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FILLING IN THE CRACKS: IMPROVING THE REGULATION OF DIRECT-TO-CONSUMER GENETIC TESTS

SERRA J. SCHLANGER*

Advances in genetic technology and the increased acceptance of genetic testing by the general public have led to the development and sale of direct-to-consumer (DTC) genetic tests.¹ Genetic testing is one of the fastest growing areas of laboratory testing.² A recent survey found more than thirty different DTC genetic testing companies offering genetic tests for both health and non-health related purposes.³ These tests range in cost from \$78 to \$68,500.⁴ The DTC genetic testing companies advertise that an

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1. Andrew S. Robertson, *Taking Responsibility: Regulations and Protections in Direct-to-Consumer Genetic Testing*, 24 BERKELEY TECH. L.J. 213, 214–15 (2009).

2. See BIN CHEN ET AL., DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION, GOOD LABORATORY PRACTICES FOR MOLECULAR GENETIC TESTING FOR HERITABLE DISEASES AND CONDITIONS, 58 MORBIDITY & MORTALITY WKLY. REP. 3 (2009) [hereinafter LABORATORY PRACTICES], available at <http://www.cdc.gov/mmwr/PDF/rr/rr5806.pdf> (describing the rapid growth in the number of available genetic tests and the number of laboratories performing genetic testing).

3. See GENETICS & PUB. POL'Y CTR., DTC GENETIC TESTING COMPANIES (Feb. 26, 2010) [hereinafter DTC GENETIC TESTING COMPANIES], available at http://www.dnapolicy.org/news.release.php?action=detail&pressrelease_id=137 (compiling a list of DTC genetic testing companies and information on what tests each company offers).

4. See e.g., *Low Cost At Home DNA Paternity Test*, HOMEDNA, <https://www.homedna.com> (last visited Mar. 1, 2011) (advertising a \$78 DNA Home Paternity Testing System); Ryan McBride, *Knome Challenged to Keep in Step With Falling Genetic Sequencing Prices*, XCONOMY, Jan. 1, 2010, http://www.xconomy.com/boston/2010/01/20/knome-challenged-to-keep-in-step-with-falling-genetic-sequencing-prices/?single_page=true (detailing Knome's complete genetic sequence service price decrease from \$350,000 in 2008 to the current price of \$68,500).

individual's genetic profile can be used to find love,⁵ to fill in a family tree,⁶ to determine genetic athletic advantages,⁷ to assist in weight loss,⁸ and to discover individual genetic risk for forty-seven different diseases and traits.⁹ Although more than 1,200 genetic tests, covering a wide variety of issues and conditions, are currently available on the consumer market, the Food and Drug Administration (FDA) has approved fewer than a dozen of them.¹⁰

DTC genetic tests currently fall through the regulatory cracks because several governmental agencies oversee individual aspects and components of genetic testing, but no single agency covers all genetic tests.¹¹ This apparent lack of cohesive regulation is startling because the general public widely believes that the government comprehensively regulates genetic testing.¹² Unaware of the minimal regulation and oversight, consumers may have misplaced confidence in the claims made by those selling genetic tests and may be unaware that a particular genetic test may not provide meaningful results or be based on accurate science.¹³ The absence of a comprehensive regulatory scheme has created an opportune environment for genetic test makers to directly target consumers and to encourage the purchase of genetic tests with unproven medical value.¹⁴ The current limited regulatory structure legally fails to protect the rights and interests of vulnerable individuals.¹⁵

5. GENEPARTNER.COM, <http://www.genepartner.com> (last visited Mar. 1, 2011).

6. *Discover DNA Ancestry and Genetic History with our DNA Test*, 23ANDME, <http://www.23andme.com/ancestry/> (last visited Mar. 1, 2011).

7. ATLAS FIRST SPORTGENE TEST, <http://www.atlasgene.com> (last visited Mar. 1, 2011).

8. INHERENT HEALTH, WEIGHT MANAGEMENT, <http://www.inherenthealth.com/our-tests/weight-management.aspx> (last visited Mar. 1, 2011).

9. DECODEME, <http://www.decode.me> (last visited Mar. 1, 2011).

10. Joan L. McGregor, *Why John Stuart Mill Would Support Restriction on DTC Marketing of Genetic Tests*, 8 AM. J. BIOETHICS 9, 9 (2008).

11. 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, 624 (2008).

12. *Consumer-Directed Promotion of Regulated Medical Products: Public Hearing Docket No. 2005N-0354* (2005) (comments of Gail Javitt, Genetics and Public Policy Center), available at http://www.dnapolicy.org/resources/FDA_Testimony.pdf.

13. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-977T, NUTRIGENETIC TESTING TESTS PURCHASED FROM FOUR WEB SITES MISLEAD CONSUMERS, 2 (2006) (prepared statement of Gregory Kutz, Managing Director of Forensic Audits and Special Investigations for *At Home DNA Tests: Marketing Scam or Medical Breakthrough: Hearing Before the S. Special Comm. on Aging*, 109th Cong. (2006)); Gail H. Javitt & Kathy Hudson, *Federal Neglect: Regulation of Genetic Testing*, 22 ISSUES SCI. & TECH. 59, 62 (2006), available at http://www.dnapolicy.org/resources/Issues_in_Science_and_Technology.pdf.

14. Javitt & Hudson, *supra* note 13, at 62.

15. Sjeff Gevers, *The Marketing of Health Products, With Special Reference to Do-It-Yourself Tests*, 22 MED. & L. 199, 206 (2003).

Part I of this Comment explains the unique nature of genetic material and the concerns that arise when individuals undergo genetic testing. These concerns focus on test result accuracy, the influence of genetic information on medical practice, adequate genetic counseling, and the psychological impact of genetic information.¹⁶ Part I also introduces the current state of clinical and DTC genetic test regulation and examines the different regulatory approaches taken by individual states.¹⁷ Part I identifies the FDA, the Federal Trade Commission (FTC), and the Centers for Medicare and Medicaid Services (CMS) as the three federal agencies that have the greatest potential to regulate DTC genetic tests and assesses the agencies' current regulations.¹⁸

The FDA has previously considered and managed similar concerns about test result accuracy, adequate result counseling, and the psychological impact of test results during the development of the HIV home test kit.¹⁹ Part II of this Comment examines the contentious development of the HIV home test kit and focuses on the arguments about home test kit accuracy and the availability of pre- and post-test counseling for home test kit users.²⁰ Part II also describes the HIV home test kit that received FDA approval in 1996.²¹

Part III of this Comment looks forward to potential new developments and solutions for the current patchwork system of DTC genetic test regulation. Part III suggests that the FDA should look to the HIV home test kit counseling requirement as a model to help combat current concerns about the impact of DTC genetic tests on individual health decision making.²² Part III also recommends that the FTC and CMS increase their efforts to protect consumers from false and misleading advertisements for DTC genetic tests.²³ Although this Comment focuses on DTC genetic test

16. See Robert M. Cook-Deegan, *NIH-DOE Joint Working Group on Ethical, Legal, and Social Issues Established*, HUMAN GENOME NEWS (Human Genome Program, U.S. Dep't of Energy, Washington, D.C.), May 1990, available at http://www.ornl.gov/sci/techresources/Human_Genome/publicat/hgn/v2n1/05elsi.shtml (identifying nine topics and issues that may arise with genome technology development); Human Genome Project, *Ethical, Legal, and Social Issues – Genome Research*, U.S. DEP'T OF ENERGY OFFICE OF SCI., http://www.ornl.gov/sci/techresources/Human_Genome/elsi/elsi.shtml (last visited Mar. 1, 2011) (raising questions related to societal concerns about the availability genetic information).

17. See *infra* Part I.A.

18. See *infra* Part I.B.

19. Ronald Bayer et al., *Testing for HIV Infection at Home*, 332 NEW ENG. J. MED. 1296 (1995).

20. See *infra* Part II.A.

21. See *infra* Part II.B.

22. See *infra* Part III.A.

23. See *infra* Parts III.B–C.

regulation, the proposed regulatory improvements may also impact and improve the quality of physician-provided genetic tests and can help provide patients and physicians with greater confidence in all genetic testing.²⁴

I. CURRENT CONCERNS AND THE STATE OF REGULATION

Genetics is the science of biological variation and includes the science and practice of diagnosis, prevention, and management of genetic disorders.²⁵ Since the double helix structure of DNA was first described in 1953,²⁶ modern genetic research has expanded as the scientific and medical communities try to gain a better understanding of the genes that control human inherited traits.²⁷ Currently a wide variety of genetic tests can provide information for more than 1,500 diseases.²⁸

A genetic test is defined as “[t]he analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect inherited disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes.”²⁹ Such clinical purposes include identifying carriers of genetic diseases, prenatal and post-birth testing for disease-causing genetic abnormalities, predicting an individual’s risk of disease development, predicting an individual’s response to specific medications, and establishing

24. Javitt & Hudson, *supra* note 13, at 66.

25. Mary B. Mahowald, *Genetic Technologies and Their Implications for Women*, 3 U. CHI. L. SCH. ROUNDTABLE 439, 440 (1996).

26. James D. Watson & Francis H.C. Crick, *A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737, 737 (1953). In addition to describing the structure of DNA, the authors also note that the structure “immediately suggests a possible copying mechanism for the genetic material.” *Id.*

27. See generally James D. Watson & Francis H.C. Crick, *Genetical Implications of the Structure of Deoxyribonucleic Acid*, 171 NATURE 964, 966 (1953) (explaining Watson and Crick’s original hypothesis about how the structure of DNA provides a template for genetic inheritance).

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

29. PROMOTING SAFE AND EFFECTIVE GENETIC TESTING IN THE UNITED STATES: FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING, 6 (Neil A. Holtzman & Michael S. Watson eds., 1998) [hereinafter FINAL REPORT], available at <http://www.genome.gov/10001733>. Genotype refers to an individual’s collection of genes. *Talking Glossary of Genetic Terms*, NAT’L HUMAN GENOME RESEARCH INST., <http://www.genome.gov/glossary/index.cfm> (last visited Mar. 1, 2011) [hereinafter *Glossary*]. One half of an individual’s genes are inherited from the mother; the other half is inherited from the individual’s father. FINAL REPORT, *supra* note 29, at 178. A mutation is a change in an individual’s DNA sequence that may be caused by DNA copying mistakes, exposure to radiation or chemicals, or infection by viruses. *Glossary*, *supra* note 29. Phenotype refers to an individual’s observable traits and characteristics that result from the interaction of the genotype with the environment. *Id.*; FINAL REPORT, *supra* note 29, at 179. Karyotype refers to an individual’s collection of chromosomes or a laboratory technique used to look for abnormal chromosome numbers or structure. *Glossary*, *supra* note 29.

an individual's clinical diagnosis or prognosis.³⁰ At first, genetic testing was only offered and available through health care providers,³¹ so genetic testing companies marketed their services to the providers.³² However, by 2002, as the potential market for genetic testing became more apparent, companies began to market their genetic tests directly to consumers.³³ Early advertisements used themes of fear, hope, and peace of mind to encourage women and certain ethnic groups to request genetic testing from their physicians.³⁴ These advertisement themes continue to be used today in an expanded genetic testing market that now encompasses more individuals and a wider variety of conditions.³⁵

Today, the majority of genetic tests are still only available in health care settings; however, some companies have made genetic tests available directly to consumers, primarily through the Internet.³⁶ The Internet currently hosts more than thirty different DTC genetic testing companies that offer a wide variety of genetic testing services.³⁷ These tests are advertised for both medical and non-medical purposes and can be grouped into four broad categories: 1) individual susceptibility to disease, 2) nutritional and metabolic assessments, 3) genetic linkage to individual traits or characteristics, and 4) ancestry information.³⁸

30. FINAL REPORT, *supra* note 29, at 6; Gail H. Javitt et al., *Direct-to-Consumer Genetic Tests, Government Oversight, and the First Amendment: What the Government Can (and Can't) Do to Protect the Public's Health*, 57 OKLA. L. REV. 251, 257 (2004). A carrier is a person who has inherited a disease-causing gene from one parent and a normal gene from the other parent. FINAL REPORT, *supra* note 29, at 177. Generally a carrier suffers no ill effects of the disease-causing gene. *Id.*

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

32. See Javitt et al., *supra* note 30, at 262 ("The major laboratories generally sell their testing services to health care providers and hospitals, not directly to consumers.").

33. See Sarah E. Gollust et al., *Limitations of Direct-to-Consumer Advertising for Clinical Genetic Testing*, 288 JAMA 1762, 1762 (2002) (recounting some of the advertisements for genetic tests and services that appeared in the popular press). As early as 2001, advertisements for breast cancer genetic testing appeared in Broadway show programs and on television. Ellen Matloff & Arthur Caplan, *Direct to Confusion: Lessons Learned from Marketing BRCA Testing*, 8 AM. J. BIOETHICS 5, 6 (2008).

34. Gollust et al., *supra* note 33, at 1762–63.

35. See Matloff & Caplan, *supra* note 33, at 6–7 (discussing Myriad Genetics DTC "public awareness campaign"); McGregor, *supra* note 10, at 9 (reporting the "amazing array of issues" covered by DTC genetic tests).

36. Javitt et al., *supra* note 30, at 262.

37. DTC GENETIC TESTING COMPANIES, *supra* note 3.

38. Marietta & McGuire, *supra* note 31, at 369. The second and fourth categories, nutritional and metabolic assessments and ancestry information, generally fall outside the use of genetic testing for medical purposes. Other non-medical uses of genetic tests include paternity and sibling testing. This Comment will primarily address issues related to the use of genetic testing for medical purposes.

Virtually all information about an individual's health and physical well-being can be considered genetic information because DNA underlies almost every aspect of human health.³⁹ However, genetic information is fundamentally different from other forms of health information, and genetic testing differs from other diagnostic tests and medical treatments.⁴⁰ Genetic test results are often used primarily for predictive purposes even though the probability that an individual will develop a condition in the future is uncertain.⁴¹ A negative test result only indicates the absence of a particular gene sequence that is linked to a disease or condition, so negative test results do not always rule out the possibility of future disease occurrence.⁴² Similarly, positive test results do not necessarily mean that an individual will develop a disease or condition because the positive result merely indicates the presence of a particular gene sequence that is associated with the occurrence of a disease or condition.⁴³ Even in circumstances where an individual's positive test result directly correlates to future disease development, the positive test result does not indicate when or how the disease will develop, or the severity of the disease manifestation.⁴⁴ Furthermore, genetic test results may have limited use because there are currently few interventions available to improve the outcome of most genetically linked diseases.⁴⁵

Although genetic information is unique to each individual, it is also inherently familial because genes are the basis of hereditary traits that pass from one generation to the next.⁴⁶ Genetic testing inevitably uncovers information about an individual's genetic relatives,⁴⁷ which may force those who undergo these tests to confront complex questions about the disclosure

39. OFFICE OF SCI., U.S. DEP'T OF ENERGY, DOE/SC-0083, GENOMICS AND ITS IMPACT ON SCIENCE AND SOCIETY, 5 (2008), available at http://www.ornl.gov/sci/techresources/Human_Genome/publicat/primer2001/primer11.pdf; Ellen Wright Clayton, *Ethical, Legal, and Social Implications of Genomic Medicine*, 349 NEW ENG. J. MED. 562, 562 (2003).

40. Javitt et al., *supra* note 30, at 260.

41. Katherine Wasson, *Consumer Alert: Ethical Issues Raised By the Sale of Genetic Tests Directly to Consumers*, 8 AM. J. BIOETHICS 16, 17 (2008).

42. FINAL REPORT, *supra* note 29, at 3; Jennifer A. Gniady, Note, *Regulating Direct-to-Consumer Genetic Testing: Protecting the Consumer Without Quashing a Medical Revolution*, 76 FORDHAM L. REV. 2429, 2435 (2008).

43. FINAL REPORT, *supra* note 29, at 3; Javitt et al., *supra* note 30, at 260.

44. Javitt et al., *supra* note 30, at 260–61.

45. FINAL REPORT, *supra* note 29, at 2–3; Gniady, *supra* note 42, at 2435.

46. See Javitt et al., *supra* note 30, at 261 (describing how related individuals may be carriers for genetic traits).

47. Patricia Roche, *Caveat Venditor: Protecting Privacy and Ownership Interests in DNA*, in HUMAN DNA: LAW AND POLICY INTERNATIONAL AND COMPARATIVE PERSPECTIVES 33, 34 (Bartha M. Knoppers ed., 1997).

of test results to their relatives.⁴⁸ In addition, individuals may be pressured by genetic relatives to undergo testing that they would not otherwise consider.⁴⁹

Though genetic test results may not be more informative than other traditional forms of health information, the general public and media often perceive genetic information as infallible.⁵⁰ Individuals who undergo genetic testing have a risk of receiving false positive or false negative results, which may lead them to make potentially harmful choices based on false information.⁵¹ Despite the predictive quality of genetic testing, individuals often interpret their results as a view of their medical destiny.⁵² In addition genetic information has “historically been used as the basis for categorizing members of society” and may still be used for purposes of discrimination.⁵³

Concerns about the unique nature of genetic information and genetic testing can be generally categorized as relating to: result accuracy and the influence of genetic information on medical practice; adequate genetic counseling and the psychological impact of genetic information; personal privacy, confidentiality, and fair use of genetic information; and the commercialization of genetic products.⁵⁴ In the 1990s, an official Task Force on Genetic Testing⁵⁵ raised concerns that certain genetic tests were made available to patients before the tests were determined “to be safe, effective, and useful.”⁵⁶ Today, many health care providers echo these concerns and worry that the genetic tests marketed directly to consumers are not as accurate, valid, or reliable as tests provided in a clinical setting.⁵⁷

Despite concerns about test result accuracy, “DTC genetic tests are becoming more widely utilized [by consumers] due to their convenience

48. *Id.*; Javitt et al., *supra* note 30, at 261.

49. Gevers, *supra* note 15, at 202.

50. Javitt et al., *supra* note 30, at 261.

51. Wasson, *supra* note 41, at 17. “A false positive test indicates a person has X when he does not and false negative tests indicates a person is free of X when he actually has it.” *Id.*

52. Clayton, *supra* note 39, at 563. See also *Is your DNA your destiny?*, NAVIGENICS, http://www.navigenics.com/visitor/genetics_and_health/dna_basics/is_dna_destiny/ (last visited Mar. 1, 2011).

53. Roche, *supra* note 47, at 34.

54. Cook-Deegan, *supra* note 16. These concerns were first identified by a joint working group established by the National Institutes of Health (NIH) and the Department of Energy (DOE) to address policy issues in response to the accelerating pace of scientific development and genomic technology following the completion of the Human Genome Project. *Id.*

55. The Task Force on Genetic Testing was an official government advisory group created by the NIH-DOE working group and charged with the task of making recommendations to assure the public that genetic tests are safe and effective. FINAL REPORT, *supra* note 29, at 4.

56. *Id.* at xii; Gregorio M. Garcia, *The FDA and Regulation of Genetic Tests: Building Confidence and Promoting Safety*, 48 JURIMETRICS J. 217, 219 (2008).

57. Wasson, *supra* note 41 at 17.

and confidential nature.”⁵⁸ Individual consumers worried about the wrongful disclosure of their genetic information may choose to use DTC genetic tests because the results are reported directly to their homes.⁵⁹ Though few cases of discrimination based on an individual’s genetic information have been reported, many consumers and patients are wary of the potential for such misuse.⁶⁰ Avoiding the traditional clinical setting prevents genetic test results from being included in an individual’s medical records and increases that individual’s protection from the potential disclosure of genetic test results to employers or insurance companies.⁶¹

The lack of physician involvement in DTC genetic testing is troublesome to many health care professionals who worry that individuals who receive their genetic test results will not understand the complex nature of these results.⁶² Patients who undergo clinical genetic testing traditionally receive genetic counseling from their health care provider who can explain the probabilistic nature of genetic test results.⁶³ Without any counseling, individuals may be confused by their results because the absence of a particular gene does not ensure that the individual will not develop a particular disease.⁶⁴ Absent genetic counseling, individuals may also face unnecessary stress about their results because the presence of a particular gene does not guarantee that the individual will develop a particular condition.⁶⁵ There is evidence that even when individuals receive counseling, “[patients] are unable to understand the explanations of test results and lack an understanding of both the risks of developing specific

58. Lauren Solberg, Note, *Over the Counter but Under the Radar: Direct-to-Consumer Genetics Tests and FDA Regulation of Medical Devices*, 11 VAND. J. ENT. & TECH. L. 711, 714–15 (2009).

59. Wasson, *supra* note 41, at 18.

60. Schlein, *supra* note 28, at 315.

61. Wasson, *supra* note 41, at 18. The disclosure of an individual’s personal health information, including genetic test results, by a health care provider is regulated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified in scattered sections of 26, 29, & 42 U.S.C.). The use of genetic information by employers and insurance companies is limited by the Genetic Information Nondiscrimination Act (GINA). Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (2008) (to be codified in scattered sections of 26, 29, & 42 U.S.C.). GINA prohibits group health plans from adjusting premium or contribution amounts on the basis of genetic information. §§ 101–106, 122 Stat. at 883–905. GINA also prohibits employers from using genetic information to make decisions regarding hiring, firing, job placement and promotions in addition to regulating how employers may acquire an employee’s genetic information. §§ 201–213, 122 Stat. at 905–920.

62. Audrey Chapman, *DTC Marketing of Genetic Tests: The Perfect Storm*, 8 AM. J. BIOETHICS 10, 10 (2008); Wasson, *supra* note 41, at 17–18.

63. See Novick, *supra* note 11, at 635–36 (describing the discussions genetic counselors have with patients deciding to undergo genetic testing).

64. FINAL REPORT, *supra* note 29, at 3.

65. *Id.*

diseases and the role that the environmental factors play.”⁶⁶ A genetic predisposition to a condition does not indicate how severe the symptoms will be, or how the individual will respond to available treatments.⁶⁷ Opponents of DTC tests assert that individuals who utilize these tests are particularly likely to face adverse effects “when the interpretation of test results requires specific expertise, [when] the outcome of the test results in options that require expert advice, and [when] the potential psychological impact makes professional support necessary.”⁶⁸ Additionally, opponents argue that consumers need counseling to understand their genetic test results and to best utilize the results when making important health care decisions based on those results.⁶⁹ Supporters of DTC genetic testing argue that many physicians are insufficiently prepared to interpret genetic test results,⁷⁰ and that individuals have a right to access their own genetic information.⁷¹ The increased use of genetic tests and the emergence of DTC genetic tests have stimulated further debate about the regulation of genetic tests.⁷²

A. State Regulation

In 2007 and 2008 New York and California sent “cease and desist” letters to thirty-one genetic testing companies that engage in DTC sales.⁷³ The letters targeted companies that provide genetic tests directly to consumers without the involvement of a licensed physician⁷⁴ and stated that the companies “need licenses to solicit specimens of DNA from state residents.”⁷⁵ Following these letters, California granted licenses to a limited number of these companies.⁷⁶ California and New York are among the

66. Gniady, *supra* note 42, at 2448.

67. *Id.* at 2435.

68. Gevers, *supra* note 15, at 202.

69. Wasson, *supra* note 41, at 17. For example, a woman who has a genetic test result that indicates a predisposition to the development of breast cancer may choose to undergo prophylactic breast surgery in order to reduce her risk of disease development.

70. Gniady, *supra* note 42, at 2448.

71. Wasson, *supra* note 41, at 17.

72. See generally *At Home DNA Tests: Marketing Scam or Medical Breakthrough: Hearing Before the S. Special Comm. on Aging*, 109th Cong. 1–2 (2006) (statement of Sen. Gordon H. Smith, Chairman, S. Special Comm. on Aging) (describing concerns regarding the oversight of and science behind DTC genetic tests).

73. Jane E. Brody, *Buyer Beware of Home DNA Tests*, N.Y. TIMES, Sept. 1, 2009, http://www.nytimes.com/2009/09/01/health/01brod.html?_r=1&nl=health&emc=healthupdateemb3#; Andrew Pollack, *Gene Testing Questioned by Regulators*, N.Y. TIMES, June 26, 2008, http://www.nytimes.com/2008/06/26/business/26gene.html?_r=1.

74. Robertson, *supra* note 1, at 213.

75. Brody, *supra* note 73.

76. Robertson, *supra* note 1, at 213.

twelve states that currently allow limited DTC testing.⁷⁷ While some states limit the use of DTC testing by focusing on specific tests that may be ordered directly by consumers,⁷⁸ other states limit the use of DTC tests to those tests ordered by licensed practitioners, physicians, or authorized professionals listed in the statute and further require that results only be reported to the authorized person who requested the test.⁷⁹

Twenty-five states and the District of Columbia allow DTC testing without any restriction,⁸⁰ while thirteen states prohibit all DTC testing.⁸¹ Many states that prohibit all DTC testing specify that the ordering of tests is limited to licensed physicians or other professionals authorized by law to make medical diagnoses.⁸² The majority of states that allow unrestricted DTC testing have no applicable state statute or regulation that addresses these tests,⁸³ which effectively allows DTC testing to occur in the state.⁸⁴ Only five states that allow unrestricted DTC testing and the District of Columbia have laws that may be interpreted to apply to DTC testing.⁸⁵ These laws generally do not address DTC testing directly, but instead focus on the need for informed consent⁸⁶ or the need for a physician to receive and interpret the results.⁸⁷ Although state restrictions that require a physician order the test and receive the test results seem to indicate a level of validity in the testing process, DTC genetic testing companies that wish

77. GENETICS & PUB. POL'Y CTR., SURVEY OF DIRECT-TO-CONSUMER TESTING STATUTES AND REGULATIONS (June 2007) [hereinafter DTC STATUTE SURVEY], available at <http://www.dnapolicy.org/resources/DTCStateLawChart.pdf>. The other states that allow limited DTC testing are: Arizona, Colorado, Florida, Illinois, Maine, Maryland, Massachusetts, Nevada, New Jersey, and Oregon. *Id.*

78. *E.g.*, ME. REV. STAT. ANN. tit. 22, § 2030 (2004); NEV. REV. STAT. ANN. § 652.190 (2008).

79. *E.g.*, ARIZ. REV. STAT. ANN. § 36-470 (2009); CAL. HEALTH & SAFETY CODE § 123148 (2006); FLA. STAT. ANN. §§ 483.181(1)–(2) (2006 & Supp. 2011); 210 ILL. COMP. STAT. 25/7-101 to -102 (2008).

80. DTC STATUTE SURVEY, *supra* note 77. The states that allow DTC testing without restriction include: Alaska, Arkansas, Delaware, Indiana, Iowa, Kansas, Louisiana, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, South Dakota, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin. *Id.*

81. *Id.* The states that prohibit all DTC testing include: Alabama, Connecticut, Georgia, Hawaii, Idaho, Kentucky, Michigan, New Hampshire, Pennsylvania, Rhode Island, South Carolina, Tennessee, and Wyoming. *Id.*

82. *E.g.*, GA. CODE ANN. § 31-22-4(a) (2009); TENN. CODE ANN. § 68-29-121 (2006 & Supp. 2010).

83. DTC STATUTE SURVEY, *supra* note 77. Twenty of the twenty-five states that allow DTC testing have state laws that are “silent on the issue.” *Id.*

84. Robertson, *supra* note 1, at 224.

85. DTC STATUTE SURVEY, *supra* note 77. Nebraska, North Carolina, Virginia, Washington, and Wisconsin have state laws that may be interpreted to apply to DTC testing. *Id.*

86. *E.g.*, NEB. REV. STAT. § 71-551 (2009).

87. *E.g.*, WASH. ADMIN. CODE § 246-338-070 (2009).

to circumvent these requirements often have “an arrangement with a physician whose name is used to order tests and report results to the consumer.”⁸⁸ However, affiliation with a physician does not necessarily indicate that the test is accurate or that the patient receives counseling about the test results.⁸⁹ Similarly, having a doctor working under a contract with the company review the consumer’s test orders before the specimens are given to the testing laboratory is not the same as having the individual’s physician order the tests.⁹⁰

In addition to regulating the provision of DTC genetic tests, states can also use their unfair or deceptive trade practice statutes to protect consumers.⁹¹ Although every state has enacted laws to generally regulate false advertising and deceptive marketing practices,⁹² none of the states have laws that directly address the advertising or marketing of genetic testing.⁹³ Instead, many of the states’ broad statutes prohibit deceptive trade practices that may confuse the consumer’s awareness of the “source, sponsorship, approval or certification of goods or services” or that “represent that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not

88. Robertson, *supra* note 1, at 224–25. This practice is especially common with DTC genetic test providers who do business through the Internet. *Id.* The use of the Internet also enables third party DTC genetic test companies to sell genetic tests that are supposed to be only clinically available directly to consumers. Stuart Hogarth et al., *Direct-to-Consumer Genetic Testing: Legal, Ethical, and Policy Issues*, 9 ANN. REV. GENOMICS & HUMAN GENETICS 161, 164 (2008) (explaining that although Myriad Genetics does not sell its tests directly to patients, consumers are able to purchase the tests from DNA Direct, a third party DTC genetic test company that uses its own healthcare providers to order the test from Myriad).

89. Robertson, *supra* note 1, at 225. *See also* Turna Ray, *CDC Advises Docs to Inform Patients of Limitations of DTC Gene Scans*, PHARMACOGENOMICS REP., July 29, 2010, <http://www.genomeweb.com/dxpgx/cdc-advises-docs-inform-patients-limitations-dtc-gene-scans> (explaining that even though some DTC companies have partnered with “wellness groups and doctors,” the CDC believes that the tests are “lacking in terms of clinical validity and clinical utility.”).

90. *See* Pollack, *supra* note 73. As the former director of the Genetics and Public Policy Center at Johns Hopkins University said “some doc on the payroll at Genes R Us’ is not the same as a personal physician.” *Id.* “A physician working for a company selling the [DTC genetic] tests is clearly not well situated to look after a patient’s best interest” when providing advice about the need for the test or when ordering the test. David Magnus et al., *Direct-to-Consumer Genetic Tests: Beyond Medical Regulation?*, 1 GENOME MED. 17 (2009), available at <http://genomemedicine.com/content/1/2/17>.

91. GENETICS & PUB. POL’Y CTR., SURVEY OF STATE FALSE ADVERTISING LAWS 1 (August 2009) [hereinafter FALSE ADVERTISING SURVEY], available at http://www.dnapolicy.org/resources/Prince_StateFalseAdvertisingLaws.pdf.

92. Alan S. Brown & Larry E. Hepler, *Comparison of Consumer Fraud Statutes Across the Fifty States*, 55 FDCC Q. 263, 263 (2005).

93. FALSE ADVERTISING SURVEY, *supra* note 91, at 1.

have”⁹⁴ Only two state statutes specifically address scientific and clinical advertising claims.⁹⁵ California’s statute prohibits false and misleading advertising claims that “purport to be based on . . . clinical evidence.”⁹⁶ Nevada’s statute states that

a person engages in a ‘deceptive trade practice’ when . . . he or she makes an assertion of scientific, clinical or quantifiable fact in an advertisement which would cause a reasonable person to believe that the assertion is true, unless, at the time the assertion is made, the person making it has possession of factually objective scientific, clinical or quantifiable evidence which substantiates the assertion[.]⁹⁷

Furthermore, California’s statute is the only one to specify that the provisions apply to advertisements over the Internet, in addition to those in more traditional publications.⁹⁸ Despite broad trade practice laws that provide states with another way to protect consumers, only one attorney general has initiated an investigation into the claims made in DTC genetic test advertisements.⁹⁹

During the past decade, the number of states that allow some form of DTC testing has increased.¹⁰⁰ Individual states have the authority to strictly regulate genetic tests,¹⁰¹ however, the majority of current state regulations do not address the major concerns about test accuracy or appropriate counseling for individuals who undergo genetic testing.¹⁰² The enforcement

94. DEL. CODE ANN. tit. 6, § 2532 (2005); GA. CODE ANN. § 10-1-372 (2009); ME. REV. STAT. ANN. tit. 10, § 1212 (2009). Many states, including Alabama, Alaska, Colorado, Delaware, Georgia, Hawaii, Idaho, Illinois, Indiana, Kansas, Maine, Maryland, Michigan, Minnesota, Mississippi, Nebraska, New Hampshire, Oregon, Pennsylvania, Tennessee, Texas, Utah, and West Virginia, have adopted provisions based on the Uniform Deceptive Trade Practices Act or Uniform Consumer Sales Practices Act, and therefore have almost identical language in their state statutes. Brown & Hepler, *supra* note 92, at 266–68, 290–308 (2005). *See also* FALSE ADVERTISING SURVEY, *supra* note 91, at 1–32 (highlighting the applicable text in each state’s statute).

95. FALSE ADVERTISING SURVEY, *supra* note 91, at 1.

96. CAL. BUS. & PROF. CODE § 17508 (2008).

97. NEV. REV. STAT. ANN. § 598.0925 (2010).

98. CAL. BUS. & PROF. CODE § 17500 (2008).

99. FALSE ADVERTISING SURVEY, *supra* note 91, at 1; Andrew Pollack, *A Genetic Test That Very Few Need, Marketed to the Masses*, N.Y. TIMES, Sept. 11, 2007, <http://www.nytimes.com/2007/09/11/business/media/11genetics.html>.

100. Matthew Schulze, *25 Percent More States Allow Direct Access Testing*, 32 LAB. MED. 661, 661 (2001). In 1999, twenty-seven states allowed consumers direct access to testing; by 2001, thirty-four states allowed direct access testing. *Id.* Thirty-seven states currently allow some form of direct-to-consumer testing. DTC STATUTE SURVEY, *supra* note 77.

101. *See* U.S. CONST. amend. X (reserving any powers not delegated to the Federal Government in the Constitution for the States). The regulation of health and safety matters is generally reserved for State consideration. Javitt et al., *supra* note 30, at 273.

102. *See supra* text accompanying notes 62–72.

of state regulation is also challenging because the majority of DTC genetic tests are offered to consumers through the Internet, and the companies that offer these tests may be outside the jurisdiction of any one state.¹⁰³ Additionally, many states have followed the precedent set by various federal agencies,¹⁰⁴ and have not implemented specific regulations for DTC genetic tests.¹⁰⁵

B. Federal Regulation

Three federal agencies have the greatest potential ability to regulate the DTC genetic tests currently available to consumers.¹⁰⁶ The Food & Drug Administration (FDA) has authority to regulate medical devices used “in the diagnosis of disease or other conditions.”¹⁰⁷ The Federal Trade Commission (FTC) has a statutory mandate to protect consumers and to prevent unfair or deceptive acts and practices, including false or misleading advertising.¹⁰⁸ The Centers for Medicaid and Medicare Services (CMS) have authority to regulate medical testing within clinical laboratories under the Clinical Laboratories Improvement Amendments of 1988 (CLIA).¹⁰⁹ The regulatory authority of each agency is dependent on how each particular genetic test is produced, marketed, performed, and interpreted.¹¹⁰

1. FDA Regulation

In 2000, an official government advisory committee recommended that the “FDA should be the federal agency responsible for the review, approval, and labeling of all new genetic tests.”¹¹¹ This committee also suggested that the FDA develop a review process that focuses on evaluating genetic test analytical and clinical validity, as well as evaluating clinical

103. Javitt & Hudson, *supra* note 13, at 64. *See generally* James R. Pielemeier, *Why General Personal Jurisdiction Over “Virtual Stores” is a Bad Idea*, 27 QUINNIPIAC L. REV. 625, 626 (2009) (explaining that courts have begun to address whether a website can be sufficient contact for a state to assert jurisdiction). Although the D.C. Circuit and Ninth Circuit have found that an accessible website can create general jurisdiction, the Fourth, Fifth, Sixth, Tenth, and Federal Circuits have not found general jurisdiction in these cases. *Id.* at 626–27.

104. *See* discussion *infra* Part I.B.

105. *See supra* notes 77–87, 91–98 and accompanying text.

106. *See* Javitt et al., *supra* note 30, at 268 (introducing current federal regulation of genetic tests); Novick, *supra* note 11, at 624–30 (discussing the current regulatory structure).

107. 21 U.S.C. § 321(h)(2) (2006).

108. 15 U.S.C. §§ 45(a)(1)–(2) (2006).

109. Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, 102 Stat. 2903 (1988) (codified at 42 U.S.C. § 263a).

110. Robertson, *supra* note 1, at 221.

111. SEC’Y’S ADVISORY COMM. ON GENETIC TESTING, NAT’L INSTS. OF HEALTH, ENHANCING THE OVERSIGHT OF GENETIC TESTS: RECOMMENDATIONS OF THE SACGT 27 (2000), available at http://oba.od.nih.gov/oba/sacgt/reports/oversight_report.pdf.

utility claims made by the test developers.¹¹² The Federal Food, Drug, and Cosmetic Act (FDCA) of 1938¹¹³ and the Medical Device Amendments of 1976¹¹⁴ give authority to the FDA to regulate medical devices. A medical device is defined as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease”¹¹⁵

The FDA utilizes three categories of medical devices to determine how much control is needed to ensure the safety and effective use of each device.¹¹⁶ Class I devices are subject to the least FDA regulation oversight and may be introduced directly into U.S. commerce.¹¹⁷ Class II devices have an increased safety risk and are subject to greater FDA controls including post-marketing surveillance and device performance standards to ensure safety and effectiveness.¹¹⁸ Class III devices are defined as those: 1) for which general controls and special control would not provide reasonable assurance of safety and effectiveness; and 2) which are either for (a) supporting, sustaining, or preventing impairment of human health, or (b) present a potential unreasonable risk of illness or injury.¹¹⁹ Only a small number of predictive medical tests are classified and regulated as Class III medical devices; predictive personal genetic tests are generally not considered Class III devices.¹²⁰

Though the definition of a medical device provides the FDA broad authority to regulate genetic tests, the FDA has chosen to limit its regulation

112. *Id.*

113. 21 U.S.C. §§ 301–399 (2006).

114. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified in scattered sections of 21 U.S.C.).

115. 21 U.S.C. § 321(h)(2) (2006). The FDA has previously considered only some genetic tests in vitro diagnostic products. *See* Garcia, *supra* note 56, at 218 (explaining that the FDA considers certain complex genetic tests *In Vitro* Diagnostic Multivariate Index Assays (IVDMIA)). However, the FDA has recently decided to consider broader regulations for all laboratory-developed genetic tests, instead of focusing on IVDMIA. Oversight of Laboratory Developed Tests; Public Meeting; Request for Comments, 75 Fed. Reg. 34,463 (June 17, 2010); Turna Ray, *FDA Shelves IVDMIA Final Guidelines in Order to Focus on Overall LDT Regulation*, PHARMACOGENOMICS REP., June 17, 2010, <http://www.genomeweb.com/dxpgx/fda-shelves-ivdmia-final-guidelines-order-focus-overall-ldt-regulation>.

116. Neil A. Holtzman, *FDA and the Regulation of Genetic Tests*, 41 JURIMETRICS 53, 59 (2000).

117. 21 U.S.C. § 360c(a)(1)(A) (2006).

118. § 360c(a)(B).

119. § 360c(a)(C).

120. Bruce Patsner, *New “Home Brew” Predictive Genetic Tests Present Significant Regulatory Problems*, 9 HOUS. J. HEALTH L. & POL’Y 237, 247 (2009). HIV tests are one of the few predictive medical tests regulated as Class III medical devices. *Id.*

of genetic tests.¹²¹ The limited regulation of new genetic tests may be due to the availability of the FDA's pre-market notification process.¹²² The pre-market notification process, also known as 510(k) abbreviated marketing clearance, requires that developers "demonstrate that their new test is substantially equivalent to a medical device currently on the market."¹²³ If the genetic test developer can produce data that demonstrates that a new test is substantially equivalent to a test already available on the market, the new test can be marketed in the same class as that test, and the developer does not need to prove the new test's safety and effectiveness in order to gain pre-market approval.¹²⁴

The limited regulation of genetic tests may also be attributed to the FDA regulatory distinction between genetic "home brew" tests, which are developed and analyzed completely within one laboratory, and genetic tests that contain components that travel in interstate commerce.¹²⁵ The FDA has chosen to regulate only the individual components and reagents used in the genetic tests, and has declined to regulate genetic "home brew" tests or the laboratories that develop and analyze them.¹²⁶ Consequently, "home brew" tests are classified as Class I or II medical devices that are subject to less regulation than other genetic tests.¹²⁷ Practically, this allows certain genetic tests to reach the consumer market without any FDA evaluation for safety, effectiveness, or accuracy.¹²⁸ Consumers who purchase these DTC genetic tests "are likely unaware that the FDA is not involved in [any] quality manufacturing control or efficacy testing" of the products.¹²⁹

In addition to the self-imposed regulatory distinctions created by individual test development and components, the FDA has stated that its regulatory power over medical devices cannot be extended to regulate genetic tests marketed as services.¹³⁰ This allows companies that market

121. See Robertson, *supra* note 1, at 223–24 (explaining that the FDA exercises "enforcement discretion" in the regulation of certain genetic tests).

122. See Solberg, *supra* note 58, at 730 (introducing the pre-market notification process).

123. *Id.* New Class III medical devices may be introduced to consumers through an abbreviated marketing application if the device is substantially equivalent to a device marketed prior to May 28, 1976, or to devices classified as class I or II since that date. Patsner, *supra* note 120, at 246.

124. Holtzman, *supra* note 116, at 60.

125. Novick, *supra* note 11, at 629.

126. Patsner, *supra* note 120, at 251–52. See also Classification and Reclassification of Restricted Devices, Analyte Specific Reagents, 62 Fed. Reg. 62,243, 62,245 (Nov. 21, 1997) (discussing the FDA's intention not to regulate the reagents used in genetic tests differently from other class I medical devices).

127. Patsner, *supra* note 120, at 249.

128. *Id.* at 254.

129. *Id.* at 249–50.

130. Robertson, *supra* note 1, at 61.

their “home brew” tests as services to circumvent the entire FDA pre-market approval process.¹³¹

In addition to the market approval regulations, genetic tests may be subject to FDA regulations regarding medical device labeling.¹³² Genetic tests that include FDA regulated components must comply with the promulgated regulations regarding general medical device labeling,¹³³ as well as with regulations for in vitro diagnostic products.¹³⁴ The FDA is responsible for the regulation of advertising for restricted medical devices, however genetic tests that are classified as Class I or II medical devices are not considered restricted medical devices.¹³⁵ DTC genetic tests and “home brew” test kits are generally not subject to these regulations, so the labels and materials included with these tests may include information that has not been substantiated.¹³⁶

2. FTC Regulation

The FTC may have a better ability to regulate the advertising of genetic tests because the FTC has statutory authority to regulate the advertising of most medical devices.¹³⁷ The FTC also has a statutory mandate to protect consumers and to prevent unfair practices and deceptive acts.¹³⁸ The FTC considers three factors in determining if a practice is unfair: “1) whether the practice injures consumers; 2) whether it violates established public policy; and 3) whether it is unethical and unscrupulous.”¹³⁹ An act is considered deceptive “if there is a misrepresentation, omission, or other practice, that misleads the consumer

131. Patsner, *supra* note 120, at 254.

132. Solberg, *supra* note 58, at 728.

133. 21 C.F.R. § 801 (2009).

134. 21 C.F.R. § 809.10 (2009). For example, the FDA requires that some genetic tests “state that their [a]nalytic and performance characteristics are not established’ . . . because they are ‘not clinically validated.’” Jennifer E. Spreng, *The Food and Drug Administration and the Pharmacy Profession: Partners to Ensure the Safety and Efficacy of the Pharmacogenomic Therapy*, 13 J. HEALTH CARE L. & POL’Y 77, 91–92 (2010). The result reports generated from these tests are also required to include a notification that the test is not cleared or approved by the FDA. *Id.* at 92.

135. See *FDA Oversight of Direct-to-Consumer Advertising of Medical Devices: Hearing Before the S. Special Comm. on Aging*, 110th Cong. (2008) [hereinafter *FDA Oversight*] (statement of Daniel Schultz, Director, Center for Devices and Radiological Health, Food & Drug Administration), available at <http://www.fda.gov/NewsEvents/Testimony/ucm096272.htm> (explaining that “few Class I and Class II devices are restricted by regulation”).

136. Solberg, *supra* note 58, at 729.

137. 15 U.S.C. §§ 52–55 (2006). See also *FDA Oversight*, *supra* note 135 (explaining that the FDA has authority to regulate restricted medical devices and the FTC has authority to regulate non-restricted medical devices).

138. 15 U.S.C. § 45(a)(1) (2006 & Supp. 2009).

139. FED. TRADE COMM’N, *FTC POLICY STATEMENT ON UNFAIRNESS* (1980), available at <http://www.ftc.gov/bcp/policystmt/ad-unfair.htm>.

acting reasonably in the circumstances, to the consumer's detriment."¹⁴⁰ The FTC is also primarily responsible for the regulation of Internet-based product advertising.¹⁴¹ FTC regulation is based on the content of the advertisement or speech.¹⁴²

Although the FTC has regularly taken action against a variety of health product manufacturers, the agency has not yet exercised this authority against any genetic test advertisement.¹⁴³ This limited FTC action may be directly related to the FDA's limited regulation of DTC genetic tests as medical devices because the FTC often looks to the FDA's labeling requirements to determine if a particular test claim is false or misleading.¹⁴⁴ However, since the FDA has limited its regulation of genetic tests, the majority of such tests are made available to consumers without any need for efficacy validation.¹⁴⁵ This affects the FTC's actions for claims about genetic test advertisements because, without a FDA standard, the FTC may not be able to clearly determine which DTC genetic test advertisements are false or misleading.¹⁴⁶ Without an FDA standard, FTC action against DTC genetic test advertisements may also face increased First Amendment scrutiny because there is little basis for the clear determination that the claims are false or misleading.¹⁴⁷

3. CLIA and CMS Regulation

CLIA¹⁴⁸ establishes regulations to ensure that every laboratory determines the analytical validity of its laboratory tests before offering them for clinical purposes, such as use for disease diagnosis, prevention, or treatment.¹⁴⁹ Although CLIA was enacted to certify valid and reliable medical testing, CLIA does not authorize or certify the validity of the individual tests.¹⁵⁰

140. FED. TRADE COMM'N, FTC POLICY STATEMENT ON DECEPTION (1983) [hereinafter FTC STATEMENT ON DECEPTION], available at <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>.

141. Javitt & Hudson, *supra* note 13, at 65.

142. Javitt et al., *supra* note 30, at 286.

143. Javitt & Hudson, *supra* note 13, at 65.

144. *Id.*

145. Patsner, *supra* note 120, at 249–50.

146. Javitt & Hudson, *supra* note 13, at 65.

147. *Id.*

148. Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, 102 Stat. 2903 (1988) (codified at 42 U.S.C. § 263a).

149. LABORATORY PRACTICES, *supra* note 2, at 3; Holtzman, *supra* note 116, at 57. For genetic tests, analytical validity refers to accurate identification of a particular genetic mutation. Javitt & Hudson, *supra* note 13, at 59.

150. Robertson, *supra* note 1, at 222.

CLIA imposes basic requirements for laboratory methodology and documentation and standards for personnel qualification in order for a laboratory to receive certification.¹⁵¹ CLIA certification also requires periodic facility inspections and the examination of proficiency sample tests for high complexity tests.¹⁵² Although genetic tests are highly complex and require precise skill to perform and interpret, CMS does not require laboratories that perform genetic testing to undergo specific proficiency examinations for the genetic tests.¹⁵³ In addition, although laboratories that perform genetic tests must meet some personnel requirements to fulfill the certification requirements for high-complexity testing, the actual laboratories are still only subject to the general CLIA methodology and documentation requirements.¹⁵⁴ Furthermore, CLIA “does not require [that] laboratories address the *clinical* validity or utility of tests [performed].”¹⁵⁵ This is particularly problematic for “home brew” genetic tests because CLIA does not include explicit authorization or a process for evaluating test accuracy.¹⁵⁶

Although CLIA requires that laboratories report any changes about offered examinations and procedures to the Secretary of Health and Human Services,¹⁵⁷ CLIA does not authorize CMS to limit or restrict the offering of a particular test.¹⁵⁸ The decision to offer new genetic tests is left to the discretion of each individual laboratory.¹⁵⁹

The Centers for Disease Control and Prevention (CDC) advises CMS on CLIA implementation, provides scientific and technical support for CMS, and sponsors the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) program.¹⁶⁰ Recently, the CDC published new

151. 42 U.S.C. §§ 263a(d)(1), (e)(2)(D), (f)(1) (2006).

152. §§ 263a(d)(3), (f)(3)(A); Javitt & Hudson, *supra* note 13, at 59. This distinction means that “there are no specified quality control, personnel, or proficiency testing requirements mandated under the CLIA regulations for most genetic tests.” *At Home DNA Tests: Marketing Scam or Medical Breakthrough: Hearing Before the S. Special Comm. on Aging*, 109th Cong. 35–36 (2006) (prepared statement of Kathy Hudson, Director, Genetics & Public Policy Center, and Associate Professor, Berman Bioethics Institute, Institute of Genetic Medicine and Department of Pediatrics, Johns Hopkins University).

153. Javitt & Hudson, *supra* note 13, at 59–61.

154. 42 C.F.R. § 493.1495 (2009); LABORATORY PRACTICES, *supra* note 2, at 3.

155. Holtzman, *supra* note 116, at 57. Clinical validity refers to whether the information provided is relevant to an individual’s health and disease. Javitt & Hudson, *supra* note 13, at 59. Clinical utility refers to “the likelihood that use of a test will lead to an individual’s improved health outcome.” *Id.* at 61.

156. Javitt & Hudson, *supra* note 13, at 61.

157. 42 U.S.C. § 263a(d)(2)(B) (2006).

158. Javitt & Hudson, *supra* note 13, at 61.

159. *Id.*

160. GENETICS & PUB. POL’Y CTR., WHO REGULATES GENETIC TESTS? (Feb. 27, 2006, updated May 30, 2008), *available at*

recommendations for good laboratory practices for ensuring the quality of genetic testing.¹⁶¹ These recommendations address issues that develop throughout the entire genetic testing process and include guidelines for providing information and informed consent to users of the laboratory services, specimen submission and handling, test referrals, quality control procedures, proficiency testing, test reporting, and specimen and record retention.¹⁶²

In addition to advising CMS on the implementation of CLIA, the CDC, through the Human Genome Epidemiology Network (Network), may have the ability to determine the validity of genetic tests.¹⁶³ By compiling anonymous samples and data on genetic test results, the Network could establish the frequencies of genotypes implicated in a variety of diseases to determine more reliable estimates of test validity.¹⁶⁴

II. HIV: A PAST EXAMPLE OF HOME TEST KIT CONTROVERSY

Los Angeles public health officials reported the first cases of acquired immunodeficiency syndrome (AIDS) in 1981.¹⁶⁵ By 1987, the CDC determined that the human immunodeficiency virus (HIV) caused AIDS, and that the disease was spread through exposure to infected blood.¹⁶⁶ The CDC, in conjunction with state and local health departments, began a national public education campaign to combat the spread of the HIV and AIDS.¹⁶⁷ Initial guidelines suggested that “[c]ounseling and testing persons

http://www.dnapolicy.org/policy.issue.php?action=detail&issuebrief_id=10. The EGAPP program makes non-binding recommendations about the validity and utility of specific genetic tests based on systematic, evidence-based genetic test assessments. *Id.*

161. LABORATORY PRACTICES, *supra* note 2, at 1.

162. *Id.* at 7.

163. Holtzman, *supra* note 116, at 57.

164. *Id.* at 57–58.

165. Michael S. Gottlieb et al., *Pneumocystis Pneumonia – Los Angeles*, 30 MORBIDITY & MORTALITY WKLY. REP. 250 (1981), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/june_5.htm. This report described the cases of a rare pneumonia in five previously healthy homosexual men. *Id.* at 250–51. The accompanying editorial note suggested that the disease was “related to a common exposure” and “acquired through sexual contact.” *Id.* at 251.

166. Ctrs. for Disease Control & Prevention, Dep’t of Health & Human Servs., *Perspectives in Disease Prevention and Health Promotion Public Health Service Guidelines for Counseling and Antibody Testing to Prevent HIV Infection and AIDS*, 36 MORBIDITY & MORTALITY WKLY. REP. 509, 509 (1987) [hereinafter *Perspectives*], available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00015088.htm>.

167. Ctrs. for Disease Control & Prevention, Dep’t of Health & Human Servs., *HIV and AIDS – United States, 1981-2000*, 50 MORBIDITY & MORTALITY WKLY. REP. 430, 433 (2001), available at <http://www.cdc.gov/mmwr/PDF/wk/mm5021.pdf>.

who are infected or at risk for acquiring HIV infection is an important component of prevention strategy.”¹⁶⁸

A. Debated Development of the Home Test Kit

In 1986 and 1987, the FDA reviewed several applications for the manufacture of a HIV home test kit.¹⁶⁹ The FDA found that the proposed kits were medical devices subject to regulation under the FDCA and determined that the kits were not eligible for 510(k) abbreviated marketing clearance.¹⁷⁰ In 1988, the FDA decided to limit the marketing of HIV testing blood collection kits to those kits intended for professional use,¹⁷¹ which effectively banned the development of a HIV home test kit.¹⁷² Critics of the home testing kits included the American Medical Association, the CDC, several congressmen, and many gay activists.¹⁷³ These objectors argued that the home tests would produce inaccurate results, increase the risk of suicide, and minimize the importance of pre- and post-test counseling.¹⁷⁴

Though the ban continued for a number of years, in 1994 the FDA announced plans to reconsider the approval of HIV home test kits.¹⁷⁵ This announcement indicated that the FDA might be receptive to the use of home HIV tests.¹⁷⁶ Once again, the debate between objectors and advocates of the HIV home test focused on concerns for users’ welfare and their understanding of the test process and results. Objectors to the home test challenged the accuracy of the tests and raised concerns about the potential harms that home testers would suffer without face-to-face pre- and post-test counseling.¹⁷⁷ Because a key aspect of the HIV home test kit was the availability of anonymous testing, objectors also raised concerns about the

168. *Perspectives*, *supra* note 166, at 509.

169. Home Test Kits Designed to Detect HIV-1 Antibody, 54 Fed. Reg. 7279, 7280 (Feb. 17, 1989). The proposed kits were to include instructions and equipment for sample collection, packaging materials for shipment to a laboratory for testing, and a confidential mechanism to receive the test results. *Id.*

170. *Id.* See also *supra* notes 122–24 and accompanying text (discussing the 510(k) abbreviated marketing clearance process).

171. Home Test Kits Designed to Detect HIV-1 Antibody, 54 Fed. Reg. at 7280.

172. Steven R. Salbu, *HIV Home Testing and the FDA: The Case for Regulatory Restraint*, 46 HASTINGS L.J. 403, 403 (1995).

173. Alexi A. Wright & Ingrid T. Katz, *Home Testing for HIV*, 354 NEW ENG. J. MED. 437, 438 (2006).

174. Bayer et al., *supra* note 19, at 1296–97; Wright & Katz, *supra* note 173, at 438.

175. Food and Drug Administration Advisory Committee Meeting; Amendment of Notice, 59 Fed. Reg. 29,814, 29,814 (June 9, 1994).

176. *Id.*; Salbu, *supra* note 172, at 403–04.

177. See Bayer et al., *supra* note 19, at 1296–97 (raising a number of questions about use of the home test kit).

impact that home HIV testing would have on public health practices and policies that mandated the reporting of HIV infection to local and state registries.¹⁷⁸ In contrast, supporters of the HIV home test argued that the availability of a home test would increase the number of people tested for HIV infection, which would lead to reductions in risk behaviors and curb the spread of HIV.¹⁷⁹

1. Test Accuracy Concerns

On both occasions when the FDA considered the approval of a HIV home test, the safety and efficacy of the home test kit was one of the most contested issues.¹⁸⁰ Opponents to home testing focused on the fact that society generally needs medical professionals because patients are unable to diagnose or treat themselves,¹⁸¹ the HIV home test raised concerns because it required patients to collect their own specimens for testing.¹⁸² The use of individual patient specimen collection also raised concerns about the effectiveness of the home test kits when compared to test products developed for clinical professional use.¹⁸³ Objectors speculated that non-professional individuals utilizing the test would compromise test accuracy through contamination or misuse.¹⁸⁴ There was also concern that users would not use the kits in a timely manner so the test kits would expire or become outdated through the inability to register new viral mutations discovered as testing technology continued to develop.¹⁸⁵

2. Pre- and Post-Test Counseling and Treatment Concerns

In addition to concerns about the safety and efficacy of the testing process, multiple concerns were raised about the need for individuals participating in HIV testing to receive appropriate pre- and post-test

178. *Id.* at 1298. See also William O. Fabbri, Note, *Home HIV Testing and Conflict with State HIV Testing Regulations*, 21 AM. J.L. & MED. 419, 419 (1995) (discussing approval of a home HIV test and various state HIV testing laws).

179. Fabbri, *supra* note 178, at 421–22; Kathryn A. Phillips et al., *Potential Use of Home HIV Testing*, 332 NEW ENG. J. MED. 1308, 1308 (1995). Researchers found that black and Hispanic respondents, people with potentially less access to health care and HIV testing, and people with less education and lower incomes were more likely to say that they would use home HIV tests. *Id.* at 1308–09. The researchers determined that this was a significant finding because “preventive services and other home tests are usually more likely to be used by people with higher incomes and more education.” *Id.* at 1309.

180. Salbu, *supra* note 172, at 413.

181. *Id.* at 412.

182. Bayer et al., *supra* note 19, at 1296; Salbu, *supra* note 172, at 412.

183. Salbu, *supra* note 172, at 415.

184. Fabbri, *supra* note 178, at 429.

185. *Id.*; Salbu, *supra* note 172, at 415.

counseling and treatment.¹⁸⁶ Objectors worried that individuals who received a positive test result over the phone would be unable to handle the “death sentence.”¹⁸⁷ There was also concern that individuals who received their test results over the phone would hang up before receiving necessary counseling.¹⁸⁸ The objectors argued that the mandatory face-to-face pre- and post-test counseling that individuals received while getting clinical HIV testing was essential.¹⁸⁹ Supporters of the HIV home test argued that the level of face-to-face counseling available at clinical offices and HIV-testing facilities was variable, and that some HIV-testing clinics provided little or no counseling at all.¹⁹⁰ Supporters asserted that specialized HIV counselors would have the opportunity to provide a consistent level of counseling to those receiving positive results over the telephone.¹⁹¹ The supporters relied on the success of other telephone counseling services including suicide hot lines and already established AIDS hot lines.¹⁹² Furthermore, supporters of home testing maintained that certain individuals would prefer to deal with an anonymous counselor over the phone instead of face-to-face counseling.¹⁹³

B. An Approved Home Test Kit

Despite the concerns raised by opponents and advocates, the FDA eventually approved the Home Access HIV-1 Test System on July 22, 1996.¹⁹⁴ This home test kit is intended for anonymous, self-use HIV testing

186. See generally Salbu, *supra* note 172, at 417–26 (grouping these concerns into four categories).

187. Fabbri, *supra* note 178, at 422–23. Some AIDS activists reinforced this concern by referencing the obituary of a man who had jumped off of the Golden Gate Bridge after learning that he was HIV-positive. Wright & Katz, *supra* note 173, at 438.

188. Fabbri, *supra* note 178, at 423. One of the greatest issues raised concerning individuals who would possibly not receive adequate counseling was the fact that the user would have a lack of knowledge regarding the possibility of false positive results. *Id.*

189. See Salbu, *supra* note 172, at 421–23 (outlining and responding to arguments that in-person counseling is a necessary part of an effective HIV testing program).

190. *Id.* at 419–20.

191. *Id.* at 423–24.

192. Fabbri, *supra* note 178, at 424.

193. *Id.* This position was supported by evidence that a significant number of individuals who underwent HIV tests in a clinical setting did not return for their test results or counseling. *Id.* See also Barnard M. Branson, *Home Sample Collection Tests for HIV Infection*, 280 JAMA 1699, 1701 (1998). Following the approval of the HIV home test kits, researchers determined that 97% of users called for results, whereas the average return rate of individuals to clinical settings for results was 67% in 1996, with a 51% chance of return to sexually transmitted disease clinics. *Id.*

194. Letter from Dr. Jay S. Epstein, Director, Office of Blood Research and Review, Ctr. for Biological Evaluation and Research, U.S. Food & Drug Admin., to Michael Wandell, Home Access Health Corp. (July 22, 1996), available at <http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm091848.htm>; U.S. Food & Drug Admin., Home Access HIV-1 Test System

by adults.¹⁹⁵ The test kit requires that each user call a toll-free telephone number to register their unique eleven-digit code.¹⁹⁶ During this phone call, the user “is asked to provide basic demographic data, . . . a history of prior HIV antibody testing, knowledge of prior test results, expected result from the current test, and risk factors for HIV infection.”¹⁹⁷ After answering these questions, the user “listens to an automated, 5-minute educational session about the HIV-1 antibody test, HIV prevention, risk reduction behavior, and AIDS.”¹⁹⁸ This registration process is available to the test user at any time, 24 hours a day, seven days a week.¹⁹⁹ During this registration process, the user also has the option of speaking with a counselor or physician to discuss any questions or concerns.²⁰⁰

After collecting their own blood specimens, users ship their samples to the Home Access Lab.²⁰¹ Once the specimen reaches the lab, the blood sample is tested by “experienced technicians using the exact same test ordered by doctors’ offices, hospitals and clinics, ensuring greater than 99.9% accuracy.”²⁰² Users retrieve their test results by calling a toll-free number and providing their unique eleven-digit code.²⁰³ The company states that “[a]ll clients with indeterminate or positive results receive the test results directly from a counselor.”²⁰⁴ In addition, a predetermined

Summary of Safety and Effectiveness 1 (1996) [hereinafter Test System], available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm091849.pdf>. The FDA also approved another home HIV test manufactured by Direct Access Diagnostics in 1996, however the company withdrew its product from the market due to “lack of demand.” Branson, *supra* note 193, at 1699.

195. Test System, *supra* note 194, at 1. Each kit includes: an instruction manual, an HIV/AIDS educational booklet in English and Spanish, two safety lancets, an alcohol wipe, a sterile gauze pad, a bandage, a safety lancet disposal container, a blood spot collection card pre-coded with a unique eleven-digit number, a foil return pouch containing a desiccant, a shipping container, and a pre-addressed, prepaid return envelope. *Id.*

196. *Id.* at 2. The Direct Access Diagnostics test did not require a registration phone call and instead used a pamphlet included with the test kit to provide pre-test counseling information. Branson, *supra* note 193, at 1699.

197. Test System, *supra* note 194, at 2. Users are asked to provide their year of birth, sex, race, and zip code. *Id.*

198. *Id.*

199. *The Home Access® HIV-1 Test System*, HOME ACCESS HEALTH, http://www.homeaccess.com/HIV_RegisterStep1.asp (last visited Mar. 18, 2011).

200. *Id.*; Test System, *supra* note 194, at 2.

201. *The Home Access® Express HIV-1 Test How it Works*, HOME ACCESS HEALTH, http://www.homeaccess.com/ExpressHIV_How_Works.asp (last visited Mar. 18, 2011) [hereinafter *How it Works*]. The laboratory is FDA approved, CLIA certified, and accredited by the College of American Pathologists. *Id.*

202. *Id.*

203. Test System, *supra* note 194, at 2. Test results are available seven days after the user ships the specimen to the laboratory, unless the user purchases an “Express” test kit, in which case the results are available the next business day after shipping. *How it Works*, *supra* note 201.

204. Test System, *supra* note 194, at 3.

percentage of clients with negative results also receive test results from a counselor, while the remaining clients receive their negative test results from an interactive voice response system.²⁰⁵ All clients, regardless of their test results, are able to speak with counselors once their results become available.²⁰⁶

As a counselor provides results to the home test user, he or she also evaluates each test user's "coping skills, availability of personal support networks, and ability to inform sexual/needle-sharing partners" of the test results.²⁰⁷ Clients with positive results are referred to local physicians, clinics, and public health services in order to facilitate notification and treatment.²⁰⁸ Counselors may also provide referrals to the National AIDS Hotline and other psychosocial services.²⁰⁹

III. FILLING IN THE REGULATORY CRACKS

The current patchwork system of DTC genetic test regulation does not adequately protect consumers from potentially suspect genetic tests.²¹⁰ Although health is generally considered an area of state regulation,²¹¹ continuing to rely on individual state DTC genetic test regulation will create a further "patchwork of non-uniform requirements."²¹² Furthermore, since the majority of DTC genetic tests are offered to consumers through the Internet, the companies that offer these tests may be outside the jurisdiction of any one state, which may make state regulatory enforcement difficult.²¹³ A more effective and comprehensive federal regulatory scheme is necessary to ensure that genetic tests are appropriately used to improve individual health.²¹⁴

A. FDA

To improve the regulation of DTC genetic tests, the FDA should follow the precedent set by the agency's decisions about the requirements and regulation of home HIV test kits. The HIV home test is currently

205. *Id.*

206. *Id.* "Clients with negative results may speak with a counselor as often as three times in a 30 day period after their results become available. Clients with positive results may speak with a counselor 6 times over 12 months after their results become available." *Id.*

207. *Id.*

208. *Id.* at 3–4.

209. *Id.* at 4.

210. *See supra* text accompanying notes 11–15.

211. Javitt et al., *supra* note 30, at 273.

212. Javitt & Hudson, *supra* note 13, at 64.

213. *Id.*

214. *Id.* at 66.

regulated by the FDA as a Class III medical device.²¹⁵ Similar classification of DTC genetic tests as Class III medical devices, in contrast to the current regulation of genetic tests as either Class I or Class II medical devices,²¹⁶ would be an appropriate way to ensure “that the FDA subjects [DTC genetic] tests to sufficient oversight without unnecessary burden.”²¹⁷

Though only a small number of predictive medical tests are currently regulated as Class III medical devices, the FDA has previously determined that HIV tests must undergo increased medical device regulation due to the possibility of dramatic health-related decisions based on the HIV test results.²¹⁸ Genetic test results are used primarily for predictive purposes and have equally great implications for dramatic health-related decisions,²¹⁹ yet the FDA has limited regulation to certain tests and reagents.²²⁰ The FDA should acknowledge that the concerns currently being raised about the potentially dangerous use of DTC genetic test results are identical to the concerns raised in the 1990s about the use of HIV home test kits.²²¹ Concerns about an individual’s use of DTC genetic test results without appropriate counseling may be addressed by the FDA imposing a counseling requirement, similar to that applied to HIV home test kits, for any individual who wishes to receive his DTC genetic test results.²²² Following the HIV home test example, DTC genetic test companies should be required to provide consumers access to telephone counseling pre- and post-genetic testing.²²³ The availability and use of pre- and post-test telephone counseling will ensure that the individual consumers receive all of the information necessary to make informed health decisions based on their genetic test results.²²⁴

The availability of personalized telephone counseling may also help individuals who are interested in genetic testing but are concerned about the

215. Patsner, *supra* note 120, at 247.

216. *Id.*

217. Solberg, *supra* note 58, at 736.

218. Patsner, *supra* note 120, at 247. *See also supra* note 187.

219. *See supra* text accompanying note 41–45 and note 69.

220. Robertson, *supra* note 1, at 223.

221. *See discussion supra* Part II.A.

222. *See supra* text accompanying notes 199, 203–208.

223. At least one DTC genetic test company has acknowledged the need to provide consumers with greater counseling options. *23andMe Partner to Provide Genetic Counseling*, GENOMEWEB DAILY NEWS, June 7, 2010, <http://www.genomeweb.com/dxpgx/23andme-partner-provide-genetic-counseling>.

224. The use of specially trained counselors to provide the genetic test results to consumers over the phone may also address concerns that some physicians are insufficiently prepared to interpret what genetic results mean for a particular patient. *See Gniady, supra* note 42, at 2448.

confidentiality of their test results.²²⁵ The convenience and confidential nature of home genetic testing is likely to attract additional consumers.²²⁶ Additional FDA regulation of DTC genetic tests will ensure that the genetic tests provided to consumers who wish to avoid traditional health care settings provide valid and useful results. Even though widespread use of home genetic tests may be limited because the tests are home collection kits,²²⁷ eventually home genetic testing may become as commonplace and as accepted as home-use pregnancy testing.²²⁸

In order for home genetic testing to be utilized to its greatest potential, the FDA must clarify or eliminate the regulatory distinction between “home brew” genetic tests and genetic tests that contain components that travel in interstate commerce.²²⁹ This distinction and the 510(k) clearance process currently enable the majority of genetic tests to reach the consumer market without any evaluation for safety, effectiveness, or accuracy.²³⁰ Reclassifying DTC genetic tests as Class III medical devices would alleviate this problem because all Class III medical devices are subject to the most stringent regulations.²³¹ Furthermore, the classification of all DTC

225. See *supra* text accompanying notes 58–61. It is important to note that the information provided to DTC genetic test companies may not be covered under HIPAA regulations because it is unclear if DTC genetic test companies are considered health care providers. See Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996). In addition, GINA regulations may not apply unless the DTC genetic test company provides the consumer’s genetic information to an employer or insurer. See Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (to be codified in scattered sections of 26, 29, and 42 U.S.C.).

226. Solberg, *supra* note 58, at 714–15.

227. A home collection kit requires that the consumer collect a sample at home and send the specimen to a laboratory for analysis. Salbu, *supra* note 172, at 416 n.65. The consumer does not have the ability, equipment, or skill necessary to analyze or interpret the test results without the assistance of a laboratory technician. The HIV home test and DTC genetic tests are both considered home collection kits.

228. The traditional home pregnancy test is considered a home-use test kit because the consumer is able to collect the specimen and interpret the test in the comfort of her own home. Since 2006, one HIV test manufacturer has been seeking approval for an over-the-counter HIV home-use test kit that will utilize saliva instead of blood. Wright & Katz, *supra* note 173, at 437–39. This test “works like a home pregnancy test, except that it uses oral fluid instead of urine.” *Id.* at 437. This test technology is currently used in clinical settings but has not been approved for over-the-counter use. See *id.* at 439 (reporting use of the rapid tests in clinics).

229. See Novick, *supra* note 11, at 629.

230. Patsner, *supra* note 120, at 254. One could argue that genetic tests should not even be eligible for 510(k) clearance due to the complexity of the tests and the lack of a pre-1976 predicate device. However, this issue may soon be addressed because the FDA has recently released a plan to revamp the 510(k) submission process. Matt Jones, *UPDATE: FDA Plans Streamlining 510(k) Process in 2011*, GENOMEWEB DAILY NEWS, Jan. 20, 2011, <http://www.genomeweb.com/dxpgx/update-fda-plans-streamlining-510k-process-2011>.

231. See 21 U.S.C. § 360c(a) (2006) (setting out the requirements for all three classes of medical devices).

genetic tests as restricted Class III medical devices would subject these tests to stricter FDA labeling requirements.²³²

B. FTC

The current FDA regulatory scheme that separates “home brew” genetic tests from other DTC genetic tests limits the FTC’s ability to pursue claims against DTC genetic companies that use unfair or deceptive practices in their advertisements.²³³ The FDA’s different labeling requirements and regulations negatively impact the viability of any currently proposed FTC claim because there is no applicable standard to determine if a DTC genetic test advertisement is misleading.²³⁴ In order for the FTC to successfully pursue claims for deceptive acts and practices, the test company’s misrepresentation, omission, or practice must be material to the consumer’s decisions regarding the genetic test.²³⁵ Though claims and omissions related to health and safety are generally considered presumptively material,²³⁶ without a clear FDA standard, the FTC does not have an incentive to use its limited resources on claims that do not appear to be causing actual harm to a large number of people.²³⁷

More comprehensive and clearly defined FDA regulations will enable the FTC to better embrace its statutory role and protect consumers from misleading genetic test advertisements.²³⁸ The classification of DTC genetic tests as Class III medical devices will impose standard regulations for labeling²³⁹ and will allow the FTC to clearly determine which test advertisements are false or misleading.²⁴⁰ Furthermore, a more clearly defined standard will limit the success of any First Amendment protected speech claims.²⁴¹

232. See *FDA Oversight*, *supra* note 135 (explaining that the current FDA oversight of “medical device advertising is limited to a subset of medical devices.”).

233. See discussion *supra* Part I.B.2.

234. Javitt & Hudson, *supra* note 13, at 65.

235. FTC STATEMENT ON DECEPTION, *supra* note 140.

236. *Id.*; Javitt et al., *supra* note 30, at 283.

237. See Javitt et al., *supra* note 30, at 286 (explaining that the FTC has historically reserved its resources for cases where there is “a showing of concrete harm to consumers from the use of . . . products as a result of claims made in advertising.”).

238. See *supra* Part I.B.2.

239. See *FDA Oversight*, *supra* note 135.

240. Javitt & Hudson, *supra* note 13, at 65.

241. *Id.*

C. CLIA

To fully fill in the regulatory cracks, better coordination and harmonization is also needed between CMS, the FDA, and the FTC.²⁴² Although CLIA was enacted to ensure the analytical validity of laboratory tests,²⁴³ the current regulations have limited effect because they only address the validity of the testing process and not the validity of the individual tests.²⁴⁴ Furthermore, the current CLIA regulations fail to impose any obligation on the laboratories to explain to patients the meaning of their test results or the limitations of specific tests.²⁴⁵ Though individual genetic test validity may be best addressed by more comprehensive and clearly defined FDA regulations, under CLIA the determination of performance specifications for genetic tests that have not been cleared or approved by the FDA will help ensure the clinical validity of these tests, regardless of how the FDA classifies or regulates them.²⁴⁶ The determination of clinical validity may also improve potential FTC action because better quality control will lead to improved reports and will allow the FTC to more clearly determine which test claims are false or misleading.

The CDC should urge laboratories to apply and utilize the recently published recommendations for good practices for ensuring the quality of genetic testing. The implementation of proficiency testing for genetic tests can help laboratories “reduce analytic deficiencies, improve testing procedures, and take steps to prevent future errors.”²⁴⁷ Finally, the CDC should consider utilizing the Human Genome Epidemiology Network to establish more reliable estimates of validity based on genotype frequencies.²⁴⁸

242. See generally Letter from Todd E. Gillenwater, Vice President, Pub. Policy, Cal. Healthcare Inst., to U.S. Food & Drug Admin. (April 14, 2009), available at <http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480953351> (describing the different approaches and criteria currently considered under CLIA and by the FDA for ensuring test safety and effectiveness). In June 2010, CMS and the FDA signed a Memorandum of Understanding that acknowledged the need for greater collaboration between the two agencies. CTRS. FOR MEDICARE & MEDICAID SERVS. & U.S. FOOD & DRUG ADMIN., MOU 225-10-0010, MEMORANDUM OF UNDERSTANDING BETWEEN UNITED STATES FOOD AND DRUG ADMINISTRATION AND CENTERS FOR MEDICARE & MEDICAID SERVICES (2010), available at <http://www.fda.gov/aboutfda/partnershipscollaborations/memorandaofunderstandingmous/domesticicmous/ucm217585.htm>. The agencies “agree[d] to work together to promote initiatives related to the review and use of FDA-regulated . . . medical devices . . .” *Id.*

243. LABORATORY PRACTICES, *supra* note 2, at 3.

244. Robertston, *supra* note 1, at 222.

245. Javitt et al., *supra* note 30, at 271 (explaining that there are no regulations regarding what laboratories may say when promoting genetic tests.).

246. LABORATORY PRACTICES, *supra* note 2, at 12–14.

247. *Id.* at 5.

248. Holtzman, *supra* note 116, at 57. See also *supra* text accompanying note 164.

IV. CONCLUSION

The unique nature of genetic information and the predictive purpose of genetic test results distinguish genetic information and genetic testing from other health information and diagnostic tests.²⁴⁹ Although genetic testing is one of the fastest growing areas of laboratory testing,²⁵⁰ proper use of this technology may be limited by the current patchwork regulatory scheme.²⁵¹ The National Institutes of Health recently announced the creation of the Genetic Testing Registry (GTR), a public database that will provide increased access to information about the availability, validity, and usefulness of genetic tests to researchers, consumers, health care providers, and the public.²⁵² The GTR is intended to be a comprehensive resource that provides detailed information about genetic tests currently available to patients; however, the information included in the GTR will be provided voluntarily by the genetic test providers.²⁵³ Since the GTR is voluntary, it is uncertain if the genetic testing companies will participate and provide meaningful or useful information about their tests.²⁵⁴

Although the GTR is a step in the right direction,²⁵⁵ a better way to ensure that researchers, consumers, health care providers, and the public have access to accurate genetic tests that provide meaningful results is to fill in the current regulatory cracks. The FDA's experience with home HIV tests provides a viable path for implementing regulatory improvements.²⁵⁶ Revamped FDA regulations and improved coordination between the FDA, FTC, and CMS will help ensure the quality of all genetic tests and will provide patients and physicians with greater confidence in genetic testing.

249. Javitt et al., *supra* note 30, at 260.

250. LABORATORY PRACTICES, *supra* note 2, at 3.

251. Robertson, *supra* note 1, at 222.

252. Press Release, Nat'l Insts. of Health, NIH Announces Genetic Testing Registry (March 18, 2010), *available at* <http://www.nih.gov/news/health/mar2010/od-18.htm>.

253. *Id.*

254. The disclosure of some information may also be hampered by the NIH's expectation that the GTR will be used to "[f]acilitate genetic and genomic data-sharing for research and new scientific discoveries." *Id.*

255. Press Release, Genetics & Pub. Pol'y Ctr., Center Applauds NIH's Newly Announced Genetic Test Registry as an Important First Step (March 18, 2010), *available at* http://www.dnapolicy.org/news.release.php?action=detail&pressrelease_id=138.

256. *See* discussion *supra* Part III.A.