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Jennifer A. Gniady

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REGULATING DIRECT-TO-CONSUMER GENETIC TESTING: PROTECTING THE CONSUMER WITHOUT QUASHING A MEDICAL REVOLUTION

*Jennifer A. Gniady**

This Note examines the existing gaps in regulating genetic tests that are sold directly to consumers and the arguments for and against greater regulation. It advocates adopting an approach that shores up existing regulation of the accuracy of genetic tests under the Food and Drug Administration and Clinical Laboratory Improvement Amendment, while continuing to promote an open market for selling tests directly to consumers. The Note looks to a variety of additional mechanisms for providing further consumer protections such as incentives for voluntary participation in the Food and Drug Administration approval process, an expanded watchdog role for professional organizations, and education programs for consumers and physicians.

INTRODUCTION

Almost weekly, news reports announce that scientific studies have connected specific genes to the development of diseases or health conditions.¹ Imagine that the next time you hear about such a study you realize there is an easy way to find out if you have that particular gene. There would be no need to visit a doctor's office—simply perform a noninvasive test at home and send it off to a laboratory. Within weeks of sending away the sample, you receive the test results in the privacy of your home. This scenario is no longer far-fetched, and it is raising questions about the accuracy of such tests and their consequences for even the most educated of consumers.

* J.D. Candidate, 2009, Fordham University School of Law. I would like to thank Dr. David J. Goldberg. This Note also would not have been possible without the heroic support and unwavering encouragement of my husband, Russell Stoll, and the inspiration of my son, Timothy.

1. For example, a search of the LexisNexis database of "News, Most Recent 90 Days" turned up 148 news articles in the first week of February 2008 that referenced a disease or condition linked to a gene or identified by a genetic test. These articles variously described links between a particular gene and a specific disease, an increased risk for particular health conditions, or a propensity for certain medications to be more or less effective based on an individual's genome.

One person who might be presumed to understand the dilemmas behind this information is Dr. James D. Watson, the Nobel laureate scientist who, along with Francis Crick, discovered the structure of DNA.² In May 2007, Watson received a complete copy of his genome at the Baylor College of Medicine's Human Genome Sequencing Center courtesy of a company called 454 Life Sciences.³ Watson is making his genome publicly available for researchers with one exception: the single gene linked to Alzheimer's disease will not be made public because he does not want to know if he is predisposed to the disease.⁴

While Watson may be uniquely positioned to have access to high-quality genetic testing and to understand the implications of this information, the last decade has seen the development of direct-to-consumer genetic testing that promises similar access to the public.⁵ In the past few years, approximately two dozen companies have begun offering genetic tests directly to consumers for a cost of anywhere from one hundred dollars to nearly a thousand dollars.⁶

Some of these companies focus on diagnostic issues, such as letting consumers find out if they carry the gene for certain kinds of breast cancer or for diseases like Huntington's or Alzheimer's.⁷ Other companies provide broader access to genetic information, including complete profiles of an individual's genome, which can be searched and compared on an ongoing basis as new genetic links are discovered.⁸

On the surface, this might not seem much different from having any other medical test done, such as going to the doctor to find out if one's blood pressure or cholesterol is higher than it should be. However, two characteristics make these tests different from the medical tests that are routine today. First, the tests can be obtained and administered by the

2. DNA, the acronym for deoxyribonucleic acid, is a molecule found primarily in the nucleus of cells and used by living beings to convey the blueprint for building the materials needed for the body to grow and function. The presence (or absence) of specific sequences of the four nucleic acids that combine to create the double helix of the DNA molecule affect the genetic material encoded for the living being, including physical traits as well as the propensity for or resistance to specific diseases and conditions. James D. Watson & Francis H.C. Crick, *Genetical Implications of the Structure of Deoxyribonucleic Acid*, 171 *Nature* 964 (1953) (publishing Watson and Crick's original research on the process of genetic inheritance implicated by the structure of the DNA molecule).

3. See Nicholas Wade, *Genome of DNA Discoverer Is Deciphered*, *N.Y. Times*, June 1, 2007, at A19.

4. *Id.*

5. See Andrew Pollack, *The Wide, Wild World of Genetic Testing*, *N.Y. Times*, Sept. 12, 2006, at G4 (describing the "rapidly expanding, chaotic and largely unregulated" field of direct-to-consumer genetic testing).

6. *Id.*

7. See, e.g., Myriad Genetics, <http://www.myriad.com> (last visited Feb. 20, 2008) (offering an analysis of a genome for the presence of the BRCA gene associated with breast cancer, as well as genetic tests for hereditary melanoma and colorectal cancer).

8. See, e.g., 23andMe, <http://www.23andme.com> (last visited Feb. 20, 2008) (offering a web-based service with interactive tools designed to assist consumers in understanding their DNA).

consumer with no need for a doctor to either give the test or analyze the results.⁹ Second, the results received are generally not indicative of any specific diagnosis or condition, but more prospective in predicting the likelihood of a disease or condition occurring in that individual.¹⁰

In most scenarios, the results are even less useful than having a cholesterol-level reading taken, where there are a variety of options for treatment of dangerously high cholesterol levels, such as exercise, diet changes, prescription medicine, or even surgical intervention when necessary.¹¹ Many of the conditions linked to the genes being tested for at this time, such as Alzheimer's or Huntington's disease, are not curable and offer limited options for treatment.¹² Moreover, even for those conditions that have limited treatment available, such as breast cancer, where a combination of therapies are often successful in treating patients, there is little that can be done in the period between discovering the existence of the gene and the time when (if ever) the cancer associated with the gene manifests itself.¹³

However, the lack of available treatments does not prevent some consumers from taking serious steps based on the knowledge gained by their genetic tests. Women who find they have a gene related to breast cancer may opt for a preemptive strike against the disease by having an elective double mastectomy rather than go through years or decades of annual monitoring by mammograms to see if the cancer ever materializes.¹⁴ Parents preparing for the birth of a child routinely undergo basic genetic

9. See, e.g., *id.* (offering access to genetic tests that consumers can order directly from the company without a physician's order).

10. See Pollack, *supra* note 5 ("[S]ome tests 'lack scientific validity and others provide medical results that are meaningful only in the context of a full medical evaluation.' Even when the tests are valid, some genetics experts say, they are so complex that consumers need a doctor or even a genetic counselor to help them interpret the results." (quoting FTC, At-Home Genetic Tests: A Healthy Dose of Skepticism May Be the Best Prescription 1 (2006), available at <http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea02.pdf>)).

11. Nat'l Cholesterol Educ. Program, Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults: What You Need to Know (2002), <http://www.nhlbi.nih.gov/health/public/heart/cholesterol/wyntk.htm>.

12. *Researchers at Mayo Discover Cause of Defective DNA Repair*, Law & Health Wkly., Oct. 29, 2005, at 253, 253 (quoting Cynthia McMurray, Ph.D., Mayo Clinic molecular biologist, as stating that "[h]ereditary neurodegenerative diseases such as Huntington's disease have no cure and no effective therapy"); *Scientists Report First Blood Test to Diagnose Alzheimer's Disease*, Law & Health Wkly., Nov. 3, 2007, at 179, 179 (stating that there is no cure for Alzheimer's disease, which afflicts 4.5 million Americans).

13. Nat'l Cancer Inst., Breast Cancer Prevention, <http://www.cancer.gov/cancertopics/pdq/prevention/breast/patient> (last visited Feb. 29, 2008) (noting that there are studies investigating cancer prevention based on lifestyle changes and treating precancerous conditions, but that these steps "may lower your risk but [do] not mean that you will not get cancer").

14. See Barbara Isaacs, *More Women Choose Preventive Mastectomy After Finding a Genetic Link to Breast Cancer*, Sacramento Bee, Nov. 12, 2006, at L6; Jessica Queller, *Cancer and Gene Testing: The Dark Knowledge That Can Save Lives*, Int'l Herald Trib., Mar. 7, 2005, at 8 (describing a patient's decision on whether to have a double mastectomy after being diagnosed with a mutation in the BRCA gene).

testing and often more extensive testing for genetic conditions that are associated with their ethnic origins or are known to run in families.¹⁵ Based on these results, the parents may choose not to conceive a child on their own, to use donors for either egg or sperm to ensure the gene is not passed on, or to terminate an existing pregnancy where there is a high likelihood of the child being born with a genetic defect.¹⁶

Each of the decisions in the scenarios above involves the tremendous burden of weighing unknown outcomes with choices about health, lifestyle, and risk assessment. None of them is undertaken lightly, but it is a matter of debate whether consumers, or even doctors, have a solid understanding of what the probabilities mean in calculating genetic risks. Yet for a small and growing segment of the consumer population, these choices may be made on the basis of mail-order tests with results that are received directly by the consumer via e-mail or a web site.¹⁷ Whether consumers can rely on the results they receive or understand precisely what those results do (or do not) mean is a question that has been overlooked as regulatory policy lags behind the commercial genetic testing industry.¹⁸

Part I of this Note provides background on the rise of genetic testing as a regular part of medical care and as a growing area of consumer awareness driven by the health news media. Part I begins with an introduction to the origins of genetic tests, including the unique challenges presented by their regulation and the potential benefits that have prompted the rapid expansion of this area of medical testing. Part I also addresses the regulatory background against which genetic testing has been overseen during the past two decades, specifically the interrelationship between the Food and Drug Administration (FDA), Federal Trade Commission (FTC), and the Clinical Laboratory Improvement Amendment (CLIA) of 1988 in promulgating regulations that govern different aspects of genetic testing. Finally, Part I examines the development of direct-to-consumer genetic tests, the issues underlying consumer understanding of the test results, and the consumer protection problems in judging the accuracy and validity of genetic tests.

Part II of this Note examines the conflict over what steps should be taken to regulate genetic tests sold directly to consumers for at-home use. Part II highlights the available options ranging from banning all consumer access to direct genetic testing to allowing the industry to self-regulate. In particular, it identifies the proponents of more regulation and less regulation

15. See Dena S. Davis, Genetic Dilemmas: Reproductive Technology, Parental Choices, and Children's Futures 9-15 (2001).

16. See *id.*

17. See Pollack, *supra* note 5.

18. See Lori B. Andrews, Future Perfect 116 (2001) (noting that misinformation may result from negligent laboratory tests, doctors who lack knowledge about testing, or patients who have "erroneous impression[s]" about the significance of genetic testing results); Michael J. Malinowski & Maureen A. O'Rourke, *A False Start? The Impact of Federal Policy on the Genotechnology Industry*, 13 Yale J. on Reg. 163, 177-80 (1996) (identifying a time lag in regulatory policy relative to the development of the commercial genetic industry).

on direct-to-consumer genetic tests along with their salient rationales for supporting their positions. Part II also examines the possible effects of both positions on consumer access to health information and how this ultimately may influence consumer behavior.

Part III of this Note concludes that a middle ground is needed to strike the appropriate level of regulation in direct-to-consumer genetic testing. Part III proposes a level of regulation that extends some regulatory standards under existing agencies while still allowing substantial consumer freedom to choose direct-to-consumer genetic testing options. Part III points to this moderate level of regulation as the best approach to provide essential consumer protections without stifling the development of a valuable market segment of medical testing, which offers significant benefits to consumers. Additionally, it advocates for regulations that take into account medical standards for providing diagnoses based on genetic tests and suggests that there may be other ways to create incentives for companies that market the tests to comply with consumer protection measures and encourage them to facilitate consumer relationships with medical or genetic counseling professionals as part of the at-home testing process.

I. HISTORIC REGULATION OF GENETIC TESTING AND RECENT CHANGES IN THE AVAILABILITY OF GENETIC TESTS DIRECTLY TO CONSUMERS

This part of the Note discusses the historic regulation of genetic testing as it has developed over the past decades alongside more traditional medical diagnostic tests. This part outlines the forms of genetic tests and the traditional measurements used to gauge the accuracy and validity of such tests. Finally, this part examines the growing trend of biotechnology companies offering genetic testing directly to consumers and the obstacles to providing an appropriate level of regulation over these consumer tests.

A. *An Overview of Genetic Testing*

Genetic testing developed by building on more than a century of basic research that grew out of the early research conducted by Gregor Mendel in the 1860s to determine how characteristics were passed from one generation of pea plants to another.¹⁹ These remarkable results established the process of genetic inheritance through a combination of dominant and recessive traits and set out the basic concepts that underpin today's understanding of genetics.²⁰ In the late 1950s, the normal human complement of chromosomes was established by researchers, and in 1953, the double helix

19. See Thomas Goetz, *23AndMe Will Decode Your DNA for \$1,000. Welcome to the Age of Genomics*, *Wired*, Nov. 17, 2007, at 258, 263.

20. *Id.*

structure of DNA was put forward as the chemical basis for the heredity of the genes controlling the traits observed.²¹

Over time, the discovery of DNA led to tests designed to identify the presence of specific genes in the DNA of human chromosomes. Today, these genetic tests can be done directly on a tissue sample obtained from an individual, usually with minimally invasive techniques.²² Prenatal testing was one of the first areas to use these techniques to test for the presence of genes in an embryo or fetus using samples of either amniotic fluid or cells extracted from the placenta.²³ Both tests involve inserting a slender needle into the uterus to aspirate and remove a small quantity of cells from the fluid or placenta to be tested.²⁴ Genetic tests on adults have also developed alongside the prenatal tests for the purposes of predicting and diagnosing genetic conditions. In contrast to prenatal tests, typical predictive and diagnostic tests can be done by using far less invasive means to collect cell samples from an individual by using a swab of cells from the inside of the cheek or a pinprick of blood from the individual's finger.²⁵ This section highlights some of the specific challenges presented by the unique nature of genetic test results in light of the increased access to genetic testing for consumers and the potential benefits provided by the tests.

1. Unique Challenges of Genetic Tests

Modern genetic tests were defined by the National Human Genome Task Force on Genetic Testing established in 1995 as a joint program of the National Institutes of Health and the Department of Energy.²⁶ Its mission was spelled out in the announcement of the task force's formation, which stated, "Upon completing its evaluation, the Task Force will draft a final report containing policy options and recommendations for the clinical delivery of safe and effective genetic tests."²⁷ In undertaking its research, the task force defined genetic tests as

[t]he analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes,

21. Watson & Crick, *supra* note 2 (publishing the initial research of Watson and Crick, which set out the double helix structure and heredity relationships of the DNA molecule). For a firsthand account of the research and discovery process, see James D. Watson, *The Double Helix: A Personal Account of the Discovery of the Structure of DNA* (1968).

22. Susan L. Crockin et al., *Genetic Tests Are Testing the Law*, *Trial*, Oct. 2006, at 44, 44 (describing the genetic test analysis of chromosomal mutations that indicate genetic disorders based on samples taken from cheek swabs or blood cells).

23. *Id.*

24. Am. Coll. of Obstetricians & Gynecologists & Am. Coll. of Med. Genetics, *Preconception and Prenatal Carrier Screening for Cystic Fibrosis: Clinical and Laboratory Guidelines 1-32* (2001) (describing the process for obtaining samples of amniotic fluid and placenta for the genetic screening of fetuses for the genetic markers indicating the presence of cystic fibrosis).

25. Crockin et al., *supra* note 22, at 44.

26. See Nat'l Insts. of Health, *Task Force on Genetic Testing* (1995), <http://www.genome.gov/10001808>.

27. *Id.*

mutations, phenotypes or karyotypes for clinical purposes. Such purposes include predicting risk of disease, identifying carriers, and establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn, and carrier screening, as well as testing in high risk families, are included.²⁸

However, in its report, the task force did not set out to create or recommend policies for specific genetic tests, opting instead to create a framework for monitoring the safety and effectiveness of the tests.²⁹ Interestingly, the task force also identified “Consumer Involvement in Policy Making” as one of the overarching principles endorsed by the group.³⁰ Specifically, the task force stated, “Consumers should be involved in policy (but not necessarily in technical) decisions regarding the adoption, introduction, and use of new, predictive genetic tests.”³¹

In the final report, the task force highlighted three important points with respect to the majority of genetic testing results. First, no interventions are currently available to improve the outcome of most genetically linked diseases, creating a “therapeutic gap” between testing and treatment.³² Second, negative test results—the absence of a gene linked to a disease or condition—do not always rule out the possibility that an individual will develop that disease or condition.³³ False negative interpretations of such a test may occur because not all mutations of a single gene have been identified or because more than one gene contributes to the onset of the disease or condition.³⁴ And third, the positive presence of a gene detected by a test is not a guarantee that the disease or condition will occur in the individual at all.³⁵

The task force stated that, even where the disease does develop, the presence of the gene in testing does not indicate how severe its symptoms will be or how responsive to treatment those symptoms will be.³⁶ In technical terms, the “[g]enotype cannot necessarily predict phenotype for rare ‘single’ gene disorders.”³⁷ One example where this is true is the life-threatening nature of cystic fibrosis, which varies based on the severity of the disease’s effect on the lungs and cannot be predicted in advance.³⁸

28. Nat’l Insts. of Health, Promoting Safe and Effective Genetic Testing in the United States: Final Report of the Task Force on Genetic Testing 6 (1997), <http://www.genome.gov/10001733>.

29. *Id.* at 7–8.

30. *Id.* at 15.

31. *Id.*

32. *Id.* at 1–3.

33. *Id.* at 2–3.

34. *Id.*

35. *Id.*

36. *Id.*

37. Edward R.B. McCabe & Linda L. McCabe, *Genomic Medicine: A Future Flooded with Risk Information*, 8 *Minn. J. L. Sci. & Tech.* 429, 430 (2007).

38. Ada Hamosh & Mary Corey, *Cystic Fibrosis Genotype-Phenotype Consortium, Correlation Between Genotype and Phenotype in Patients with Cystic Fibrosis*, 329 *New Eng. J. Med.* 1308, 1311 (1993) (noting that the presence of the genotype for cystic fibrosis

2. Expansion and Benefits of Modern Genetic Tests

Despite these potential drawbacks, the benefits of genetic testing are not insubstantial. A positive result could allow an individual to make lifestyle changes that would be beneficial in the event the disease develops.³⁹ Positive results might also encourage closer monitoring and allow the individual to share that information with family members who are likely to have inherited the same susceptibility or to be carriers of the genetic mutation.⁴⁰ Negative test results provide peace of mind to some individuals, particularly those with a family history of a specific genetic disorder.⁴¹ Negative results also allow individuals to forego extensive monitoring, as in the case of those predisposed to cancer, and may assist them in purchasing health care and insurance at standard rates.⁴²

Today, more than 1000 genetic tests are available as clinical tests and hundreds more can be performed in a research laboratory setting.⁴³ These tests can be connected to approximately 200 different medical conditions.⁴⁴ This number does not even include the anecdotal observations of genes loosely linked to genetic traits that do not have any substantial impact on health, such as genes for detecting bitter tastes or lactose intolerance.⁴⁵

Despite their proliferation, the tests themselves are still not regulated by any government requirements mandating standards of effectiveness or safety.⁴⁶ Although this lack of regulation has developed organically, as discussed below, it is not likely to continue for long in light of growing public and business interest in developing more genetic tests.

B. Regulatory Oversight of Genetic Testing

Regulation of laboratory tests evolved out of the Food, Drug, and Cosmetic Act, which has been enforced primarily by the FDA.⁴⁷ The CLIA extended some additional regulation over testing processes.⁴⁸ However, neither of these regulatory mechanisms anticipated the advent of genetic testing or its availability directly to consumers outside of the traditional health care system. As a result, direct-to-consumer tests, along with most other genetic testing, falls into a gap in the regulatory structure that governs

is not indicative of the phenotype of the disease in a way that would allow for predicting whether the effects of the disease will be severe or mild in the given individual).

39. See Nat'l Insts. of Health, *supra* note 28, at 2-3.

40. See *id.*

41. See *id.*

42. See *id.*

43. See Denise Caruso, *Genetic Tests Offer Promise, but Raise Questions, Too*, N.Y. Times, Feb. 18, 2007, at C5.

44. Malinowski & O'Rourke, *supra* note 18, at 173.

45. See Amy Harmon, *My Genome, Myself: Seeking Clues in DNA*, N.Y. Times, Nov. 17, 2007, at A1.

46. See Caruso, *supra* note 43.

47. 21 U.S.C. §§ 301, 355(d), 360k(a) (2000).

48. 42 C.F.R. § 493 (2007).

medical procedures and treatments.⁴⁹ This section outlines the existing framework for regulating medical and laboratory testing through federal statutes and agencies. In particular, the section considers the aspects of genetic tests that are regulated under this framework, as well as those testing areas left unregulated.

1. Food, Drug, and Cosmetic Act

The majority of drugs and medical devices are regulated under the Food, Drug, and Cosmetic Act.⁵⁰ First passed in 1906, the initial law grew out of the government's interest in banning adulterated drugs and mediating debates about natural foods.⁵¹ When it was initially passed, the law's focus was on protecting the consumer from harm and deceitful marketing practices.⁵² The assumption of the law was that "the average man was prudent enough to plot his own course and would avoid risks if labeling made him aware of them."⁵³

Today's Food, Drug, and Cosmetic Act is based on the subsequent law passed in 1938, which included many provisions added to the original 1906 Act. This statute mandates that all new drugs be proved safe before marketing, makes therapeutic devices and cosmetics subject to regulation, and establishes standards of identity and quality that are required for foods.⁵⁴

As a federal regulation, the Food, Drug, and Cosmetic Act enjoys precedence over existing state laws under the doctrine of federal preemption established through the Supremacy Clause of the U.S. Constitution.⁵⁵ Although the statute does not contain an explicit statement of federal preemption, implied preemption exists where claims against approved products are brought in state courts, a position generally considered favorable to the product manufacturers who submit their products for FDA approval.⁵⁶

49. See Francis Fukuyama, *Our Posthuman Future: Consequences of the Biotechnology Revolution* 203 (2003).

50. 21 U.S.C. § 360k.

51. See James Harvey Young, *FDA, The Long Struggle for the 1906 Law*, *FDA Consumer*, Jan. 1981, <http://www.cfsan.fda.gov/~lrd/history2.html>.

52. See *id.*

53. See *id.*

54. FDA, *A Guide to Resources on the History of the Food and Drug Administration* (2002), <http://www.fda.gov/oc/history/resourceguide/background.html>.

55. U.S. Const. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme law of the land . . ."). See generally Viet D. Dinh, *Reassessing the Law of Preemption*, 88 *Geo. L.J.* 2085 (2000); Betsy J. Grey, *The New Federalism Jurisprudence and National Tort Reform*, 59 *Wash. & Lee L. Rev.* 475, 503–10 (2002).

56. See *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 867–68 (2000) (finding that the existence of an express provision is not exclusive in determining the scope of preemption and finding the implied preemption of claims based on the failure to include driver's side air bags).

Based on this statute, the FDA has a clear mandate to provide regulatory oversight for the marketing and use of drugs and devices for medical treatment to protect both the consumer's health and financial interests.⁵⁷ Devices are defined to include any "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."⁵⁸ The range of devices regulated covers everything from artificial hearts to at-home pregnancy tests.⁵⁹

However, under the Act, regulation of human biotechnology has lagged behind other areas, such as agricultural biotechnology, despite the fact that the existing regulatory system remains applicable to newly developing biotechnologies.⁶⁰ As a result, genetic tests lack the level of regulation consumers might normally expect from other drugs and devices they encounter on the market.

2. Food and Drug Administration Regulations

Currently, the FDA regulates the production of reagents and test kits manufactured and sold for others to use to perform testing.⁶¹ Thus, FDA regulation of genetic tests turns on whether a laboratory is using its own reagents and protocols, also known as using home brew tests, or whether the test uses a "kit" that is manufactured and sold to clinics or laboratories that perform the test.⁶²

Genetic tests performed using a kit are regulated by the FDA as "in vitro diagnostic devices" (IVDs).⁶³ Common IVDs are tests used to diagnose the presence of HIV in an individual or to detect pregnancy.⁶⁴ Kit tests subject to FDA review make up only about one percent of the more than 1100 genetic tests commercially available today.⁶⁵

As a result of the division in testing classifications, manufacturers and private laboratories have so far been able to avoid the routine FDA review process for diagnostic tests and compliance with applicable federal

57. 21 U.S.C. §§ 355, 360k (2000).

58. *Id.* § 321(h)(2).

59. See Ctr. for Devices & Radiological Health Consumer Info., What Is a Medical Device or Radiation Emitting Product?, <http://www.fda.gov/cdrh/consumer/product.html#1> (last visited Feb. 20, 2008).

60. 21 U.S.C. § 321.

61. See Medical Device Amendments (MDA) of 1976, 21 U.S.C. § 360k (2000).

62. See Genetics & Pub. Policy Ctr., Who Regulates Genetic Tests? 2 (2006), http://www.dnapolicy.org/policy.issue.php?action=detail&issuebrief_id=10; *infra* notes 83–88 and accompanying text.

63. See *id.*

64. See *id.*

65. See *id.*

regulations. They do this by manufacturing and using their own reagents in-house and selling these home brew testing services.⁶⁶

The FDA, in response to the actions taken by biotechnology companies, such as IVF, Myriad, and OncorMed, offering direct-to-consumer tests, has proposed regulations to bring genetic testing services more directly within its purview.⁶⁷ This represents an expansion of its historical stance limiting regulation largely to holding suppliers of active ingredients to good manufacturing standards, which require FDA reporting of all adverse events possibly attributable to products.⁶⁸

As part of the effort to extend its ability to regulate genetic tests, the FDA's Center for Devices and Radiological Health held a public meeting on February 8, 2007, to discuss guidelines to regulate a type of test, called in-vitro diagnostic multivariate index assays, for both safety and effectiveness.⁶⁹ These tests measure multiple genes or proteins taken from a patient and then analyze the information using an algorithm or software program.⁷⁰ In singling out these tests for further regulation, the agency officials focused on the fact that such algorithms are proprietary and can make it more difficult for doctors to evaluate and interpret the results of the genetic analysis.⁷¹

However, the meeting was far from a clear-cut victory for the agency, with representatives from many test manufacturers in attendance to denounce the draft guidelines circulated by the FDA.⁷² Most complained that the proposed guidelines were confusing, and several also held the position that the agency lacked legal authority to regulate the tests under the "devices" arm of the agency.⁷³

3. Clinical Laboratory Improvement Amendment of 1988 Regulations

Regulation of laboratory tests is also provided by the CLIA.⁷⁴ The CLIA governs all laboratories that perform tests designed to provide information about a person's health.⁷⁵ These regulations, set down by the Centers for

66. See Medical Devices; Classification/Reclassification; Restricted Devices; Analyte Specific Reagents, 61 Fed. Reg. 10,484 (proposed Mar. 14, 1996) (codified at 21 C.F.R. pts. 809, 864) ("FDA currently regulates the safety and effectiveness of diagnostic tests that are traditionally manufactured and commercially marketed as finished products. However, in-house developed tests have not been actively regulated by the Agency and the ingredients used in them generally are not produced under FDA assured manufacturing quality control."); see also *infra* notes 84–86 and accompanying text.

67. See Caruso, *supra* note 43.

68. Andrew Pollack, *F.D.A. Seeks to Regulate New Types of Diagnostic Tests*, N.Y. Times, Sept. 6, 2006, at C4.

69. See FDA, Public Meeting: In Vitro Diagnostic Multivariate Index Assays 3–11 (2007).

70. See Pollack, *supra* note 68.

71. *Id.*

72. See Caruso, *supra* note 43.

73. See *id.*

74. 42 C.F.R. § 493 (2007).

75. Genetics & Pub. Policy Ctr., *supra* note 62.

Disease Control under the Department of Health and Human Services, govern protocols and reagents used in genetic tests by laboratories providing clinical testing services.⁷⁶ The regulations also extend to qualifications for laboratory personnel and quality control procedures.⁷⁷ These regulatory requirements vary depending on the tests performed, with increasingly strict requirements correlating to the complexity of the tests being analyzed.⁷⁸ While the CLIA regulates the laboratory components of some genetic tests, it does not address any regulations specifically to genetic testing as a separate specialty.⁷⁹ The result is that under the CLIA there is no requirement for genetic tests to meet specific standards for accuracy, reliability, or clinical validity.⁸⁰

C. Genetic Testing Moves from the Laboratory to the Home

The combination of regulations by the FDA and CLIA may have appeared sufficient while genetic testing was still in its infancy. This is particularly true in light of the FDA's traditional reliance on the medical profession both to review new products and to set the standard of care in cases of liability where genetic tests inevitably led to the growth of related genetic malpractice suits.⁸¹ However, this patchwork of regulations and industry pressure may no longer provide enough coverage to address concerns about direct-to-consumer genetic tests adequately.⁸² This section provides background on the classification of genetic tests and the methods of measuring the reliability of their results, as well as the consumer-protection concerns raised by the growth of the direct-to-consumer genetic testing market.

76. See *id.*; see also Laura Sternesky, *Oversight of Genetic Testing*, Genetics Brief, Jan. 2002, available at <http://www.ncsl.org/programs/health/genetics/Oversight.pdf>.

77. See Genetics & Pub. Policy Ctr., *supra* note 62.

78. See *id.*

79. See *id.* (noting that the Clinical Laboratory Improvement Amendment (CLIA) of 1988 maintains specific requirements for cytology and microbiology laboratories). The Department of Health and Human Services has proposed to recognize genetic testing as a specialty, but no regulations have been implemented. See Notice of Intent; Genetic Testing Under the Clinical Laboratory Improvement Amendments, 65 Fed. Reg. 25,928-02 (May 4, 2000).

80. See Genetics & Pub. Policy Ctr., *supra* note 62.

81. See, e.g., Elaine A. Lisko, *Genetic Malpractice Claims Raise Legal and Ethical Issues*, Health L. Persp., Nov. 23, 1998, <http://www.law.uh.edu/healthlaw/perspectives/Genetics/981123Malpractice.html>; Claudia MacLachlan, *Spine-Tingling Dispute: Bone Screw Suit Places FDA in 4-Way Squeeze*, Nat'l L.J., Jan. 8, 1996, at A1 (describing *In re Orthopedic Bone Screw Products Liability Litigation*, 79 F.3d 46 (7th Cir. 1996), where plaintiffs in a product liability case alleged that the FDA approved the defective device because it relied in part on medical reports from doctors who stood to profit from the device).

82. See Pollack, *supra* note 5 (describing criticism of the reliability of genetic tests and inquiries by Congress into the regulation of the tests).

1. Types of Genetic Testing Available

Genetic testing can take several different forms. With respect to the regulation of genetic tests, or any laboratory tests, the regulatory agencies divide the tests into two types.⁸³ The first type includes those tests that are done in a laboratory using the laboratory's own reagents and protocols for examining the genetic makeup of a sample.⁸⁴ These are generally referred to as "home brew" tests.⁸⁵ This type is subject to very limited regulation, such as the quality of the reagents used in the test, as well as any CLIA regulations associated with the laboratory itself.⁸⁶ The second type of test is a "kit" test, which involves a manufacturer supplying a prepackaged test that can be performed outside of the laboratory by a physician or other health professional.⁸⁷ Due to the manufactured nature of kit tests, the FDA is able to exercise greater authority over these tests. However, kit tests remain an extreme minority among all genetic tests available today.⁸⁸

Regardless of the format of the genetic tests and the method of their manufacture and use, these tests can also be classified by the type of results they provide to individuals. As a result, the available genetic tests fall into general categories described as predictive, diagnostic, and prenatal, each of which may be carried out as part of regular patient testing or prenatal testing.⁸⁹ Currently, the primary focus of at-home tests is on nonprenatal predictive and diagnostic tests, which can usually be done using minimally invasive procedures, such as a cheek swab or pinprick blood test.⁹⁰

Predictive testing determines the "probability that a healthy individual with or without a family history of a certain disease might develop that disease."⁹¹ In contrast, tests used for diagnostic purposes will most likely be conducted as part of a clinical evaluation to diagnose a specific disease that has already manifested itself.⁹² While the diagnostic tests may or may

83. Genetics & Pub. Policy Ctr., *supra* note 62.

84. *Id.*

85. Nat'l Insts. of Health, Sec'y's Comm. on Genetic Testing, *Enhancing the Oversight of Genetic Tests: Recommendations of the SACGT 10* (2000); *see also supra* text accompanying note 66.

86. *See supra* Part I.B.3.

87. Genetics & Pub. Policy Ctr., *supra* note 62; *see also supra* text accompanying notes 63–65.

88. Genetics & Pub. Policy Ctr., *supra* note 62 (stating that of more than 900 genetic tests only a dozen fall under the FDA review for test kits).

89. Pilar N. Ossorio, *Product Liability for Predictive Genetic Tests*, 41 *Jurimetric: J.* 239, 242 (2001) (describing three categories of genetic tests: predictive, diagnostic, and prenatal); *see also* Univ. Hosp., *Ethics of Genetic Testing*, <http://www.theuniversityhospital.com/adultgenetics/ethics.htm> (last visited Feb. 14, 2008).

90. *See* Crockin et al., *supra* note 22.

91. Notice of Meeting and Request for Public Comments on Preliminary Final Recommendations on Oversight of Genetic Testing, 65 *Fed. Reg.* 21,094, 21,096–97 (Apr. 19, 2000). By definition, this category would appear to cover not just isolated tests for specific gene mutations, but also the results of complete genotypes being marketed to consumers.

92. *Id.*

not be subject to greater regulation depending on whether the test is a kit or home brew type as discussed previously, these tests are at least more likely to involve a physician or genetic counselor in the course of administering and interpreting the results of the test.⁹³

The third type of testing, prenatal testing, has probably received even more attention than the other types of testing. At this time, however, the majority of prenatal testing remains substantially more invasive than nonprenatal predictive and diagnostic tests.⁹⁴ Prenatal tests are not entirely excluded from this Note's general discussion, though, since some companies have begun making inroads into prenatal testing by relying on trace fetal cellular material present in the maternal blood supply.⁹⁵ The discovery of the limited reliability of these results makes for an illustrative example of the stakes involved in the test results.⁹⁶ However, since these tests are less common at this time, they remain largely outside the scope of this Note.

2. Common Measurements of Valid Genetic Tests

With regard to direct-to-consumer or at-home tests, there is no uniform system in place to evaluate the tests before they are offered to consumers.⁹⁷ Like their laboratory-based counterparts, though, they require at least two basic measurements to determine the validity of the tests.⁹⁸

The first measurement is the analytical validity, which evaluates how consistently the test successfully predicts the presence or absence of a specific gene or gene mutation.⁹⁹ In genetic testing, an analytically valid test would be positive when the particular gene mutation is present (based on the test's analytical sensitivity, or the limit of a substance that can be detected by an assay) and negative when the gene mutation is absent (based on the test's analytical specificity, or freedom from other substances interfering with detection of the target of the test).¹⁰⁰ In other words, the analytical validity indicates the probability that the test's positive or negative result will correlate with the gene sequence being targeted by the test.¹⁰¹ Although a determination of analytical validity must be made

93. See *supra* notes 83–88 and accompanying text.

94. See *supra* Part I.A (concerning methods of obtaining cell samples for DNA analysis).

95. See Consumer Genetics—The Pink or Blue Company, Am I Having a Boy or a Girl? The Science Behind Gender Testing..., http://www.tellmepinkorblue.com/science_behind_it.php (last visited Feb. 18, 2008).

96. See, e.g., Baby Gender Investigation Home Page, <http://www.babygenderinvestigation.com/> (last visited Feb. 18, 2008) (describing a class action lawsuit against Acu-Gen Biolabs for inaccurate gender determination results based on maternal blood samples filed in Massachusetts).

97. See Genetics & Pub. Policy Ctr., *supra* note 62.

98. *Id.*

99. *Id.*

100. See Nat'l Insts. of Health, *supra* note 85, at 15.

101. Nat'l Insts. of Health, *supra* note 28, at 25.

before the test is offered in a clinical setting, the analytical validity standard is based only on a comparison to the most definitive “gold standard” test on the market.¹⁰² In cases where a test has not existed before, as in the case of early genetic tests for specific types of cancer, the “gold standard” is merely the first test, whether or not this test actually shows a high level of analytical validity.¹⁰³

The second measure, clinical validity, measures whether the test correctly correlates with the presence, absence, or increased risk of a specific disease.¹⁰⁴ This validity measurement involves multiple factors, including the correlation between positive or negative results and the presence or absence of the predicted genetic disorder.¹⁰⁵ Clinical validity also includes the probability measurement for whether a person with the gene detected will eventually develop the condition or disease linked to that gene.¹⁰⁶ Newer genetic tests’ clinical validity will depend on the quality of the clinical data on which it is based and the algorithms used to compute the test result.¹⁰⁷

3. Development and Marketing of Genetic Tests for Consumers

The need for consumer protections and additional regulation of genetic tests marketed directly to consumers has become apparent over the last two years as an influx of companies cater to the market for at-home genetic testing.¹⁰⁸ The problems cited however are not new. For example, more than a decade ago there were concerns regarding earlier commercial genetic tests, such as those for breast cancer and AIDS, due to the fact that health care providers were largely dependent on commercial and academic laboratories to provide them with an understanding of the results of genetic tests.¹⁰⁹ As such, it was suggested then that neither consumers nor their health care providers were in a position to evaluate the genetic testing technology.¹¹⁰

The sudden growth of direct-to-consumer genetic tests makes these concerns prominent once more. The direct-to-consumer movement of

102. *Id.*

103. *Id.*

104. *Id.* at 26.

105. *Id.*

106. *Id.*

107. See Sec’y’s Advisory Comm. on Genetic Testing, Notice of Meeting, 65 Fed. Reg. 21,094, 21,102–03 (Dep’t of Health and Human Servs. Apr. 18, 2000) (announcing notice of meeting and requesting public comments).

108. Andrew Pollack, *A Genetic Test That Very Few Need, Marketed to the Masses*, N.Y. Times, Sept. 11, 2007, at C3.

109. Michael J. Malinowski & Robin J.R. Blatt, *Commercialization of Genetic Testing Services: The FDA, Market Forces, and Biological Tarot Cards*, 71 Tul. L. Rev. 1211, 1245–46 (1997).

110. *Id.* (addressing prenatal multiplex testing and stating that, “until this informational asymmetry between providers/patients and biotechnology companies is decreased through the compilation of clinical data and education, heavy reliance upon market forces like consumer and provider demand is misplaced”).

genetic testing began with advertising genetic tests to consumers, in much the same way prescription drugs are advertised in newspapers, magazines, and television advertisements.¹¹¹ While objections to such direct advertising focus on the influence of intense marketing campaigns to persuade consumers to purchase these tests without regard to their necessity and effectiveness, these objections appear, at this time, to be unavailing given the apparent success in deregulating drug advertisements in general, as well as in light of commercial free speech trends.¹¹²

However, new concerns associated with the direct-to-consumer approach have resurfaced in part because of the ease with which these new genetic tests are performed and the results distributed. Each test costs from a few hundred dollars up to several thousand dollars.¹¹³ In addition to testing for the presence of specific genes, companies such as Consumer Genetics offer evaluative tests such as paternity testing and tests that purport to tell consumers how their genes affect responses to substances such as caffeine, wine, or specific medications.¹¹⁴

Most of these tests allow consumers to use a cheek swab to collect the sample cells needed for genetic testing and send the kit to the company for analysis.¹¹⁵ Based on these samples, consumers can find out if they carry the genetic markers for conditions such as cystic fibrosis, diabetes, blood clotting disorders, breast cancer, or colon cancer.¹¹⁶ Three recent arrivals in the market also plan to provide consumers with comprehensive genotypes, essentially a complete and searchable record of the individual's genome.¹¹⁷ The results are delivered directly to consumers via e-mail or by having individuals log on to a web site.¹¹⁸ It is precisely this unmediated access to potentially jarring health revelations that creates the most concern over direct-to-consumer genetic tests.

D. Existing Issues in Regulating Direct-to-Consumer Genetic Testing

Many of the tests currently being made available directly to consumers may be unproven or unnecessary according to testimony at a July 2006

111. See Pollack, *supra* note 108.

112. See *infra* Part I.D.2 (discussing commercial free speech limitations on FTC regulation of advertising to prohibit false or misleading statements).

113. See *id.*

114. See, e.g., Consumer Genetics, <http://www.consumergenetics.com/index.php> (last visited Feb. 18, 2008).

115. See, e.g., Consumer Genetics, Caffeine Test: How Does the Test Work?, http://www.consumergenetics.com/ct_test_procedures.php (last visited Feb. 29, 2008).

116. See, e.g., DNA Direct, http://www.dnadirect.com/patients/tests/test_pricing.jsp (last visited Feb. 18, 2008).

117. Harmon, *supra* note 45 (describing companies that have started to provide or are in the planning stages of providing services to test consumers' DNA, including 23andMe, decode Genetics, and Navigenics).

118. See, e.g., 23andMe, How the Process Works, <https://www.23andme.com/ourservice/process/> (last visited Feb. 18, 2008) (describing the consumer ability to log into a web site to receive and review the results of comprehensive genetic profiling through a "personal genome account").

Senate hearing on at-home DNA testing.¹¹⁹ The hearing was the result of an earlier investigation by the Government Accountability Office into direct-to-consumer genetic testing, which found that test kits purchased over the Internet misled consumers by making unproven predictions about health conditions and representing the information as diagnoses.¹²⁰ The majority of these tests involved claims by dietary supplement companies that touted “personalized” nutrition recommendations based on an individual’s genetic profile.¹²¹ Scientists at research universities have, in fact, begun studying the relationship between genetics and diet, but the results are far from conclusive at this point with the FDA and Centers for Disease Control stating that there is an absence of scientific proof that such tests can be used to make nutritional choices in a safe and effective way.¹²² Although the concerns regarding these tests encompass some of the broader issues with direct-to-consumer testing, it should also be noted that such customized genetic-based prescriptions are not that far-fetched. For example, in the summer of 2007, the FDA approved the first genetic test designed to target the correct drug dosage of a blood thinner for individual patients.¹²³ However, despite the possibility of such personalized genetic profiles in the near future, current tests claiming to provide such information to consumers present a risk of misleading consumers with respect to the results obtained and their potential for valid medical uses. This section identifies some of the issues faced by consumers in determining the accuracy of and implications for the results of genetic tests when the tests are not interpreted by health care professionals. The section then looks at the limits of consumer protections applied to these tests and explores analogies to earlier direct-to-consumer medical tests.

1. Accuracy and Consumer Understanding of Genetic Tests Results

In order for consumers to make an informed decision about using genetic tests, there must be some assessment of the tests’ benefits and risks.¹²⁴ Presumably, before a genetic test is created, there must be a scientifically valid (i.e., peer-reviewed) study that links the genetic markers being tested

119. See Pollack, *supra* note 5 (describing the remarks of Senator Gordon H. Smith, who compared the genetic tests to “modern-day snake oil”).

120. GAO, *Nutrigenetic Testing: Tests Purchased from Four Web Sites Mislead Consumers 7–19* (2006), available at <http://www.gao.gov/new.items/d06977t.pdf>.

121. *Id.*

122. For an in-depth discussion of the marketing of dietary advice based on genetic profiles and the government investigations into companies specializing in this area, see Laura Hercher, *Diet Advice from DNA?*, *Scientific Am.*, Dec. 2007, at 84, 89. See also FTC, *At-Home Genetic Tests: A Healthy Dose of Skepticism May Be the Best Prescription* (2006), available at <http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea02.pdf>; Am. Soc’y of Human Genetics, *Statement on Direct-to-Consumer Testing in the United States*, 81 *Am. J. Hum. Genetics* 635, 635–37 (2007).

123. See Hercher, *supra* note 122, at 89.

124. Nat’l Insts. of Health, *supra* note 28, at 12.

with the occurrence of a disease.¹²⁵ The accuracy of the test itself is then defined by two separate components.¹²⁶ The first component is the validity of the test.¹²⁷ As discussed previously, the validity of the test is further broken down into two parts based on its clinical validity and analytical validity.¹²⁸ The second component of a laboratory test's accuracy is the analysis and interpretation of the results generated by the test.¹²⁹ This section looks at both the validity and utility of genetic tests provided directly to consumers, as well as the potential for errors in understanding these tests where the role of professional genetic counselors is eliminated.

a. *Difficulty of Ascertaining the Clinical Utility of Genetic Test Results*

Assuming a test is considered valid under both the analytical and clinical standards, there remain two aspects of accuracy in test results that relate to the usefulness of the tests—the clinical utility of the test and the accurate analysis of the test results. A test's clinical utility will determine how readily it will be accepted in clinical practice.¹³⁰ Typically, the clinical utility is thought of in terms of the benefits and risks associated with the test.¹³¹ Unlike most tests, though, genetic tests are unique in that the risk in having the test done is small but the tangible medical benefit may be remote, such as where an individual receives test results indicating a condition for which treatments and therapies have not yet been developed.¹³² However, even during this “therapeutic gap” there are thought to be benefits to testing that are related to monitoring opportunities, providing information to family members, or providing peace of mind to the individual.¹³³ As with other medical tests, the clinical utility of genetic tests is expected to increase as more information is gained about the connection between genes, their disorders, and potential therapies.¹³⁴

b. *Problems in Assuring the Accurate Analysis of Genetic Test Results*

Obtaining an accurate analysis of the results of genetic tests depends first on the quality assurance in place where the DNA samples are analyzed. Early commentators on the policy implications of widespread genetic testing claimed that it is more difficult to maintain the quality of genetic tests than other medical tests.¹³⁵ Additionally, because most genetic testing

125. *Id.* at 23–25.

126. *Id.*

127. *Id.*

128. *See supra* Part I.C.2.

129. Nat'l Insts. of Health, *supra* note 28, at 28.

130. *Id.*

131. *Id.*

132. *See Andrews, supra* note 18, at 5–7.

133. *Id.* at 35–37.

134. Nat'l Insts. of Health, *supra* note 28, at 23–25.

135. *See Inst. of Med., Assessing Genetic Risks: Implications for Health and Social Policy* 127 (Lori B. Andrews et al. eds., 1994).

results are negative, meaning nothing out of the ordinary is found, the vigilance of laboratory personnel might be less than the level of scrutiny normally exercised where test results vary more often between positive and negative outcomes.¹³⁶ Another concern about direct-to-consumer tests is that the results no longer come from a local laboratory that is affiliated with a network of physicians and health care professionals in the community. Instead, the tests may be performed in specialized laboratories far from where the sample is collected and analyzed as part of a high-volume centralized business, thereby increasing the risk of mix-ups between samples.¹³⁷

One recent example of the impact that inaccurate test results may have was brought to light when a test called BabyGenderMentor failed to deliver on its promise to determine the sex of a fetus as early as five weeks into a pregnancy.¹³⁸ The test was supposed to measure genetic cellular material from the mother's blood to determine the gender of the fetus.¹³⁹ As a result of the test's inaccuracy, a class action suit has been filed on behalf of more than 100 consumers who received inaccurate test results.¹⁴⁰ At this time, it is unclear whether the source of the alleged errors was that the tests were truly invalid or that the testing process was not closely monitored to ensure the correct results were sent to consumers.¹⁴¹ However, while the public complaints regarding the alleged mistakes are most often associated with the surprise at having been told the expected child was the "wrong" gender, other allegations have extended to include "advice" from the company that the fetuses had chromosomal abnormalities.¹⁴² Unlike the comparatively harmless error of having chosen incorrectly between pink and blue for a nursery and clothing for a baby, a more serious concern is presented where parents may choose to terminate a pregnancy based on gender or genetic information that is inaccurate.

136. *See id.* at 117.

137. *See id.* at 133.

138. *See* Carey Goldberg, *Gender Test's Accuracy Is Questioned*, Boston Globe, Oct. 17, 2005, at C1; *Morning Edition: Critics Question Accuracy of Fetus Sex Test* (NPR broadcast Sept. 29, 2005), available at <http://www.npr.org/templates/story/story.php?storyId=4867895>.

139. Goldberg, *supra* note 138.

140. First Amended Complaint and Jury Demand, *Blumer v. Acu-Gen Biolabs, Inc.*, No. 06 CA 10359 RCL (D. Mass. Mar. 27, 2006). Additional information about the lawsuit, including class member complaints posted to describe their experiences and results with the test, is available at Baby Gender Investigation Home Page, <http://www.babygenderinvestigation.com/> (last visited Feb. 29, 2008).

141. Goldberg, *supra* note 138 (noting that the technique used by the company to determine the gender of the fetus was not published or reviewed but was based on research that had been published in peer-reviewed scientific journals and offering other explanations for the discrepancies).

142. *See* First Amended Complaint and Jury Demand, *supra* note 140, at 45–47.

c. *Errors in Interpretation and Comprehension of Test Results*

Notwithstanding the potential for human error introduced into the tests, the issue of physician and consumer understanding of the results goes even deeper. Although many new genes and links to genetic disorders are identified each month and can be isolated by clinical diagnostic tests, physicians are often insufficiently prepared to interpret what the results mean for patients.¹⁴³ In a survey of accurate interpretations of genetic diagnoses, out of nearly 2000 primary care physicians the average respondent had a correct response rate of only seventy-four percent.¹⁴⁴ Another study showed that one-third of physicians surveyed interpreted the results of genetic testing for colorectal cancer erroneously.¹⁴⁵ The issue has continued to be such an ongoing concern that in 2004 the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) drafted a resolution on genetics training for health care professionals.¹⁴⁶ Among the issues cited by the committee were concerns that "insufficient education and training in genetics and genomics has led, and may continue to lead, to inaccurate or delayed disease diagnoses, misguided disease management, inadequate family planning counseling, an exacerbation of health disparities, and unnecessary costs."¹⁴⁷ The resolution proposed tasks that included sweeping efforts ranging from education programs for students spanning elementary to undergraduate levels, greater integration of genetics professionals in the public health sector, and required continuing education of health care professionals.¹⁴⁸

Even when such genetic tests are accurately explained, there is evidence that patient-consumers are unable to understand the explanations of the test results and lack an understanding of both the risks of developing specific diseases and the role that environmental factors play.¹⁴⁹ For example, a recent advertising campaign by Myriad Genetics urges women to consider being tested for mutations in genes called BRCA1 and BRCA2.¹⁵⁰ While the campaign focuses on fears about breast cancer, critics question whether

143. Lori B. Andrews, *A Conceptual Framework for Genetic Policy: Comparing the Medical, Public Health, and Fundamental Rights Models*, 79 Wash. U. L.Q. 221, 252–53 (2001) (describing the measures of physician error in interpreting genetic tests and detailing one study in which one-third of physicians erroneously interpreted the results of a genetic test for colon cancer).

144. *Id.* at 253.

145. Francis M. Giardiello et al., *The Use and Interpretation of Commercial APC Gene Testing for Familial Adenomatous Polyposis*, 336 New Eng. J. Med. 823, 824–25 (1997).

146. Nat'l Insts. of Health, Resolution of the Secretary's Advisory Committee on Genetics, Health, and Society on Genetics Training and Education of Health Professionals (2004), *available at* <http://www4.od.nih.gov/oba/SACGHS/reports/EducationResolutionJune04.pdf>.

147. *Id.*

148. *Id.*

149. Bailey Kuklin, *Probability Misestimates in Medical Care*, 59 Ark. L. Rev. 527, 546 (2006) (describing how a patient's misunderstanding of accurately explained genetic test results in terms of probability affects tort liability under the doctrine of informed consent).

150. See Pollack, *supra* note 108.

the test's cost—in excess of \$3000—is justified when only five to ten percent of all breast cancer cases are a result of mutations in these genes.¹⁵¹ The test has been described as “moderately accurate” but is recommended only for those women in high-risk groups, such as those having a strong family history of breast cancer.¹⁵² In fact, women in low-risk categories are more likely to receive inaccurate test results.¹⁵³

The Myriad test is primarily available through licensed physicians, and consumers are urged to contact their doctors about it.¹⁵⁴ This allows doctors to screen out low-risk candidates as long as the doctors feel comfortable refusing a patient's request for the test.¹⁵⁵ However, a similar test is also available to consumers directly from DNA Direct that has no gate-keeper physician barrier to prevent low-risk candidates from having the test and receiving potentially erroneous results about their susceptibility to breast cancer.¹⁵⁶

d. *Lack of Opportunities for Professional Genetic Counseling with Direct-to-Consumer Genetic Test Results*

As the previous example makes clear, the concerns about direct-to-consumer genetic testing may be correctly focused on the high-stakes decisions people make based on the results of these tests. While patients in a doctor's office will likely receive some counseling regarding the results of their tests, at-home tests may bring undesirable results directly to the consumer in the absence of advice from anyone knowledgeable about the meaning of the results or possible courses of action.¹⁵⁷

At DNA Direct, a pretest consultation is required only for tests for the breast cancer gene and infertility screening.¹⁵⁸ While pretest consultation for other tests is recommended, the site offers an “order now” option that

151. *Id.*

152. Michael Wilkes, *Inside Medicine: Breast Cancer Test Isn't for Everyone*, Sacramento Bee, Oct. 27, 2007, at K10 (objecting to Myriad's advertising as “predatory” and “misleading” and describing a woman with no family history or risk factors for breast cancer who requested the BRCA tests).

153. *Id.*

154. See Pollack, *supra* note 108.

155. *Id.*

156. See Adam J. Wolfberg, *Genes on the Web—Direct-to-Consumer Marketing of Genetic Testing*, 355 *New Eng. J. Med.* 543, 544 (2006) (noting that “[i]f you visited the DNA Direct Web site in mid-July 2006 and indicated that you were interested in testing . . . but reported no personal, family, or ethnic risk factors . . . the Web site would advise that full-sequence BRCA testing was the most appropriate, at a cost of \$3,456”); see, e.g., DNA Direct, <http://www.dnadirect.com> (last visited Feb. 18, 2008) (providing a service where consumers interested in genetic testing fill out an online form to select the tests to be performed and requiring a pretest consultation with a genetic counselor, but not with a physician, for breast and ovarian cancer tests).

157. Victoria Colliver, *Home DNA Tests: When You Just Have to Know*, S.F. Chron., Aug. 21, 2007, at C1.

158. See DNADirect, Order a Test, http://www.dnadirect.com/patients/testing_services/ordering.jsp (last visited Feb. 18, 2008).

foregoes pretest counseling.¹⁵⁹ In addition, the results of all tests are unmediated and returned to the consumer through the DNA Direct web site.¹⁶⁰ Although another telephone counseling session is available after the results are reported, it is unclear how many consumers take advantage of this opportunity.¹⁶¹ Other direct-to-consumer genetic testing companies offer even more limited opportunities for consumers to have a genetics professional assist with determining if the tests are necessary and interpreting the results. At LabSafe, consumers visit a CLIA-certified laboratory to have blood drawn and receive written test results.¹⁶² However, they are not referred by physicians for the tests and receive no genetic counseling unless they are willing to pay seventy-five dollars for a staff physician to provide a fifteen-minute consultation regarding the results of the test.¹⁶³

Geneticists and medical professionals maintain that even the limited counseling available from the companies is insufficient since the company providing the counseling has an interest in selling more tests.¹⁶⁴ Medical ethicists are also concerned about how consumers will act on the information, as in cases where women seek abortions based on the gender of an unborn child.¹⁶⁵ Where the error rate for some at-home genetic tests is high, the tests may also cause undue distress similar to that claimed in the ongoing lawsuit against Acu-Gen Biolab for providing inaccurate results to more than 100 women across the country regarding the gender of their babies.¹⁶⁶ These cases do not even begin to consider the extremes to which individuals may go upon learning about their genetic makeup if that information is not fully understood. A woman falsely diagnosed with a high-risk of breast cancer may undertake extreme surgical steps—such as undergoing a double mastectomy—under erroneous pretenses.¹⁶⁷ Or an individual given a diagnosis of Alzheimer's or Huntington's, who, as a result, expects to have a shortened lifespan or limited ability to enjoy a

159. *Id.*

160. *Id.*

161. See Wolfberg, *supra* note 156, at 544.

162. LabSafe, Why Direct Lab Testing?, <http://www.labsafe.com/why> (last visited Feb. 18, 2008).

163. See Wolfberg, *supra* note 156, at 544; see also LabSafe, How the LabSafe Process Works, <http://www.labsafe.com/how> (last visited Mar. 20, 2008). As of publication, this web site had removed references to fees for additional genetic counseling and instead suggests that consumers contact their doctors to discuss test results. *Id.* It was unclear whether the additional fee-based counseling remained available to those who purchased tests from the company.

164. Wolfberg, *supra* note 156, at 544.

165. Colliver, *supra* note 157.

166. First Amended Complaint and Jury Demand, *supra* note 140 (listing more than 100 plaintiffs in the class action suit complaint against Acu-Gen Biolabs, Inc.); Carey Goldberg & Shelley Murphy, *Lowell Firm Is Sued on Fetal Gender Test*, Boston Globe, Mar. 1, 2006, at B3 (describing the anxiety created by inaccurate test results).

167. This result is not unforeseen given that this step has been taken by those who have received an accurate diagnosis of genetic predisposition toward breast cancer. See, e.g., Anne Underwood, *When "Knowledge" Does Damage*, Newsweek, Apr. 10, 2000, at 62, 62.

particular quality of life in old age, may make lifestyle choices that are riskier or more shortsighted than if the individual otherwise expected to have a normal life span.¹⁶⁸

2. Limits of Consumer Protection Under Existing Regulatory Bodies

Despite the existence of multiple assessment criteria and more than a few concerns about the uses of direct-to-consumer genetic tests, no federal or state entity regulates genetic tests offered directly to consumers.¹⁶⁹ The FDA appears to be the most logical place for regulatory oversight to rest,¹⁷⁰ but the agency has shown hesitancy to regulate genetic testing generally without a clear mandate that such consumer products fall under its jurisdiction.¹⁷¹ Likewise, the CLIA remains limited to regulating the laboratories where tests are performed, but exerts no authority over who develops the tests or how they reach consumers in the health care system.¹⁷² As shown in the case of direct laboratory companies like LabSafe, even the use of CLIA laboratories does not fully address consumer-oriented fears that individuals will misunderstand the results of genetic tests or incorrectly assign risks and benefits to the analyses they receive.¹⁷³ Calls for greater regulatory control over all genetic tests, not just direct-to-consumer services, frequently identify the FDA and CLIA as joint forces to be united to create a more stringent regulatory regime.¹⁷⁴

In addition to the formal regulatory bodies for drugs, devices, and laboratory tests, a number of specialized groups within the government have been involved in advising on genetic testing over the past decades, and although they do not have any direct regulatory authority, they have taken positions on direct-to-consumer genetic tests. One of the earliest such committees was the Secretary's Advisory Committee on Genetic Testing (SACGT), which was formed by the secretary of the Department of Health and Human Services in June 1998. Its purpose was "to advise the Department of Health and Human Services . . . on the medical, scientific, ethical, legal, and social issues raised by the development and use of genetic tests."¹⁷⁵ SACGT worked on establishing criteria that could be used to

168. See Andrews, *supra* note 18, at 36 (describing an individual with a fifty percent chance of having the gene for Huntington's disease who, prior to being diagnosed as not having the gene, took up skydiving, assumed large amounts of debt, and terminated long-term relationships under the assumption that he would have an early death).

169. See Caruso, *supra* note 43.

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

171. See, e.g., Anny Huang, *FDA Regulation of Genetic Testing: Institutional Reluctance and Public Guardianship*, 53 Food & Drug L.J. 555, 570–72 (1998) (detailing the history of the FDA forays into regulation of testing and their general lack of positive experiences and enthusiasm in regulating genetic tests).

172. See *supra* Part I.B.3.

173. See *supra* notes 162–63 and accompanying text.

174. See, e.g., Douglas A. Grimm, *FDA, CLIA, or a "Reasonable Combination of Both": Toward Increased Regulatory Oversight of Genetic Testing*, 41 U.S.F. L. Rev. 107 (2006).

175. See Nat'l Insts. of Health, *supra* note 85, at 1.

assess genetic testing and identifying methods of monitoring genetic testing.¹⁷⁶

SACGHS has since replaced SACGT and is mandated to “advise the Secretary of Health and Human Services . . . on policy issues raised by the development and use of genetic technologies and their integration into clinical and public health practice.”¹⁷⁷ This new committee aims to “address the broader implications resulting from the development and application of genetic technologies.”¹⁷⁸ In particular, the committee examines the overarching issue of gaps in adequate oversight of genetic testing programs that could harm the public’s health.¹⁷⁹ The most recent result of the committee’s work is a draft report on the current system of oversight for genetic testing, which was open for public comments through late December 2007.¹⁸⁰ The draft marks the committee’s progress toward “development of a comprehensive map of the steps needed” to oversee genetic tests to improve the overall quality of health.¹⁸¹

The overarching recommendation of the committee in the November 2007 report was for “the [Health and Human Services] Secretary [to] take steps to enhance interagency coordination of the activities associated with the oversight of genetic testing, including policy and resource development, education, regulation, and knowledge generation.”¹⁸² Though the report and recommendations will not be finalized until sometime in 2008, the majority of the recommendations address requiring increased regulation of the validity of genetic tests through increased funding and cross-agency relationships.¹⁸³ The report also calls for a public-private partnership to register genetic tests available to the public.¹⁸⁴ The committee further suggests that Health and Human Services should “step up its efforts” to encourage collaborations between agencies, states, and consumer groups to consider additional measures to protect consumers from potential harm from direct-to-consumer genetic tests.¹⁸⁵

Some additional regulation of these tests exists indirectly where advertising of genetic tests falls under the FTC regulatory authority.¹⁸⁶ However, the extent of the FTC’s regulatory authority extends only to prohibiting false or misleading advertising, making it a limited avenue for

176. *Id.*

177. Sec’y’s Advisory Comm. on Genetics, Health, & Soc’y, U.S. System of Oversight of Genetic Testing 2 (Draft Report, 2007) [hereinafter SACGHS Draft Report].

178. Suzanne M. Cox et al., *International Genetic Testing*, Genetics in Medicine, May–June 2003, at 176, 176–78.

179. SACGHS Draft Report, *supra* note 177, at 2.

180. *Id.*

181. *Id.* at 12.

182. *Id.* at 17.

183. *See id.* at 17–20.

184. *Id.* at 19.

185. *Id.* at 23.

186. Nat’l Genome Research Inst., Overview of Genetic Testing, <http://www.genome.gov/10002335> (last visited Feb. 29, 2008).

accomplishing widespread protection of consumers.¹⁸⁷ The FTC has played a similar enforcement role supporting FDA regulations in other areas, such as dietary supplements.¹⁸⁸ In those cases, the FTC focused on dietary supplements that made false claims or failed to carry the appropriate disclaimer.¹⁸⁹ The disclaimer required by the FDA for products making claims that have not been cleared by the agency states, “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”¹⁹⁰ Products that fail to comply with the disclaimer requirement may become targets of FTC enforcement actions. By requiring the disclaimer for claims that have not been cleared by the FDA approval process, the combined FDA and FTC regulatory roles provide one mechanism for ensuring that consumers have accurate information regarding claims made by product manufacturers who choose not to undergo the FDA approval process for their products.

3. Similar Areas of Direct-to-Consumer Medical Testing

While direct-to-consumer genetic testing is unique in many respects, it is hardly the first at-home test the regulatory agencies have had to confront. During the 1970s, consumers and physicians saw the invention of at-home pregnancy tests, which were largely endorsed by most physicians and paved the way for educational campaigns on the importance of early prenatal health care.¹⁹¹ Though not genetic tests but detectors of human chorionic gonadotropin—a hormone produced in the bodies of pregnant women—these tests were designed to meet all of the requirements of the FDA Medical Devices Act.¹⁹²

In contrast, during the late 1980s, the FDA banned similar home testing kits for HIV, a decision that was widely criticized.¹⁹³ However, the ban

187. See Gayle 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, 282–87 (2004) (describing First Amendment commercial free speech limitations on FTC regulations that prohibit advertising that deceives customers and discussing the lack of authority for the FTC to determine whether there is some benefit to consumers from receiving certain information).

188. See Paula Kurtzweil, *An FDA Guide to Dietary Supplements*, FDA Consumer, Sept.–Oct. 1998, http://www.fda.gov/FDAC/features/1998/598_guid.html (as revised in Jan. 1999).

189. *Id.*

190. Regulations on Statements Made for Dietary Supplements, 65 Fed. Reg. 1000–01 (Jan. 6, 2000) (to be codified at 21 C.F.R. pt. 101); *see also* 21 U.S.C. § 343; Food Labeling, 62 Fed. Reg. 49,826 (Sept. 23, 1997) (codified at 21 C.F.R. pt. 101); FDA, Food Labeling & Nutrition—Dietary Supplements Label Claims: Structure/Function Claims, <http://www.cfsan.fda.gov/~dms/labstruc.html> (last visited Feb. 14, 2008).

191. Office of NIH History, *A Thin Blue Line: A History of the Pregnancy Test Timeline*, <http://history.nih.gov/exhibits/thinblueline/timeline.html> (last visited Feb. 18, 2008).

192. *Id.*

193. See Warren E. Leary, *Government Panel Hears Call for Expanded AIDS Testing*, N.Y. Times, June 23, 1994, at A18; Judy Mann, *In the Privacy of Your Own Home*, Wash.

was supported by AIDS advocates who feared that tests sold directly to consumers would create the potential for “widespread suicides, panic and a rush to public health clinics” by consumers who discovered they were HIV-positive.¹⁹⁴ As a result, the FDA delayed approval of the at-home tests for nearly nine years, reversing its ban in 1995 and approving the first test the following year.¹⁹⁵ Subsequent test kits were permitted by federal drug officials with the caveat that they include counseling and professional support.¹⁹⁶ In 2005, the FDA announced it would consider a new rapid at-home AIDS test, and in 2006, the test entered studies in order to obtain FDA approval.¹⁹⁷

Despite these breakthroughs in at-home testing, in the mid-1990s the FDA also attempted to adopt a similar ban on home drug-testing kits and as a result drew attacks for attempting to limit consumer access to information.¹⁹⁸ One commentator summed up the problem of FDA bans on direct-to-consumer tests by saying, “While physicians, scientists, consumer advocates and other thoughtful individuals repeatedly declare that some screening for validity should be undertaken, the general public may still question attempts to limit their access to information, however uncertain the information may be.”¹⁹⁹

It is apparent from the preceding discussion that the existing regulations are imperfectly applied to encompass the majority of genetic tests. In particular, tests offered directly to consumers are largely unregulated. The ability to regulate these tests is limited by the current scope of regulatory authority available to create and enforce standards for these tests despite the potentially life-altering information they provide. As a result, several different schemes for regulating direct-to-consumer genetic tests have been put forth by various interest groups. The various proposals are discussed further in Part II of this Note with an emphasis on identifying those groups supporting each proposal and the potential effects on both the producers and consumers of direct-to-consumer genetic tests.

Post, Apr. 22, 1994, at E3; Elliott J. Millenson, *AIDS Tests: Do It Yourself?: FDA's No-Home-Testing Policy Is Endangering Everyone*, Wash. Post, Aug. 27, 1989, at C5.

194. Gardiner Harris, *F.D.A. to Weigh At-Home Testing for AIDS Virus*, N.Y. Times, Oct. 13, 2005, at A1.

195. See Laurie Garrett, *Panel Asks OK on Home AIDS Test*, Newsday, June 23, 1994, at A7; Press Release, Dep't of Health & Human Servs., FDA Approves First HIV Home Test System (May 16, 1996), available at <http://www.hhs.gov/news/press/1996pres/960514.html> (“Until now, all HIV tests, whether using blood or saliva samples, were done under the supervision of a health professional at medical facilities, clinics, physicians’ offices or blood establishments. The new testing system is comprised of three integrated components: an over-the-counter home blood collection kit, HIV-1 antibody testing at a certified lab, and a test result center that provides test results, counseling and referral anonymously.”).

196. Harris, *supra* note 194.

197. *Id.*

198. See Daniel J. Murphy, *FDA Ridiculed for Blocking At-Home Drug Testing*, Investors Bus. Daily, Oct. 1, 1994, at A4.

199. Huang, *supra* note 171, at 572 (citation omitted).

II. PROPOSALS FOR THE REGULATION OF DIRECT-TO-CONSUMER GENETIC TESTS

Part II of this Note examines the conflict over what steps should be taken to regulate genetic tests sold directly to consumers for at-home use. It draws on congressional legislative efforts and hearing testimony on the issue, statements by genetic test manufacturers, and comparisons of case law relating to genetic malpractice (where doctors fail to use appropriate tests or incorrectly analyze genetic test reports) and product liability cases (where similar drug and diagnostic tools are involved). These sources highlight the range of opinions on the matter—from banning all consumer access to direct genetic testing to allowing the industry to self-regulate. Part II also includes an evaluation of the proposed solutions with respect to their ability to balance consumer protection with consumer access to information.

A. *Advocacy for Greater Regulation of Genetic Tests Sold Directly to Consumers*

Commentary on genetic testing within both the legal and health professional communities appears to emphasize the need for greater regulation of genetic tests.²⁰⁰ However, even among those who advocate stricter standards of test quality and direct consumer access, there is no clear agreement on what the parameters of such restrictions would look like. This section examines greater regulation of direct-to-consumer genetic tests, including the proponents of this view and the rationales of their arguments. It also looks at the effect of greater regulation on both consumers and the growing genetic testing industry.

1. Proponents of and Rationales Behind the Push for More Regulation

SACGT was among the first groups to propose prohibiting direct consumer access to genetic tests; it recommended a prohibition on all promotion or advertising of such tests directly to patients or consumers as a way of eliminating potential risks in providing critical and easily misunderstood health information in the absence of professional guidance.²⁰¹ Although this prohibition is not explicitly supported by the newer SACGHS draft report, which declines to call for a complete ban on the tests, the initial proposal retains some weight within the debate on

200. See generally Gail H. Javitt & Kathy Hudson, *Federal Neglect: Regulation of Genetic Testing*, Issues Sci. & Tech., Spring 2006, at 59, 63–66, available at http://www.dnapolicy.org/resources/Issues_in_Science_and_Technology.pdf; Michael J. Malinowski, *Separating Predictive Genetic Testing from Snake Oil: Regulation, Liabilities, and Lost Opportunities*, 41 *Jurimetrics J.* 23 (2000); Malinowski & O'Rourke, *supra* note 18, at 238–46.

201. Nat'l Insts. of Health, *supra* note 85, at 31–32 (recommending a ban on the promotion and advertising of genetic tests to consumers, but acknowledging that an alternative would be to permit promotion and advertising while continuing to enforce regulations against false or deceptive claims).

consumer access to genetic tests.²⁰² In fact, the SACGT's position was later joined by the American Medical Association (AMA), which officially discourages direct-to-consumer genetic tests based on the organization's fears that nonphysicians will begin encroaching on the practice of medicine reserved for its constituent members.²⁰³ The AMA even recommends that states ban direct consumer access to tests, as states such as New Jersey, New York, and Rhode Island already have.²⁰⁴ As of June 2007, a study by the Johns Hopkins University Genetics and Public Policy Center found that thirteen states had statutes banning genetic tests from being sold directly to consumers.²⁰⁵ Twelve additional states had imposed limitations on such tests, some of which were minor restrictions while others essentially created de facto bans on the tests.²⁰⁶

A ban on the tests could also be of interest to the insurance industry, which has a vested interest in obtaining equal access to consumer health information as a means of evaluating the risk and setting pricing for specific health and life insurance policies.²⁰⁷ Consumers could have genetic tests performed privately and then use the results to add or drop specific forms of insurance linked to genetic conditions.²⁰⁸ The result feared is that consumers without genetic risks will opt out of the insurance market.²⁰⁹

202. SACGHS Draft Report, *supra* note 177, at 137.

203. Direct-to-Consumer Genetic Testing, House of Delegates Resolution 502, A-04 (AMA, 2004); *see also* Diagnosis of Disease and Diagnostic Interpretation of Tests Constituting Practice of Medicine to Be Performed by or Under the Supervision of Licensed Physicians, House of Delegates Resolution 904, I-06 (AMA, 2006).

204. Jennifer Alsever et al., *The Patient Knows Best*, Business 2.0, Nov. 9, 2006, http://money.cnn.com/magazines/business2/business2_archive/2006/10/01/8387104/index.htm.

205. Genetics & Pub. Policy Ctr., Johns Hopkins Univ., Survey of Direct-to-Consumer Test Statutes and Regulations (2007), *available at* <http://www.dnapolicy.org/resources/DTCStateLawChart.pdf> (presenting the results of a nationwide survey of state law concerning access to direct-to-consumer genetic tests and noting that thirteen states banned such tests outright while twelve additional states imposed various restrictions on the availability of such tests to their residents); *see, e.g.*, Ga. Code Ann. § 31-22-4(a), (c) (2006); Mich. Comp. Laws § 333.17001(1)(f) (2001); Tenn. Code Ann. § 68-29-121 (2006); Wyo. Stat. Ann. § 33-34-108 (2007).

206. Genetics & Pub. Policy Ctr., *supra* note 204 (citing a range of limitations, including the requirement that companies notify consumers that they should contact their physicians and the restrictions that only licensed physicians may order tests and/or obtain test results); *see, e.g.*, Ariz. Rev. Stat. Ann. §§ 36-470 to 36-479 (2006); Cal. Bus. & Prof. Code §§ 1241, 1246.5 (West 2003); Fla. Stat. Ann. § 483.181 (West 2006); 210 Ill. Comp. Stat. Ann. 25/7-101 (West 2000); Md. Code Ann., Health-Gen. § 17-202.1 (LexisNexis 2004); Mass. Ann. Laws ch. 111D, §§ 4, 8 (LexisNexis 2005); Nev. Rev. Stat. Ann. § 652.190 (LexisNexis 2004).

207. Colin S. Diver & Jane Maslow Cohen, *Point/Counterpoint: Genophobia: What Is Wrong with Genetic Discrimination?*, 149 U. Pa. L. Rev. 1439, 1443-44 (2001) (describing "genetic testing's dark side" and identifying one example of genetic discrimination as the use of certain genetic information by health insurance companies to assign insurance applicants to appropriate risk classifications).

208. *Do Not Ask or Do Not Answer?*, Economist, Aug. 25, 2007, at 69, 69-71 (considering the possibility of a looming crisis in the insurance industry regarding personal medical health information).

209. Diver & Cohen, *supra* note 207, at 1443-44.

The insurance companies would then be forced to rely on consumers to make good faith disclosures of information linked to genetic risks when the companies issue new policies or custom policies. This concern of companies represents the mirror image of consumer fears that insurance companies will require genetic testing for the purposes of excluding them from coverage for the very diseases or conditions to which they are most susceptible.²¹⁰ A ban on offering genetic tests directly to consumers would go a long way toward preventing this risk from becoming widespread and possibly even putting an end to the risk-based insurance industry itself.²¹¹ As a result, it would be a natural position for the insurance industry to oppose direct-to-consumer genetic tests even as legislative efforts seek to impose limits on the industry's ability to incorporate genetic information in a discriminatory manner.²¹²

a. *Regulating Genetic Tests in Line with Other Medical Diagnostic Tests*

Advocates supporting greater regulation of genetic testing services emphasize the differences between genetic tests and more traditional diagnostic tools.²¹³ Such differences are thought to include the lack of valid tests, inadequate physician understanding and ability to communicate the results of the tests, and consumer susceptibility to media hype about the connections between genes and diseases or conditions.²¹⁴ The result of these combined factors is to encourage both overreliance by consumers on negative test results and overtreatment for consumers who have positive test results.²¹⁵ There is also the possibility that those who have such tests may open themselves up to discrimination based on their genetic characteristics since the regulations governing health information privacy may be only loosely observed by companies that do not have connections to the traditional health care community.²¹⁶

210. E.K. Clemons et al., *Information Technology and Information Asymmetry: The Future of Private Individual Health Insurance*, 3 *Sys. Sci.* 240 (1997); Amy Harmon, *Insurance Fears Lead Many to Shun or Hide DNA Tests*, *N.Y. Times*, Feb. 24, 2008, at A1 (describing patients who are concerned about losing their health insurance and who undergo genetic testing but do not disclose their results, which indicate existing medical conditions, even to their physicians).

211. *Do Not Ask or Do Not Answer?*, *supra* note 208.

212. *See* Diver & Cohen, *supra* note 207, at 1443–44.

213. *See, e.g.*, Malinowski & Blatt, *supra* note 109, at 28.

214. *Id.* at 35–39.

215. These concerns originated more than a decade ago at the time of the initial breast cancer genetic testing. *See, e.g.*, David Plotkin, *Good News and Bad News About Breast Cancer*, *Atlantic Monthly*, June 1996, at 53, 53–55 (speculating that a proliferation of methods for testing for breast cancer may have caused overtreatment, such as unnecessary mastectomies, while doing little to affect the disease's mortality rate); Meredith Wadman, *Women Need Not Apply*, *Wash. Post*, May 5, 1996, at C3 (“Scientists argue that testing in non-research settings is fraught with peril. Negative test results, they say, could lull women into a false sense of security, when in truth 90 to 95 percent of breast and ovarian cancers aren't inherited but occur spontaneously.”).

216. *See* Malinowski & Blatt, *supra* note 109, at 1284.

b. *Promoting Regulation of Genetic Tests for Business Development Reasons*

Advocates also see potential benefits to business interests in creating additional regulation in the genetic testing market.²¹⁷ Primarily, they claim that the industry as a whole may be harmed by a few unscrupulous companies whose actions damage the reputation of legitimate genetic testing providers.²¹⁸ “There is no way for a consumer to distinguish between the dubious and the decent,” says Kathy Hudson, director of the nonprofit Genetics and Public Policy Center in Washington, D.C.²¹⁹

Regulatory recommendations by legislative and executive committees tasked with studying the matter frequently call for mandatory oversight by the FDA and encourage heightened scrutiny of product promotion in advertisements by the FTC²²⁰ to provide incentives for the industry to offer higher quality products and more accurate results.²²¹ A related option is to delegate some amount of regulation to professional associations, such as the American College of Medical Genetics or the American Society of Human Genetics.²²² Independent organizations such as these are thought to provide the benefit of being able to act more quickly based on input from practitioners in the field of genetic testing, counseling, and treatment without being subject to the forces of changing political administrations.²²³

c. *Preserving Tort Liability Remedies by Regulating Genetic Tests*

Finally, proponents of restrictions on direct-to-consumer tests point out that the role of the physician or genetic practitioner may be an important one in the overall policy of compensating for torts related to inaccurate test results.²²⁴ For physicians and health care professionals in genetics, this

217. See Alsever et al., *supra* note 204.

218. See *id.*

219. *Id.*

220. See, e.g., FTC, *supra* note 122.

221. Robert Pear, *Growth of Genetic Tests Concerns Federal Panel*, N.Y. Times, Jan. 18, 2008, at A12.

222. See Grimm, *supra* note 174, at 128 (detailing the number of professional organizations involved with genetic testing, including the Association of Public Health Laboratories, the American College of Medical Genetics, the College of American Pathologists, the National Committee on Clinical Laboratory Standards, the Commission on Office Laboratory Accreditation, the American Society of Human Genetics, the National Advisory Council for Human Genome Research, and the Working Group on Ethical, Legal, and Social Implications of the Human Genome Project).

223. *Id.*

224. See Ossorio, *supra* note 89, at 258 (“The traditional rule for prescription medical products is that the manufacturer discharges its duty to warn or instruct the ultimate user (the patient) by supplying information to physicians. The justification for this ‘learned intermediary rule’ is that prescribing physicians who are properly informed of the potential harms, benefits, and side-effects will use their expert medical judgment to weigh these factors and determine the best product for the patient. Because physicians were perceived as the gatekeepers, they were seen as the appropriate target of warnings and instructions. Also,

liability is incurred through the tort doctrine of the learned intermediary.²²⁵ Under direct-to-consumer sales of genetic tests, there are mixed opinions as to whether the liability remains attached to the learned intermediary doctrine or accrues to the manufacturer of the test.²²⁶

Historically, examples of liability are frequently found when a physician fails to inform parents of genetic testing results and later a child is born with a condition that could have been avoided if the parents had access to the information from the test results obtained during a previous pregnancy.²²⁷ The fact that the diagnosis of the first child is tied to an inheritable trait creates novel issues that are not normally found in diagnoses that are merely curable infections.²²⁸ Here, the medical professional is thought to have not only the duty of beneficence, but also to face ethical decisions regarding the information's confidentiality and potential for disclosure.²²⁹

For instance, in *Didato v. Strehler*, the defendants had a duty to convey the results of the screening tests performed on the daughter of parents who carried the gene for sickle cell anemia.²³⁰ Even though the parents were not the patients, the court found that they pleaded sufficient facts to allow a reasonable jury to find a duty to report the results to them, which would have alerted the plaintiffs to the possibility that a subsequent child could have the disease.²³¹ The court found that the plaintiffs could survive summary judgment even if they were unable to establish that the standard of care required that a reasonably prudent pediatrician communicate certain information to them.²³²

Without a physician ordering or analyzing the results of the genetic tests, the plaintiffs in that case would likely have been left without a means of

they were seen as the appropriate person to convey this information to the patient comprehensibly.”).

225. *See id.*

226. *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1257 (N.J. 1999) (“Prescription drug manufacturers that market their products directly to consumers should be subject to claims by consumers if their advertising fails to provide an adequate warning of the product’s dangerous propensities.”). *But see In re Norplant Contraceptive Prods. Liab. Litig.*, 165 F.3d 374, 378 (5th Cir. 1999) (holding that even if direct-to-consumer marketing could negate the learned intermediary rule it cannot do so where there is no specific evidence that the plaintiffs saw the manufacturer’s claims or acted in reliance on them).

227. *Didato v. Strehler*, 554 S.E.2d 42, 46–48 (Va. 2001).

228. *Cf. Louis J. Elsas II, A Clinical Approach to Legal and Ethical Problems in Human Genetics*, 39 *Emory L.J.* 811, 818 (1990) (contrasting the diagnosis and treatment of meningitis in a child as compared to that of sickle cell disease where the effects of sickle cell are chronic for the patient and the genetic risks are shared by family members).

229. *Id.*

230. *Didato*, 554 S.E.2d at 48.

231. *Id.*

232. *Id.*; *see also Park v. Chessin*, 400 N.Y.S.2d 110, 111 (App. Div. 1977) (finding that negligently performed genetic counseling can result in liability where a physician told parents that the risk of a subsequent child being born with the same kidney disease as their first child was “practically nil” even though the disorder was genetic). The court awarded costs for care and treatment of the second child born with the disease under a wrongful life suit brought by the parents when the second child died less than three years after birth. *Id.*

compensation for the oversight of failing to convey the full meaning of the genetic test results to them. Consumers who order the tests themselves may not receive complete or accurate information and may not understand the larger implications for their health or lifestyle based on those results. Assuming a direct-to-consumer testing company provided an accurate, if not easily understandable report, it is difficult to see how liability, and therefore compensation, could be established.

2. Evaluation of Possible Effects of More Regulation on Consumers and the Genetic Testing Market

The need to close the gap in regulation of genetic testing has reached critical mass among those who work in the genetics field.²³³ If the FDA and CLIA agencies were to work in concert, this likely would be an improvement over the existing regulatory gap since “CLIA’s regulatory tools are different than those available to the FDA, [so] some reasonable combination of both might be used to address the concerns regarding genetic testing.”²³⁴ This option would allow the agencies to draw on each other’s strengths and focus solely on creating rules to cover the existing gaps in regulatory coverage, as opposed to reinventing regulatory law for direct-to-consumer genetic tests as a separate category.²³⁵ But some commentators are doubtful that these existing regulatory bodies are capable of adapting their historic missions to accommodate the current and future advances in genetic testing.²³⁶

a. Existing Agencies Inadequate to Meet New Regulatory Challenges

Among the obstacles cited by commentators is that the existing agencies will be reluctant to add to their regulatory scope and that any additional oversight they assume will necessarily reduce their efficacy in the existing regulatory duties.²³⁷ Additionally, the regulatory oversight of the past turned in large part on the ability of the government to exert control over research and development through the power of the purse strings.²³⁸ Today that control is greatly reduced as funding by the National Institutes of

233. See Pollack, *supra* note 68 (“There’s been a gaping hole in the oversight of genetic tests. . . . We have seen a tenfold increase in the number of genetic tests available over the last decade and an even greater increase in the complexity of those tests.” (quoting Dr. Kathy Hudson of Johns Hopkins University)).

234. Karen Lusky, *FDA Puts ASR Rule Back on the Table*, CAP Today, Oct. 2003, available at <http://www.cap.org/> (follow “Reference Resources and Publications” hyperlink; then follow “Periodicals; CAP Today” hyperlink; then follow “2003 Articles” hyperlink; then follow “October” hyperlink).

235. See generally Grimm, *supra* note 174.

236. See Huang, *supra* note 171, at 580–81.

237. Fukuyama, *supra* note 49, at 213–14.

238. *Id.*

Health or other federal government agencies, though still the largest source of research funding, is being replaced in large part by private sources.²³⁹

The strength of the FDA reform movement further reduces the likelihood that a comprehensive regulatory response to the commercialization of genetic testing services will be introduced.²⁴⁰ Therefore, regulation of genetic testing in biotechnology will be forced to follow precedents set by pioneering companies in this field such as IVF, Myriad, and OncorMed.²⁴¹

b. *Assisting Consumers to Better Understand the Results of Genetic Tests*

There is also much debate about how much responsibility the consumer should have. Earlier opinions on the responsibility shared between consumers and health professionals considered the possibility that consumers largely preferred to have medical decisions dictated to them by more knowledgeable experts.²⁴² More recent commentators have taken a more moderate position on shared responsibility for choosing genetic testing and understanding its implications by focusing on a more commonsense approach to physician-required advice.²⁴³ “Simply telling patients something or giving them a handout is quite different from making sure that they understand what they have been told.”²⁴⁴ The key function of genetic professionals then becomes making sure “by whatever means are needed and in whatever time is required, that patients are given medical information that is clear and understandable, and that they understand it.”²⁴⁵

Not only is there a sense that consumers need to be protected from their own ignorance, but there is also a belief among some professionals that direct consumer-driven health care may ultimately “endanger the health and well-being of the chronically ill (those most reliant on health coverage).”²⁴⁶ Others allege that an increase in direct consumer-marketed products will further exacerbate health care costs at a time when health care expenses are spiraling out of control.²⁴⁷ Another problem is that uninsured persons may

239. *Id.*

240. *Id.* at 214–15.

241. Malinowski & Blatt, *supra* note 109, at 1242.

242. Raisa B. Deber, *Shared Decision Making in the Real World*, 11 *J. Gen. Internal Med.* 377, 377 (1996) (stating that informed consent realists “have—in the dead of night—asked whether patients wish to be involved in decision making at all”).

243. See, e.g., Marshall B. Kapp, *Patient Autonomy in the Age of Consumer Driven Health Care: Informed Consent and Informed Choice*, 2 *J. Health & Biomedical L.* 1 (2006).

244. *Id.* at 15 (quoting Barry D. Weiss & Cathy Coyne, *Communicating with Patients Who Cannot Read*, 337 *New Eng. J. Med.* 272, 273 (1997)).

245. *Id.*

246. John V. Jacobi, *Consumer-Directed Health Care and the Chronically Ill*, 38 *U. Mich. J.L. Reform* 531, 533 (2005).

247. Margot Roosevelt, *Health Insurance? Turn Left at Aisle 6*, *Time*, July 25, 2005, at 14, 14 (stating that a fragmented free market for health care is less necessary than “a publicly accountable and organized system of health insurance”). *But see* Stephen T. Parente et al., *Evaluation of the Effect of a Consumer-Driven Health Plan on Medical Care Expenditures*

scrape together funds for a test but cannot afford health care to monitor or cope with the resulting diagnosis.²⁴⁸ The outcome feared is that extensive testing in an inadequate system of health care and insurance protections will make individuals diagnosed with certain conditions virtual outcasts deprived of a social safety net.²⁴⁹ Patients' rights advocate George Annas speaks to the issue by saying,

Consumer choice becomes the central mantra of the market metaphor. . . .

The market metaphor is also a myth The consumer-patient is not always right The market metaphor . . . pretends that there is such a thing as a free market in health insurance plans, and that purchasers can and should be content with their choices when an unexpected injury or illness strikes²⁵⁰

c. Protecting Consumers from Industry by Regulating Genetic Tests

In comparison to ordinary consumer disclosure laws, the physician's duty to disclose genetic information is necessary in order to allow a patient to make an informed decision about medical care.²⁵¹ This grows out of the long-standing belief that patients are entitled to the information necessary to make those decisions.²⁵² However, there is no comparable right in ordinary consumer affairs, which is why consumer disclosure laws are necessary to protect the consumer population; such laws require companies to provide product and service information to consumers who consent to the risks and benefits associated with the goods or services being purchased.²⁵³ Proponents of legislation to give individuals more control over genetic testing critique the existing legislation regulating genetic information for being too limited in scope.²⁵⁴ Patients' rights critiques focus on identifying potential abuses of such tests and the belief that the negative effects of

and Utilization, 39 Health Serv. Res. 1189, 1203 (2004) (reporting that enrollees in a consumer-driven health plan had lower total expenditures than other consumers).

248. See generally Malcolm Gladwell, *The Moral-Hazard Myth: The Bad Idea Behind Our Failed Health-Care System*, New Yorker, Aug. 29, 2005, at 44, 44-49 (faulting consumer-driven health care for giving insufficient attention to the role of health insurance in redistributing resources).

249. See Wendy K. Mariner, *Can Consumer-Choice Plans Satisfy Patients? Problems with Theory and Practice in Health Insurance Contracts*, 69 Brook. L. Rev. 485, 492-93 (2004) (discussing the problems of information imbalance and bargaining power in the medical context of managed care programs).

250. George J. Annas, *Some Choice: Law, Medicine, and the Market* 46 (1998).

251. See Mariner, *supra* note 249, at 493.

252. See *id.*

253. See *id.*

254. See generally George J. Annas et al., *Drafting of the Genetic Privacy Act: Science, Policy, and Practical Considerations*, 23 J.L. Med. & Ethics 360 (1995); Patricia (Winnie) Roche et al., *The Genetic Privacy Act: A Proposal for National Legislation*, 37 Jurimetrics J. 1 (1996).

further legislation are overstated in light of the consumer protections needed.²⁵⁵

Similarly, advocates for more direct regulation also argue that the influence drug developers and manufacturers exercise over scientific research must not be underestimated.²⁵⁶ Many find that medical researchers are highly susceptible to the influence of the private biotechnology industry and are further conflicted by the fact that many researchers hold monetary interests in developing or promoting new biotechnology products.²⁵⁷ Accordingly, they argue that the influence of the industry over public health policy should not be assisted by a lax federal regulatory approach.²⁵⁸ The approach these advocates urge is to increase regulation of genetic tests sold directly to consumers in order to protect the consumers and rein in potential abuses by the biotechnology industry in this newly expanding area of health information.

B. *Advocacy for Less Regulation and More Direct Consumer Access to Genetic Testing*

The majority of the genetic testing industry has called for self-regulation, citing the detrimental effect increased regulation would have on a fledgling business that benefits consumers.²⁵⁹ Increased regulation is also adamantly opposed by a wider array of interest groups ranging from biotechnology policy groups and research scientists to advocacy groups for specific diseases.²⁶⁰ This section looks at those groups advocating less regulation of direct-to-consumer genetic tests and supporting greater access to genetic testing.

255. See, e.g., Annas, *supra* note 250, at 97–111. Two pieces of legislation have been introduced in the Senate during the 110th Congress in an attempt to address the regulatory gaps in genetic testing. See Genomics and Personalized Medicine Act of 2007, S. 976, 110th Cong. (proposing the creation of an interagency working group, the development of a national biobank for the collection of genomic data, and an increase in genetics and genomics training); Laboratory Test Improvement Act, S. 736, 110th Cong. (2007) (deeming laboratory tests to be devices for the purposes of regulation, requiring public disclosure concerning the tests, and requiring reporting of direct-to-consumer genetic tests under 21 U.S.C. §360k).

256. Malinowski & Blatt, *supra* note 109, at 1284.

257. See David Blumenthal et al., *Relationships Between Academic Institutions and Industry in the Life Sciences—An Industry Survey*, 334 *New Eng. J. Med.* 368, 368 (1996) (“Ninety percent of companies conducting life-science research in the United States had relationships involving the life sciences with an academic institution in 1994. Fifty-nine percent supported research in such institutions, providing an estimated \$1.5 billion, or approximately 11.7 percent of all research-and-development funding received that year.”); see also Steven A. Rosenberg, *Sounding Board: Secrecy in Medical Research*, 334 *New Eng. J. Med.* 392, 392–93 (1996).

258. See Malinowski & Blatt, *supra* note 109, at 1285–86.

259. FDA, *supra* note 69, at 25–28, 44–45, 81–82 (expressing the concerns of industry executives and investors that regulation apart from the existing industry processes would inhibit the development of small biotechnology companies, delay and increase the costs of genetic testing, and harm consumers in the long run).

260. Fukuyama, *supra* note 49, at 215 (pointing out the wide variety of interest groups behind those who oppose additional limitations on genetic testing and information).

1. Proponents of and Rationales Behind Advocating for Greater Freedom of Access to Personal Genetic Information

During 2007, the FDA set out to begin the process of extending its regulation to genetic tests by issuing guidelines for tests that measure multiple gene variables identified as “multivariate index assays.”²⁶¹ News reports of the agency’s public meeting on the guidelines indicated that many diagnostic test manufacturers were displeased with the proposed regulation.²⁶² Complaints rolled in that the guidance offered by the agency was “confusing” and a “disincentive to innovation” along with suggestions that the FDA was outside its legal authority to regulate genetic tests under its approval process for devices.²⁶³

One industry executive, Sharon F. Terry, president of the Genetic Alliance, said that the “guidelines should be withdrawn and formal rules approved,” an action that would require several years for the agency to accomplish.²⁶⁴ Presumably, pushing back the guidelines for such an extended period of time would allow manufacturers a wide window during which they could continue to offer their products under the Department of Health and Human Services laboratory improvement guidelines.²⁶⁵ This section examines the arguments for reduced regulation of direct-to-consumer genetic tests. It also looks at the effect a more laissez-faire approach to the direct-to-consumer genetic test market would have on both consumers and the growing genetic testing industry.

a. *Creating Unnecessary Limits on the Development of Genetic Testing*

Some experts noted that the proposed guideline requirements would further discourage the development of new tests by raising the costs of introducing them. “I’m not sure we could exist at all if we were required upfront to have F.D.A. approval,” Randy Scott, chief executive of Genomic Health, explained in response to the initial proposal and at the public comments meeting.²⁶⁶

Advocates of regulatory restraint support the existing absence of specific regulation for genetic tests and claim that industry abuses can be curbed by other means, citing the industry’s current incentive to avoid product liability as one effective means of policing potential abuses.²⁶⁷ They claim the regulatory effect of legal liability should not be underestimated, citing the risks associated with foregoing the FDA review process and subjecting a

261. Caruso, *supra* note 43.

262. *Id.*

263. *Id.* (internal quotation marks omitted).

264. *Id.*

265. Pollack, *supra* note 68.

266. *Id.*

267. See Malinowski & Blatt, *supra* note 109, at 1279–83.

company to greater product liability at the state level.²⁶⁸ The recommended response to companies that prematurely market predictive genetic tests is to encourage greater enforcement of existing regulations for product labeling and laboratory standards instead of using the situation as an opportunity to impose additional regulation.²⁶⁹ Likewise, it is argued that physicians who fail to advise patients properly or who order excessive genetic tests should be penalized under professional disciplinary standards or through malpractice suits rather than have the federal government limit access to genetic testing.²⁷⁰

b. *Using Product Liability to Adequately Address Potential Harms to Consumers and Promote Industry Standards*

Manufacturers or distributors of genetic testing products may be subject to several kinds of liability, including breach of express or implied warranty, negligence, and product liability. Product liability includes liability for manufacturing defects, design defects, and defects in warnings or instructions.²⁷¹ These forms of liability provide compensation to injured consumers and a measure of deterrence intended to force manufacturers of at-home genetic tests to improve their products rather than suffer the consequences of large-scale lawsuits negligence and product liability lawsuits.²⁷²

c. *Promoting Consumer Rights Through Greater Access to Genetic Tests*

Concerns about consumers having access to their genetic information are in line with the historical concerns of biomedical ethicists who argue that individuals should not be coerced into specific medical choices for autonomy and privacy reasons.²⁷³ The goal of this approach is to free the patient “from both controlling interference by others and from limitations, such as inadequate understanding, that prevent meaningful choice.”²⁷⁴

268. See 21 C.F.R. § 808.1(d) (2007), available at http://a257.g.akamaitech.net/7/257/2422/26mar20071500/edocket.access.gpo.gov/cfr_2007/a/prqtr/pdf/21cfr808.1.pdf (laying out the procedures for claiming an exemption from state and local liability by means of federal preemption under the statute); H.R. Rep. No. 853, at 45 (1976) (explaining that, if manufacturers comply with FDA requirements and do not commit fraud, state law claims generally are preempted).

269. See SACGHS Draft Report, *supra* note 177, at 113–14.

270. See, e.g., Wadman *supra* note 215; Malinowski & Blatt, *supra* note 109.

271. See generally Restatement (Third) of Torts: Product Liability § 2 (1998).

272. See John J. Kircher & Christine M. Wiseman, Punitive Damages: Law and Practice § 6.07 (2d ed. 2000); Mark P. Robinson & Gerald H.B. Kane, Jr., *Punitive Damages in Products Liability Cases*, 6 Pepp. L. Rev. 139, 140 (1979) (defending punitive damages in civil product liability cases).

273. See Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* 12–13 (5th ed. 2001) (identifying a relationship between and the importance of patient autonomy and privacy concerns).

274. *Id.* at 58.

As such, the interest in preventing inadequate patient understanding from inhibiting free choice goes to the tort liability frequently found in genetic cases for wrongful birth and wrongful life actions. One of the earliest cases recognizing this cause of action was *Curlender v. Bio-Science Laboratories*, which involved misinterpreting a test screening for Tay-Sach's disease that resulted in the birth of a Tay-Sach's afflicted infant.²⁷⁵ The California court permitted the infant's claim and awarded damages for pain and suffering as well as special pecuniary losses due to the condition.²⁷⁶ The damages in that case stemmed from the physician's responsibility to accurately interpret and convey the information contained in the genetic tests. However the courts have not yet been faced with a case where a layperson undertakes the task of understanding and interpreting similar genetic test results on his or her own.

In the end, advocates for consumer freedom and less regulation appear willing to let the burden fall on the consumer where there is room for error or misunderstanding with regard to what the results of genetic tests mean and what course of action may be appropriate for a specific test result. In return, these advocates believe that existing guidelines coupled with the threat of product liability suits will provide sufficient protection and an incentive for industrywide improvements to direct-to-consumer genetic tests. To impose additional layers of regulation or oversight would result in the loss or delay of increased access to genetic information for the public.

2. Evaluation of Possible Effects of Less Regulation on Direct-to-Consumer Genetic Tests

The arguments for less regulation and more consumer access to direct-to-consumer tests put a premium on the ability of consumers to exercise their right to make choices about appropriate genetic diagnostic and screening tests.²⁷⁷ In spite of the low clinical utility of the tests, they argue that even the most experimental genetic tests may offer benefits to some patients.²⁷⁸ Benefits include clarification of risk status, more accurate diagnosis of

275. *Curlender v. Bio-Science Labs.*, 165 Cal. Rptr. 477, 488–90 (Ct. App. 1980). *But see* *Becker v. Schwartz*, 386 N.E.2d 807, 813–14 (N.Y. 1978) (dismissing a wrongful life claim based on the court's inability to value nonlife versus handicapped life).

276. *Curlender*, 165 Cal. Rptr. at 488–90. *Curlender* highlights another potential problem with relying on tort liability and allowing increased test usage, stating that there was no reason why a suit could not be brought against parents who proceeded with a pregnancy when they knew the fetus had a genetic defect. *Id.*; see Lois Shepherd, *Sophie's Choices: Medical and Legal Responses to Suffering*, 72 Notre Dame L. Rev. 103, 107–15 (1996).

277. See Andrews, *supra* note 18, at 27–29 (describing the fundamental rights model as one approach to genetic testing, which arises out of a patient's rights to make choices concerning medical care); Kuklin, *supra* note 149, at 540–49 (discussing the need for accurate information about genetic tests and their misinterpretation in the context of tort liability under the informed consent doctrine). *But see* *Abdulaziz v. City of Philadelphia*, No. 00-5672, 2001 U.S. Dist. Lexis 10156 (E.D. Pa. June 26, 2001) (expressing the minority view that informed consent requirements only apply to surgical procedures).

278. Olufunmilayo I. Olopade, Editorial, *Genetics in Clinical Cancer Care—The Future Is Now*, 335 New Eng. J. Med. 1455, 1455 (1996).

symptomatic individuals, detection of carrier status, and guidance for selecting the most prudent course of surveillance treatment.²⁷⁹ Additionally, the tests' utility will improve as medical science begins to overcome obstacles to using the information to predict how and when genetic disorders will manifest from mere genetic mutations and as research reveals more therapies for currently untreatable genetic conditions.²⁸⁰ In fact, regulatory critics claim that the more patient samples are accumulated through the use of these tests, the greater the financial incentives will be to develop more genetic tests and the more rapidly gene therapies will be developed.²⁸¹ This hope is echoed in the support for more access to genetic testing among interest groups working for increased attention for those with genetic disorders and the need for additional research and funding for prevention and cures.²⁸² These groups say that overregulating the industry may have the opposite effect and chill interest in providing easy access to accurate genetic information.²⁸³

a. *Increased Regulation: Creating Burdens That Exceed the Benefits of Direct Access to Genetic Tests*

Proponents of a less regulated approach argue that there is only a limited benefit to adding requirements such as that consumers be afforded additional genetic counseling or be restricted to tests only on the basis of physician recommendation. Some cite the questionable propriety of genetic counseling's attempt to act as a neutral arbiter of predictive genetic information.²⁸⁴ They point out that such counseling may never be neutral even though the genetic community subscribes to an ethic of neutrality in presenting choices to consumers.²⁸⁵ The idea of neutrality in genetic counseling is further complicated by the need for medical professionals to weigh the often conflicting requirements of professional and legal duties. This problem is summed up as follows:

When an inheritable defective genetic trait is discovered, some counselees may not wish to warn other family members about the potential risk to those family members. This puts the counselor in a precarious position. If the counselor takes it upon himself to warn relatives, he faces a possible

279. *Id.* ("It is no longer unusual for women with newly diagnosed breast cancer to seek genetic testing before choosing between mastectomy and lumpectomy combined with radiation therapy.")

280. See Richard Saltus, *Breast Cancer Testing: Do You Want to Know?*, Boston Globe, Mar. 11, 1996, at 25.

281. See Malinowski & Blatt, *supra* note 109, at 1217.

282. Fukuyama, *supra* note 49, at 215 (identifying disability rights groups as supporters of increased access to genetic information that might be limited under some regulation).

283. See Pear, *supra* note 221 (quoting the president of the American Clinical Laboratory Association as saying that overly stringent regulations would "stifle innovation").

284. See Davis, *supra* note 15, at 20 (describing the possible counseling perspectives available to a genetic counselor attempting to maintain a values-neutral approach when faced with a couple wishing to ensure their children will carry a gene that causes deafness).

285. *Id.*

lawsuit from the counselee based on a violation of privacy. However, if the counselor does not warn a relative, he might be sued by the relative based on the failure to prevent the unnecessary birth of a genetically defective child. The quick answer is that since the counselee has no duty to inform relatives, the counselor has no such duty and no business to warn the relatives. The commentators are split.²⁸⁶

Legislation to address direct-to-consumer genetic testing is also criticized as burdening consumers more than the tests.²⁸⁷ Opponents of legislation specific to genetic testing point out that many preexisting routine diagnostic tests reveal characteristics, such as blood cholesterol levels, that are genetically based or influenced.²⁸⁸ As a result, statutes targeted solely at consumer access to predictive genetic testing may impose unnecessary limitations on medical practice and ongoing research.²⁸⁹

b. Compensation for Harms Done: Providing an Effective Alternative to Increased Regulation for Both Consumers and Producers of Genetic Tests

Other industry voices argue that increased regulations do not always increase the accuracy of diagnostic tests.²⁹⁰ As a result, it would be better merely to compensate individuals for harm actually done than to undertake regulations that, in past experience, do not achieve the desired improvement in results.²⁹¹ The argument is that the tests themselves carry few medical risks, and the real risk comes from individual decisions based on the test results, which can result in harm.²⁹²

However, in genetic testing tort cases, there remains the problem that the element of causation will undoubtedly be difficult to prove in many instances. Harm is particularly difficult to prove because the tests are probabilistic about future health conditions, leaving consumers to establish proximate cause for harms that result from subsequently adopted preventive or prophylactic measures.²⁹³ For example, in one case a consumer submitted material to genetic testing company OncorMed and was told she had a mutation indicating a high risk of developing breast and ovarian cancer.²⁹⁴ Based on this information, she had her ovaries surgically

286. Carolyn Lee Brown, Editorial Note, *Genetic Malpractice: Avoiding Liability*, 54 U. Cin. L. Rev. 857, 877-78 (1986); see also Alexander Morgan Capron, *Tort Liability in Genetic Counseling*, 79 Colum. L. Rev. 618, 677 (1979) (addressing the ethical and professional norms in genetic counseling and identifying three potential problem areas in applying tort liability to the new field of genetic counseling).

287. See Pear, *supra* note 221 (describing industry opposition to the regulation of genetic tests based on the small risk relative to the benefits offered to consumers).

288. Malinowski, *supra* note 200, at 28.

289. *Id.* at 28-29.

290. James O. Westgard et al., Final Rule vs Final Word on Quality (2004), <http://www.westgard.com/essay62.htm>.

291. See Ossorio, *supra* note 89, at 243.

292. *Id.*

293. *Id.*

294. See Underwood, *supra* note 167, at 62.

removed and was consulting with a doctor about undergoing a double mastectomy when it was discovered that OncorMed misreported the test result.²⁹⁵

Not all industry interests agree on this point either, with some claiming that relying on litigation as an enforcement mechanism also risks a chilling effect on the industry. For example, one argument against wrongful life suits focuses on the fact that the mere existence of this cause of action encourages litigation and discourages genetic testing advances by making work in this area cost prohibitive.²⁹⁶

c. Decreased Regulation: Offering the Industry Opportunities to Explore More Effective Self-regulatory Measures

Finally, in promoting the idea of self-regulation, industry insiders find that maintaining the status quo of nonregulation may offer some significant public health benefits.²⁹⁷ This is because it allows the industry to address the ethical issues associated with commercial technologies in ways that, it is argued, are more effective than what could be achieved by government-mandated regulation.²⁹⁸ As evidence for this, they point to the fact that even a decade ago several multinational pharmaceutical companies funded ethics programs centered on these issues, and many other biotechnology companies have since hired ethicists to advise them in the development of consumer products and services.²⁹⁹

Whether the ultimate effect of a lesser degree of regulation is beneficial or detrimental appears to turn on one's view of the consumers themselves. Proponents of less regulation believe the result will be to assist consumers in understanding their genetic predisposition (or lack thereof) to specific conditions and allow them more direct access to health information with which they can make choices for themselves. At the same time, the market created for this information will drive improvements to the tests and increased development across the industry. These effects are the opposite of those posited by proponents of increased regulation of the tests under the rationale of providing greater consumer protection from potentially misleading information. While both viewpoints provide persuasive arguments, neither is a wholly adequate solution to the regulatory gap that exists today.

295. *Id.*

296. Kevin R. Costello, *The Limitations of Wrongful Life Claims and Genetic Diagnosis*, L.A. Lawyer, Apr. 2007, at 14, 16 (citing preimplantation genetic diagnosis of embryos as an "essential technology" for "improving the quality of life" of children by ensuring that they are born without genetic defects and arguing that permitting wrongful life suits will prevent such diagnoses from becoming widespread).

297. *See generally* Malinowski & Blatt, *supra* note 109, at 1280.

298. *Id.*

299. *Id.* at 1280–81.

III. A PROPOSAL FOR APPROPRIATE REGULATION OF DIRECT-TO-CONSUMER GENETIC TESTING

Part III of this Note concludes that the appropriate level of regulation in direct-to-consumer genetic testing involves bringing the validity of the tests firmly under the FDA regulations to ensure that consumers receive reliable results from tests marketed for both predictive and diagnostic purposes, including complete genotype library services. However, at its heart the argument about genetic testing weighs more heavily on the side of consumer access to information, and so the direct-to-consumer tests should not be heavily regulated except as state tort and product liability law demands.

A. Extreme Regulatory Solutions Fail Consumers by Providing Either Excessive or Inadequate Protections

Prohibiting all direct commercial sales of genetic tests to the public is not a practical solution. There is consumer demand for direct genetic testing, so, at best, this would drive such businesses to countries (or states) where there are no such prohibitions and still allow the tests to be sold over the Internet.³⁰⁰ A complete ban would thus be a poor solution both because it forces consumers to do business with companies of unknown quality and decreases the options for regulating such tests.

Likewise, relying solely on tort liability as an incentive mechanism is inadequate for two reasons. First, many of these companies are newly created and have few assets with which to compensate consumers, and any possible recovery would be disproportionately low.³⁰¹ Second, consumers may have an insurmountable barrier in building cases where it is difficult to prove how errors occurred, and test errors may not come to light for months or even years.³⁰²

B. Regulation of the Accuracy and Validity of Tests Can Be Accomplished Under the Existing Regulatory Framework

Increased regulation of test manufacturing and accuracy are essential components of the regulatory patchwork needed to govern consumer genetic testing. Regulations should be made explicit in terms of the regulating authority and the requirements for accuracy and clinical validity of at-home genetic tests.³⁰³ The primary form of regulation should involve the increased oversight and enforcement of joint FDA and CLIA regulations for genetic tests and laboratories that process those tests sold directly to consumers. This mandate fits squarely within the existing regulatory framework by focusing not on how the genetic tests or their

300. See *supra* note 108–20 and accompanying text.

301. See Harmon, *supra* note 45; Pollack, *supra* note 5.

302. See *supra* notes 292–95 and accompanying text.

303. See *supra* notes 233–35 and accompanying text.

results reach the consumer but on the protocols, personnel, and standards of the processing of those tests.³⁰⁴ As such, it interferes little with a consumer's right to access personal health information while providing greater assurance that the actual results of the tests are accurate and provide adequate information to consumers faced with medical decisions.³⁰⁵

Bringing the tests under the umbrella of the FDA and CLIA requirements can be done by permitting a broad interpretation of the agencies' mandates to regulate the facilities associated with all diagnostic tests related to consumer-patient health.³⁰⁶ Arguably, all genetic tests, including complete genotype library services, relate to consumers' health-related decision-making processes—even if the consumer initially requests such tests only out of curiosity or for nondiagnostic purposes—because the information obtained can be directly correlated to potential health problems.³⁰⁷ The prime example of this is the option for consumers using companies such as 23andMe where the genetic information is compiled once, but access to it is provided on an ongoing basis so the results can be continuously matched against whatever new genetic findings come out.³⁰⁸

C. *FDA Approval Coupled with FTC Enforcement Can Provide Both Consumer Protection and Industry Incentives*

FDA device regulation is not necessary as a mandatory requirement for direct-to-consumer genetic testing. Unlike classical medical drugs and devices, the information contained in one's genome is not an inherently dangerous substance that must be carefully screened because of the risks associated with its use.³⁰⁹ However, that is not to say that the FDA should not play a role if companies are interested in the voluntary use of the approval process.

Under an opt-in system of FDA device approval for direct-to-consumer genetic tests, manufacturers would have the option of submitting their test through the existing approval process. For companies that consent to working with the FDA, the existing incentive is to insulate the product from liability in state courts.³¹⁰ Similarly, legislators interested in promoting greater voluntary use of the device approval process could offer legislation to limit the ability of states to exclude direct-to-consumer genetic tests from being sold within the state.³¹¹ In making the tests federally approved for use anywhere in the United States and preempting state-level suits, the

304. *See supra* Part I.B.2–3.

305. *See supra* notes 249–53 and accompanying text.

306. *See supra* notes 233–35 and accompanying text.

307. *See generally supra* Part I.A.1 (describing the unique qualities of genetic tests that make genetic information predictive of future diagnoses of diseases or conditions regardless of the original reason for the genome mapping).

308. *See* Harmon, *supra* note 45.

309. *See supra* notes 9–13 and accompanying text (comparing genetic tests to standard diagnostic tests).

310. *See supra* notes 50–60 and accompanying text.

311. *See supra* notes 205–06 and accompanying text.

legislature would create an additional incentive for manufacturers to participate in the approval process, particularly as more tests are developed, and in turn create further paths for fast-track approvals based on preexisting consumer genetic tests.³¹² At the same time, states could continue to place some limited restrictions on direct-to-consumer tests, such as requiring consumers to be provided with referrals for genetic counseling or reminded to have physicians interpret the test results.³¹³ Such restrictions would function on a state-by-state basis, but where the tests had obtained FDA approval the state would not be permitted to negate the direct-consumer link (e.g., limiting direct-to-consumer test sales to doctors or requiring companies to report results only through a state-licensed physician).³¹⁴

In contrast, companies that choose not to voluntarily enter into the FDA device approval process would continue to be subject to state-imposed bans on direct-to-consumer tests.³¹⁵ As discussed earlier in this section, it is unlikely that such complete bans would be particularly effective given the options for online ordering and delivery of tests via standard parcel post carriers. In addition, the unapproved tests could be penalized further by encouraging stricter enforcement of labeling by the FTC.³¹⁶ This would address the problem of false or misleading advertising of the type identified by the Government Accountability Office report on nutrigenomics tests, which were advertised directly to consumers but offered little or no valid scientific or medical purpose.³¹⁷

Non-FDA-approved genetic tests sold directly to consumers could also be required to carry disclaimers comparable to those carried on dietary supplements. Where the supplements are not FDA approved, the label includes a statement below the benefit claims that indicates that the statements have not been evaluated by the FDA and the product is not intended to “diagnose, treat, cure, or prevent any disease.”³¹⁸ Such a disclaimer alerts the consumer that the product is not FDA approved and presumably would help consumers choose whether or not to purchase tests from companies that have not made the effort to go through the review process. Like dietary supplements, the disclaimer can hardly be expected to eliminate the market for such direct-to-consumer genetic tests but does have the benefit of creating a truth-in-advertising check for consumers.³¹⁹

312. *See supra* Part II.B.2.

313. *See, e.g.*, Genetics & Pub. Policy Ctr., *supra* note 205.

314. *See id.*

315. *See id.*

316. *See supra* notes 186–87 and accompanying text.

317. *See supra* note 120 and accompanying text.

318. FDA, Labeling of Dietary Supplements FAQ, <http://www.cfsan.fda.gov/~dms/ds-labl.html> (last visited Feb. 19, 2008).

319. *See supra* notes 186–87 and accompanying text.

D. *An Additional Role Remains for Agencies and Professional Groups in Providing Consumer Education About Genetic Testing*

None of the proposed steps will directly address the ongoing problem of inadequate understanding of genetics by consumers and physicians or the difficulties in communicating the precise meaning of test results to consumers. Most likely this will continue to be an item of concern to groups like SACGHS that have identified improved genetic awareness as a priority. Over time, the understanding gap will close slightly due to medicine's improved ability to interpret the probabilistic connections between genetic information and genetic conditions.³²⁰ Additionally, consumers will likely become more comfortable with genetic testing as it increases in availability and becomes more accepted as a part of routine health care with appropriate safeguards for privacy and against discrimination.

To improve this process, the FDA should consider issuing advisories on language that can be used in explanations of the results of genetic tests offered directly to consumers. For tests that undergo FDA approval, this is already one way to ensure that manufacturers are limited in the liability borne for reporting results directly to consumers.³²¹ Unapproved tests may choose to model explanations on the FDA-approved language in the hope of creating a rebuttable presumption in potential tort actions that the test results were adequately communicated to consumers. However, even this step is unlikely to provide the same level of protection from liability afforded to FDA-approved tests.³²² Such advisories might also be undertaken by the FTC or developed in conjunction with groups such as SACGHS, the AMA, or genetics policy groups.³²³

Finally, professional and policy groups should continue to take an active role in promoting consumer and physician awareness of developments in genetic testing. These groups play an important role, mediating between government and industry.³²⁴ On the one hand, they remain largely unattached to specific political administrations and free to advocate a broad mix of constituencies from consumers and physicians to disability rights advocates and research scientists.³²⁵ On the other hand, they lack some of the product-based loyalties of the biotechnology sector that may become entangled in a conflict between consumer good and profits.³²⁶ As such, these professional and policy groups are uniquely situated to continue reviewing and commenting on the development of genetic testing and to act as watchdogs over consumer behavior stemming from direct-to-consumer genetic tests and access to genetic information generally.

320. See Nat'l Insts. of Health, *supra* note 28, at 2–3.

321. See *supra* notes 50–60 and accompanying text.

322. See *supra* notes 50–60 and accompanying text.

323. See *supra* notes 222–24 and accompanying text.

324. See *supra* notes 222–24 and accompanying text.

325. See *supra* notes 222–24 and accompanying text.

326. See *supra* notes 222–24 and accompanying text.

CONCLUSION

Direct-to-consumer genetic tests represent a leap forward in consumers' access to their personal medical history and health information. Unlike a drug or device used in classical medical care, these tests are minimally invasive with little or no risk in obtaining the samples needed for the test.³²⁷ Therefore, regulating them in precisely the same manner as an inherently dangerous substance, such as a medication for a chronic condition or an artificial assistive device such as a stent or pacemaker, is an excessive burden given the risks involved. The information provided by the genetic tests is only risky because of the choices that individuals make based on it and the potential for consumer misinterpretation of it.³²⁸

To address the existing concerns about genetic testing and further encourage innovation in this area, the regulatory scheme should be limited to FDA and CLIA approval requirements for test materials and laboratories carrying out the test processing for direct-to-consumer tests. The FDA approval process for devices should be offered as a further incentive to manufacturers by providing the added benefit of overcoming state-specific bans on direct-to-consumer genetic tests.³²⁹ At the same time, states could still require concessions on issues such as genetic counseling or physician counseling to consumers purchasing the tests in those states.³³⁰ Direct-to-consumer tests that bypass the FDA approval process would continue to be subject to state-specific bans in addition to being subject to state liability laws. In addition, unapproved tests would undergo a higher level of scrutiny by both the FDA and the FTC to ensure that those companies' products carried the appropriate disclaimers noting that the products were not scientifically or medically valid or necessary.³³¹

Consumers could be made aware of the distinction between products that were approved and unapproved through increased education by professional and policy groups.³³² Their understanding of the results received from direct-to-consumer genetic tests would also be enhanced where the FDA, or other public interest groups, was able to implement advisory language for companies to use in providing test analysis directly to consumers.³³³ This would allow for continuing improvement in consumer understanding of genetics information as it becomes a more common part of individual health and medical treatment plans.

The combination of laboratory regulation, dual tracks for genetic tests based on voluntary FDA approval, and consumer advisories and education provides a multipronged approach to addressing the most prominent concerns about offering genetic tests directly to consumers. The existing

327. *See supra* notes 22–25 and accompanying text.

328. *See supra* notes 143–49 and accompanying text.

329. *See supra* notes 205–06 and accompanying text.

330. *See supra* notes 205–06 and accompanying text.

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

332. *See supra* notes 222–24 and accompanying text.

333. *See, e.g., supra* note 318.

lack of regulation must be addressed, but should not discourage further innovation in genetic testing. At the same time, consumers should be encouraged to take appropriate proactive steps to understand the role genetics plays in their health and well-being. By using a minimalist but layered approach to regulation, all of these goals may be achieved.

Notes & Observations