra* note 178.

195. *Id.*

196. NAVIGENICS, Press Release, Navigenics Statement, *supra* note 191.

Upon the launch of the Navigenics Health Compass services in 2008, the company released a ten point list of model standards for the personal genomics industry.¹⁹⁷ These standards include validity, accuracy, clinical relevance,¹⁹⁸ actionability, access to genetic counseling, security and privacy, ownership of information, physician education and engagement, transparency, and measurement.¹⁹⁹

Navigenics' business model does not vary between states and is designed to comply with the most stringent requirements currently in place.²⁰⁰ Navigenics only offers its genetic analysis services through physicians and corporate wellness programs.²⁰¹ For those patients whose physicians do not offer the service, Navigenics provides a list of available physicians in a number of states who have integrated the service into their practice.²⁰² Physicians are not listed in every state, and Navigenics disclaims any apparent endorsement or recommendations of any physician's capabilities.²⁰³ Rather than employing a company physician to order tests on behalf of customers, Navigenics appears to take much more of a hands-off approach, encouraging potential customers to find their own physician who is willing to order the test on their behalf. This allows the company to avoid any potential violations of physician prescription or informed consent requirements. In addition, a disclaimer is present at the bottom of every page on Navigenics' website, "Navigenics does not provide medical advice, diagnosis or treatment."²⁰⁴ The "Frequently Asked Questions Page" specifically directs residents of New York to call for more information about

197. Press Release, Navigenics proposes standards for personal genomics services, coupled with prospective outcomes studies, to safeguard consumers, NAVIGENICS (April 8, 2008), http://www.navigenics.com/visitor/about_us/press/releases/standards_release_04_0808/ (on file with author).

198. Navigenics defines clinical relevance as only using genetic risk factors that have been shown to have consistent effect sizes with supporting information vetted by competent reviewers, and with content screened by leading medical institutions or reputable independent providers. *Id.*; *Our selection criteria*, NAVIGENICS (2012), http://www.navigenics.com/visitor/about_us/our_science/selection_criteria/ (on file with author).

199. NAVIGENICS, Press Release, Navigenics proposes standards for personal genomics services, coupled with prospective outcomes studies, to safeguard consumers, *supra* note 197.

200. *Service FAQs*, NAVIGENICS, http://www.navigenics.com/visitor/what_we_offer/faqs/ (last visited Sept. 22, 2012) (on file with author).

201. *Id.*

202. *Find a physician*, NAVIGENICS, http://www.navigenics.com/visitor/about_us/find_a_physician/ (last visited Sept. 21, 2012) (on file with author).

203. *Id.*

204. *Navigenics, Gene-ius, A smart way to look at your health*, NAVIGENICS, <http://www.navigenics.com> (last visited Oct. 22, 2012).

ordering,²⁰⁵ and provides a link to special ordering instructions and forms for Maryland residents.²⁰⁶

B. deCODEme

Iceland-based deCODE received its California Clinical Laboratory License in 2009, allowing California residents to purchase its deCODEme products.²⁰⁷ Also in 2009, the CLIA-registered laboratory was accredited by the College of American Pathologists.²⁰⁸ This accreditation carries deeming authority from the CMS, and may help deCODE to meet some state certification requirements.²⁰⁹

Rather than entirely eliminating their DTC service, deCODEme has chosen to alter business practices between states when necessary, to comply with stricter state laws. The deCODEme Service Agreement acknowledges that some states do not permit residents to obtain information from genetic scans without the involvement of a qualified healthcare professional.²¹⁰ Therefore, unless the scan is ordered under the supervision of a physician who provides qualified counseling, certain genetic risk information may be omitted for residents of Arizona, California, Connecticut, Georgia, Maryland, Michigan, New Jersey, New York, Pennsylvania, Rhode Island, and Wyoming.²¹¹ It also admits that deCODEme does not have the required state laboratory licenses in Maryland and New York, and therefore, their services are not available to residents of those states.²¹²

C. 23andMe

23andMe participated in the two-day FDA advisory panel meeting in March 2011, expressing concern that in the future tests may only be available through a physician, and reiterating its founding belief that

205. NAVIGENICS, *Service FAQs*, *supra* note 200.

206. *Maryland ordering instructions*, NAVIGENICS, http://www.navigenics.com/visitor/what_we_offer/faqs/maryland_orders/ (last visited Sept. 21, 2012) (on file with author). These instructions involve completing the order through a physician or corporate wellness program, completion of a Test Request Form by the patient and physician, and faxing the completed form to Navigenics Member Services. *Id.*

207. *deCODE Receives California Clinical Laboratory License*, DECODE GENETICS (Feb. 19, 2009), <http://www.decode.com/news/news.php?story=52>.

208. *deCODE Genotyping Laboratory Receives College of American Pathologists Accreditation*, DECODE GENETICS (May 20, 2009), <http://www.decode.com/news/news.php?story=49>.

209. *Id.*

210. *deCODEme Genetic Scan Service Agreement and Informed Consent*, DECODEME (April 16, 2012), <http://www.decode.me/service-agreement>.

211. *Id.*

212. *Id.*

individuals have the right to access their own genetic information.²¹³ 23andMe received a license from the California Department of Public Health in 2008, allowing them to serve customers in that state.²¹⁴ 23andMe does not employ its own genetic counselors, but rather has partnered with Informed Medical Decisions, Inc. to offer independent genetic counseling to its customers.²¹⁵ This service is optional, and comes with an additional cost.²¹⁶

23andMe does not appear to acknowledge state limitations as openly on its website as some other personal genetics companies. Buried in the Terms of Service is a statement admitting that there are some jurisdictions where service is not available because the company lacks the required licenses.²¹⁷ A customer does not learn of many of these restrictions until he or she attempts to buy a test kit. Upon trying to ship to New York, a notice appears to warn the customer that 23andMe is not able to process samples mailed from New York, because of a lack of laboratory license and physician involvement.²¹⁸ However, the customer has the option of having the kit shipped to New York, and is required to affirm the sample will not be collected in, nor mailed from New York.²¹⁹ Although it is illegal to spit in a test-tube for a DTC genetic test in New York, there is nothing to prevent a consumer from going to another state to spit and have the test performed.²²⁰ Upon trying to ship to Maryland, the pop-up states that 23andMe is currently unable to offer services in that state, without further explanation.²²¹ Upon selecting other restricted states such as California, no such notice arises.²²² Unlike Navigenics, 23andMe seems intent on continuing the direct-to-consumer service as long as possible, until it is directly faced with a serious threat of state action.

213. *The Spittoon, DTC Genetic tests and the future of regulation: Make your voices heard*, 23ANDME (April 4, 2011), <http://spittoon.23andme.com/2011/04/04/dtc-genetic-tests-and-the-future-of-regulation-make-your-voices-heard/#more-8727>.

214. Pollack, *California Licenses 2 Companies to Offer Gene Services*, *supra* note 160.

215. *23andMe Enlists Informed Medical Decisions to Make Independent Genetic Counseling Services Available to Customers*, 23ANDME (June 3, 2010), <https://www.23andme.com/about/press/20100603/>.

216. *Id.*

217. *Terms of service*, 23ANDME (2012), <https://www.23andme.com/about/tos/>.

218. *Store*, 23ANDME, <https://www.23andme.com/store/shipping/> (last visited Sept. 21, 2012).

219. *Id.*

220. Brody, *supra* note 21.

221. 23ANDME, *Store*, *supra* note 218.

222. *Id.*

VI. ANALYSIS

Ultimately, some standards need to be implemented. Regulation cannot be left to the industry itself or to market forces, without first causing some amount of irreparable harm. Additionally, companies that are able to meet federal standards will gain an air of legitimacy, while those companies who are unwilling or unable to meet standards will be filtered out. It may be argued that in implementing regulation, the government is being overly paternalistic and denying individuals the right to know information about their own genetic code.²²³ However, proponents would counter that discovery of genetic information is not being withheld, but rather being forced to be filtered through a different pathway. Others may claim that this is just another way in which politicians are bending to the will of influential physician and health system lobbyists.²²⁴ While there may be an element of truth to this argument, it does not change the fact that these DTC genetics tests are a very powerful tool, and without some form of regulation, there is a high likelihood of misuse and abuse.

A. *What Type of Regulations?*

Regulation should occur at the federal level to reduce the cost and confusion of complying with multiple state laws. As Mari Baker, chief executive of Navigenics stated, "in the end this needs to be regulated at the federal level rather than as a patchwork of state regulations."²²⁵ Although a small number of states have been successful in enforcing compliance, the majority of the states are permitting DTC genetic testing to proceed unregulated.²²⁶ Some may argue that regulation at the federal level is an unwanted intrusion into an area traditionally regulated by states, namely the definition of the scope of the practice of medicine.²²⁷ However, this would be just one more example in a list of attempts by the federal government to regulate the practice of medicine, including examples such as the control of medical marijuana in California, physician-assisted suicide in Oregon, and

223. See *Support Your Right to Access Your Clinical Lab Results*, 23ANDME (Nov. 4, 2011), <http://spittoon.23andme.com/news/support-your-right-to-access-your-clinical-lab-results/>.

224. See, e.g., Daniel MacArthur, *American Medical Association: You Can't Look At Your Genome Without Our Supervision*, WIRED, Feb. 24, 2011, <http://www.wired.com/wiredscience/2011/02/american-medical-association-you-cant-look-at-your-genome-with-out-our-supervision/> (arguing the "'doctor as universal gatekeeper of health information' model has to die, no matter how desperately the AMA and its proxies try to keep this obsolete, paternalistic vision alive.").

225. Pollack, *California Licenses 2 Companies to Offer Gene Services*, *supra* note 160.

226. GENETICS & PUB. POLICY CTR., *supra* note 63, at 1-2, 4-5, 7, 10, 12-13.

227. Noah, *supra* note 125, at 149.

FDA efforts to restrict distribution of approved pharmaceuticals.²²⁸ The practicality of a single system and the industry's calls for a uniform system would likely prevail over any federalism concerns. If state actions are failing to protect consumers, the federal government should not hesitate to interfere.²²⁹

B. *Which Tests Should Be Regulated?*

The most practical approach appears to be the one taken by states that impose regulations only on certain types of DTC genetic tests. Regulators need to make a distinction between those tests that are purely recreational, such as those that test for ancestry, eye color, or types of earwax, and those that have an impact on medical treatments and decisions. Tests that involve risk factors for disease development, reactions to pharmaceuticals, and risks of disease inheritance should not be permitted to be marketed directly to consumers. These types of tests clearly implicate medical considerations and may even be approaching the status of diagnostic and medical devices. The risk stratification approach has proved successful before when dealing with other direct-to-consumer medical devices such as pregnancy tests, and also when dealing with over-the-counter drugs.²³⁰

The Personalized Medicine Coalition distinguishes between medical genetic tests that are usually ordered by a healthcare provider and informational genetic tests that can be ordered by individual consumers.²³¹ This distinction is important; however, the coalition's inclusion of tests meant to "gain a better understanding of general health and disease susceptibility," and of tests for risks of diseases such as Alzheimer's disease, diabetes, heart attacks and several types of cancer, in the definition of informational genetic tests is overly broad.²³² These are the kinds of tests that clearly implicate medical decisions. They have an impact on lifestyle and future treatment and therefore, should be included in the category of tests that are only ordered through physicians or other healthcare providers. Genetic tests should be categorized into medical tests and recreational tests.

Some may argue that drawing a line between medical and recreational genetic tests will be difficult if not arbitrary.²³³ However, these are the types

228. See *id.* at 153, 181-84.

229. *Id.* at 154.

230. Frueh et al., *supra* note 24, at 512.

231. PERSONALIZED MED. COAL., AN INTRODUCTION TO INFORMATIONAL GENETIC TESTING 2-3, available at http://www.personalizedmedicinecoalition.org/sites/all/themes/zen_pmc/documents/Medco-PMC-consumer-genetics.pdf.

232. *Id.* at 3.

233. Jennifer K. Wagner, *Understanding FDA Regulation of DTC Genetic Tests within the Context of Administrative Law*, 87 AM. J. HUM. GENETICS 451, 453 (2010).

of decisions regularly faced by the FDA and state licensing boards. While some tests may fall within a grey area, new laws and regulations can build a framework to help decision makers come to reasonable conclusions. For example, a factors test could be used to determine if a particular test belongs in the medical or recreational category. This test could consider things such as whether the results of the test are likely to affect a patient's behavior or lifestyle, have an impact on the course of current or future medical treatment, have a strong and lasting emotional effect, or have an impact on future reproductive decisions.

Those in the industry may argue that this kind of risk stratification of tests will rob consumers of the convenience of purchasing a single test and using a single swab to receive all the answers to their genetic questions at one time. While this is true, sacrificing convenience is a small price to pay for ensuring consumers are protected. Dividing the industry into medical tests with more rigid standards and recreational tests with fewer regulatory hurdles may actually be beneficial for the industry. It would open up two separate markets, allowing some companies to still market recreational tests directly to consumers, while allowing those who wish to target the medical sciences a way to continue to provide valuable services. This system will still allow consumers the freedom to have their DNA analyzed to satisfy curiosity about trivial facts, while protecting them from misleading and complicated medical results that can easily be misinterpreted and lead to harmful reactions or behaviors.

C. *What Should The Regulations Include?*

Federal regulators should incorporate lessons from those states that have successfully managed to impose regulations on the industry. Under the traditional idea of using the states as laboratories, there have been experiments with various models.²³⁴ Following the examples of states such as New York, California and Maryland, the federal government should create regulations that include a combination of physician prescription, laboratory licensing, and informed consent. Regulation of medical genetic tests should target both the accuracy and availability of the tests.

First, genetic tests should be performed in CLIA-certified and state licensed laboratories, and should be subject to testing for both analytical and clinical validity.²³⁵ Regulators could impose their own certification standards, or require independent accreditation from organizations such as

234. Noah, *supra* note 125, at 156-57.

235. Frueh et al., *supra* note 24, at 513.

the College of American Pathologists.²³⁶ These kinds of regulations will ensure that consumers are receiving high quality tests and the most accurate information science can currently provide.²³⁷

Second, medical genetic tests should only be available through a physician. Both the AMA and the American Clinical Laboratory Association support the need for physician guidance in genetic testing.²³⁸ The Federal government needs to implement regulations that ensure physicians are present to protect consumers from gaps in understanding that can lead to damaging consequences.²³⁹ Simply mandating DTC genetic test companies to disclose volumes of information would only add to the confusion. Rather, the regulations should call for a physician, or other qualified intermediary, who can provide appropriate counseling and answer questions. In order to ensure adequate counseling, communication, and proper administration of any informed consent documents, this must be a traditional face-to-face doctor patient relationship. Physician employees of the DTC genetic testing companies who rubber stamp requests for medical genetic tests should not be able to satisfy this requirement. The return of the results through a physician also ensures patients are not left to their own devices in interpretation, and are given appropriate medical advice regarding the consequences. In addition, by filtering the results through a personal physician, other factors in disease such as family history, lifestyle, and environment can also be taken into consideration.²⁴⁰

Recommendations from industry should also be incorporated into these new regulations. For example, principles from Navigenics' proposed standards are highly relevant to those seeking to construct an effective regulatory framework.²⁴¹ Principles of validity, accuracy, quality, clinical relevance, and actionability can be used to help stratify genetic tests and determine which belong in the medical or recreational categories.²⁴² Principles of security, privacy, transparency, and ownership of genetic information can shape regulation of the business practices of DTC genetic testing companies.²⁴³ Incorporating recommendations from the industry not

236. Press Release, ACLA Supports Physician Guidance in Patient-Centered Genetic Testing, AM. CLINICAL LAB. ASS'N (May 12, 2010), available at <http://www.acla.com/sites/default/files/dtcrelease.pdf>.

237. *Id.*

238. *Id.*; Maves, *supra* note 25.

239. AM. CLINICAL LAB. ASS'N, *supra* note 236.

240. *See id.*

241. NAVIGENICS, Press Release, Navigenics proposes standards for personal genomics services, coupled with prospective outcomes studies, to safeguard consumers, *supra* note 197.

242. *Id.*

243. *Id.*

only encourages cooperation and compliance, but also draws upon the knowledge of those who know the industry best.

D. How Should The Regulations Be Enforced?

The federal government can also learn important lessons on enforcement from state experiences. 15 states claim to prohibit DTC genetic testing on the books, but very few have actually been successful in enforcement.²⁴⁴ Thanks to industry reactions, we now know what methods are most effective at bringing DTC genetic testing companies into compliance with strict regulations.²⁴⁵

When faced with non-compliance, recent history has shown that the federal government will have to take an active role in enforcement.²⁴⁶ Clearly banning the industry on the books is not enough.²⁴⁷ Tools such as cease and desist letters, threats of substantial civil fines, and negative publicity will likely be effective at bringing those errant companies into compliance. The FDA may also be able to utilize licensing or an analogous stamp of approval to entice companies into compliance. Such a credential would give a cooperative company an advantage over competitors, and would also reassure potential customers about the quality of the tests. By offering both punishment for disobedience and rewards for compliance, the federal government should be successful in quickly bringing the DTC industry in line with the new regulations.

E. Other Considerations?

In addition to the implementation and enforcement of new regulations, public education on genetics is essential to arm the population with the ability to protect themselves from misleading and fraudulent opportunists. Many of those who were the first to order these tests were enthusiasts who were well educated in genetics and were able to interpret the results.²⁴⁸ However, as the tests have become more mainstream, the average consumer is less likely to have this level of understanding, and the results of the test can cause more harm than good.²⁴⁹ If genetic medicine is truly going to become part of everyday healthcare, the general public will need to be further educated. When the public has the ability to receive results of genetic tests with the appropriate level of skepticism and understanding, there will be less reliance on government regulations for protection.

244. GENETICS & PUB. POLICY CTR., *supra* note 63, at 1-9, 11-12, 14.

245. *See supra* Part V.

246. *See supra* Part IV, V.

247. *See supra* Part IV, V.

248. Frueh et al., *supra* note 24, at 511.

249. *Id.*

However, until public understanding has had the chance to catch up with these scientific advances, it is the responsibility of the government to ensure this new industry develops in a way that is beneficial and not harmful. In addition to public education, the AMA recommends that provider education should also become a priority.²⁵⁰ Physicians must be prepared to provide interpretation and counseling to patients who present them with results of genetic tests.²⁵¹ The AMA has stated that it is prepared to work together with the FDA to ensure physicians are aware of the risks and benefits of DTC genetic testing.²⁵²

Additionally, the FDA should work with the Federal Trade Commission to monitor advertising practices of the genetic testing industry. Regulations should ensure that all relevant information is clearly communicated, including both the capabilities and limitations of the tests.²⁵³ Similar to other consumer protections, these concepts need to be obviously presented, in simple language to facilitate understanding by the non-scientific public.

New developments in science and regulation will likely increase the uniformity and quality of genetic tests. On February 29, 2012, the National Institutes of Health and CMS launched the Genetic Testing Registry (GTR), which could help to reduce concerns about abuses in the industry.²⁵⁴ This online registry compiles data on indications for use, validity, and usefulness of genetic tests, encouraging transparency in the industry.²⁵⁵ Presently, participation in the GTR is voluntary; however if participation rates remain low, it may need to become mandatory to remain effective.²⁵⁶ As science improves, many of the concerns about DTC genetic testing will likely decrease and perhaps, the DTC model can then be revisited. However, at the present time, neither science nor the public are ready.

Critics may claim it is impractical and overly restrictive to impose these regulations on the medical genetic testing industry. Since this science is rapidly evolving, it may be difficult to constantly screen every algorithm and methodology used. A practical approach may be to require approval when new traits are added to the screen, and regular reviews of existing tests to evaluate them in the light of new scientific discoveries. Critics may also claim that the physician prescription requirement will needlessly burden an

250. Maves, *supra* note 25, at 3.

251. *Id.*

252. *Id.*

253. *Id.* at 2.

254. LEACHMAN ET AL., *supra* note 150; *Confused by genetic tests? NIH's new online tool may help*, NAT'L INSTS. OF HEALTH (Feb. 29, 2012), <http://www.nih.gov/news/health/feb2012/od-29.htm>.

255. *Genetic Testing Registry*, OFFICE OF SCI. POLICY, NAT'L INSTS. OF HEALTH, http://oba.od.nih.gov/GTR/gtr_intro.html (last visited Sept. 30, 2012).

256. Maves, *supra* note 25, at 3.

already strained healthcare system. However, those consumers who currently order medical genetic tests directly would likely already discuss the results with a family physician, particularly if the results are troubling. Even so, new requirements may result in extra visits to the physician for the sole purpose of having a genetic test performed. However, like other kinds of new technology, eventually these genetic screens will simply become another tool available to the general practitioner in the normal care of patients, and may even be incorporated into typical physical examinations.²⁵⁷ In the meantime, this form of regulation may slightly increase the load of the system; however this cost is outweighed by the benefit of reducing the level of stress of consumers and the hazards of misinterpretation of results.

VII. CONCLUSION

Genetic testing has the potential to unlock enormous amounts of personalized information that can be used to improve each individual's health. The purpose of regulation should not be to stifle scientific advances and technological innovation, but rather to protect naive consumers with blind faith in seemingly omniscient entrepreneurs. Regulation needs to occur at a uniform federal level, but should incorporate lessons learned from state attempts at enforcement and regulation.

When consumer rights are protected and testing companies are held to high standards, everyone will benefit from these exciting scientific advances. The genetic testing industry holds enormous promise. Given a balanced regulatory framework, it will inevitably play a large role in making future medical decisions, encouraging people to take a proactive role in their health, and in improving human wellbeing. As long as the industry is developed responsibly, genetic testing can soon fulfill its highly touted role in improving medicine and the quality of human life.

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257. PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. & BIOMEDICAL & BEHAVIORAL RESEARCH, SCREENING AND COUNSELING FOR GENETIC CONDITIONS: A REPORT ON THE ETHICAL, SOCIAL, AND LEGAL IMPLICATIONS OF GENETIC SCREENING, COUNSELING, AND EDUCATION PROGRAMS 10-11 (1983), available at http://bioethics.georgetown.edu/pcbe/reports/past_commissions/geneticscreening.pdf.

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