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The Need for Regulation of Direct-to-Consumer Genetic Testing in the United States: Assessing and Applying the German Policy Model

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THE NEED FOR REGULATION OF DIRECT-TO-CONSUMER GENETIC TESTING IN THE UNITED STATES: ASSESSING AND APPLYING THE GERMAN POLICY MODEL

INTRODUCTION: OVERVIEW OF GENETIC TESTING

In 2008, *Time Magazine* declared 23andMe's¹ retail DNA test the "Invention of the Year."² The actual value of this and other direct-to-consumer ("DTC") genetic tests remains to be seen, however, and government agencies worldwide have been left to decide if and how strictly to regulate this relatively new but growing field of genetic technology.

The study of genetics began in earnest with Gregor Mendel's principles of heredity in the 1860s.³ The importance of his work, however, was not recognized until 1900, when Hugo de Vries and two other researchers independently verified and published Mendel's results.⁴ From there, scientists developed the chromosomal theory, and in 1953, Watson and Crick discovered the double helix structure of DNA as the chemical basis

1. See *How it Works*, 23ANDME, <https://www.23andme.com/howitworks/> (last visited Nov. 9, 2012) ("23andMe is a DNA analysis service providing information and tools for individuals to learn about and explore their DNA."); see also Anita Hamilton, *Best Inventions of 2008: The Retail DNA Test*, TIME (Oct. 29, 2008), http://www.time.com/time/specials/packages/article/0,28804,1852747_1854493_1854113,00.html ("The 600,000 genetic markers that 23andMe identifies and interprets for each customer are 'the digital manifestation of you'"). Other prominent DTC testing companies include deCODE Genetics, Pathway Genomics, Map My Gene, and Gene Planet. See *GPPC Releases Updated List of DTC Genetic Testing Companies*, GENETICS & PUB. POLICY CTR. (Aug. 11, 2011) [hereinafter *GPPC List*], http://www.dnapolicy.org/news.release.php?action=detail&pressrelease_id=145, <http://www.dnapolicy.org/resources/DTCtableAug2011Alphabydisease.pdf>.

2. Hamilton, *supra* note 1.

We are at the beginning of a personal-genomics revolution that will transform not only how we take care of ourselves but also what we mean by personal information. [N]ow personal genotyping is available to anyone who orders the service online and mails in a spit sample. Not everything about how this information will be used is clear yet—23andMe has stirred up debate about issues ranging from how meaningful the results are to how to prevent genetic discrimination—but the curtain has been pulled back, and it can never be closed again. And so for pioneering retail genomics, 23andMe's DNA-testing service is Time's 2008 Invention of the Year.

Id.

3. Mendel's 1865 research revealed that "[e]ach parent contributes one factor of each trait shown in offspring," that the "two members of each pair of factors segregate from each other during gamete formation," that "males and females contribute equally" to their offspring's traits, and that "[a]cquired traits are not inherited." See M. Tefvik Dorak, *Landmarks in the History of Genetics*, DORAK.INFO, <http://www.dorak.info/genetics/notes01.html> (last updated May 7, 2009).

4. *Id.*

for gene heredity.⁵ Throughout the mid and late twentieth century, genetic researchers made substantial advances, beginning with newborn screening for phenylketonuria⁶ in the 1960s, which ultimately led to screening for numerous other genetic diseases in the 1970s and 1980s.⁷ In 1990, scientists began the Human Genome Project, an international effort to discover and study all human genes and make them accessible for further biological research.⁸ Scientists also strove to determine the complete sequence of the three billion DNA base pairs in the human genome.⁹ The project was completed in 2003, two years ahead of schedule.¹⁰

As a result of these efforts, scientists have now developed genetic tests for more than 2,200 diseases; around 2,000 of those tests can be used today in clinical settings.¹¹ However, since researchers have yet to pinpoint most of the genetic components that cause diseases, genetic testing may not provide a complete or totally valid result.¹² Some genetic tests focus on a single gene or genetic mutation to detect a specific genetic disorder, but so-called genomic technologies¹³ have been developed to examine “multiple genes that may increase or decrease a person’s risk of

5. *Id.*

6. Phenylketonuria is a rare genetic error of metabolism that, if left untreated, leads to mental retardation and other health abnormalities. Treatment involves placing newborns on a special diet from which most of the phenylalanine has been removed. *See* Diane B. Paul, *The History of Phenylketonuria Testing in the U.S.*, in FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING A5 (Neil A. Holtzman & Michael S. Watson eds., 1997), available at <http://biotech.law.lsu.edu/research/fed/tfgt/appendix5.htm>.

7. *See* Ricki Lewis, *A Brief History of Genetic Testing*, SCIENCE PROGRESS (May 5, 2008), <http://scienceprogress.org/2008/05/a-brief-history-of-genetic-testing/> (In the 1970s, scientists began newborn and population testing for Tay-Sachs disease and Sickle Cell disease. This was followed by advances in prenatal and carrier testing for diseases such as Down’s syndrome and cystic fibrosis).

8. *See History of the Human Genome Project*, OAK RIDGE NAT. LAB., http://www.ornl.gov/sci/techresources/Human_Genome/project/hgp.shtml (last update June 4, 2012).

9. *Id.*

10. Press Release, Int’l Human Genome Sequencing Consortium, Int’l Consortium Completes Human Genome Project (Apr. 14, 2003), http://www.ornl.gov/sci/techresources/Human_Genome/project/50yr/press4_2003.shtml. Other stated goals of the Human Genome Project were to store the genomic information in databases, “improve tools for data analysis, transfer related technologies to the private sector, and address the ethical, legal, and social issues (ELSI) that may arise from the project.” *See About the Human Genome Project*, OAK RIDGE NAT. LAB., http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml (last updated Sept. 19, 2011) (emphasis in original).

11. *See Public Health Genomics: Genetic Testing*, CTNS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/genomics/gtesting/> (last updated May 3, 2012).

12. *Id.*

13. *See Public Health Genomics: Genomics and Health*, CTNS. FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/genomics/public/index.htm> (last updated Sept. 18, 2012) (“Genomic” hyperlink). Genomic testing refers to the study of a person’s entire genetic makeup, rather than gene-specific testing, and “the relationship between genes, environment, and behaviors” which can explain “why some people get sick, while others do not.” *Id.*

common diseases, such as cancer or diabetes.”¹⁴ These types of tests analyze an individual’s DNA for individual base¹⁵ changes called single nucleotide polymorphisms (“SNPs”)¹⁶ to then estimate the individual’s risk for certain conditions, both common and rare.¹⁷ Estimated risk predictions are based on studies comparing the existence of certain SNPs to the occurrence of certain conditions and diseases within a greater population.¹⁸

Direct-to-consumer (“DTC”) marketing for genome-wide genetic tests emerged as the Human Genome Project came to an end.¹⁹ Companies began using print, television, and Internet advertising to reach consumers—a framework previously employed predominantly by pharmaceutical companies.²⁰ More DTC testing companies emerged worldwide as internet access and usage increased throughout the next decade, allowing consumers to directly order test kits online without ever involving a physician or genetics specialist.²¹ Typically, consumers go to one of the DTC testing company websites, order the test kit,²² take either a saliva sample or cheek swab using the kit, send the kit back to the company, and receive their results within several weeks, usually via the

14. *Id.*

15. “The information in DNA is stored as a code made up of four chemical bases . . .” (adenine, guanine, cytosine, and thymine). There are about three billion bases in human DNA. The sequence of these bases determines the information available for building and maintaining an organism (i.e. a person’s genetic code). *See What is DNA?*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/handbook/basics/dna> (last updated May 13, 2013).

16. “Single nucleotide polymorphisms, frequently called SNPs . . . are the most common type of genetic variation. . . . Each SNP represents a difference in a single DNA building block [or base], called a nucleotide.” There are about ten million SNPs in the human genome, and most have no effect on a person’s health. *What Are Single Nucleotide Polymorphisms (SNPs)?*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/handbook/genomicresearch/snp> (last updated May 13, 2013). However, some of these SNPs may help physicians and researchers “predict an individual’s response to certain drugs, susceptibility to certain environmental factors . . . and risk of developing particular diseases. SNPs can also be used to track the inheritance of disease genes within families.” *Id.*

17. *See* Karen Norrgard, *DTC Genetic Testing for Diabetes, Breast Cancer, Heart Disease and Paternity*, 1 NATURE EDUC. 1, 1 (2008), available at <http://www.nature.com/scitable/topicpage/dtc-genetic-testing-for-diabetes-breast-cancer-698>.

18. *Id.*

19. *See Direct to Consumer Marketing of Genetic Tests*, NAT’L HUMAN GENOME RESEARCH INST. (Mar. 23, 2004), <http://www.genome.gov/12010659>.

20. *Id.* (“The advertising of health-related products directly to consumers, a \$3 billion per year industry, first appeared in the early 1980’s with the marketing of prescription drugs in print and television advertisements.”)

21. Jane Kaye, *The Regulation of Direct-to-Consumer Genetic Tests*, 17 HUMAN MOLECULAR GENETICS R180 (2008), available at <http://hmg.oxfordjournals.org/content/17/R2/R180.full.pdf+html>.

22. Test kits typically include instructions on how to collect the DNA sample, a tube and/or swab to be used for saliva collection, and a pre-addressed package to send the sample to the DTC testing company. *Consumer’s Guide to Genetic Testing*, CTR. FOR JEWISH GENETICS (2008), <http://www.jewishgenetics.org/?q=content/consumer%E2%80%99s-guide-direct-consumer-genetic-testing>.

internet.²³ Depending on the amount of genetic information involved and whether or not the test kit purchased includes a genetic counseling component, DTC testing can cost as little as one hundred dollars.²⁴

According to a study conducted by the Genetics and Public Policy Center, there were twenty DTC testing companies in the United States and seven additional DTC companies that required physicians to request the DNA tests as of August 2011.²⁵ Of the twenty DTC testing companies, eight offer some sort of genetic counseling to consumers, though only five do so without additional costs.²⁶ Each company tests for predispositions to various diseases and characteristics, differing widely depending on the company. They test for genetic conditions ranging from serious, untreatable diseases such as Alzheimer's disease and Lou Gehrig's disease ("ALS") to physical characteristics, such as male pattern baldness, and personality traits.²⁷

This Note explores the ever-evolving genetics testing industry, specifically DTC tests that are manufactured and marketed by private companies.²⁸ Part I evaluates the arguments in favor of DTC genetic testing, and Part II assesses the concerns held by those opposed to DTC testing. After giving an overview of the current United States regulatory framework in Part III, Part IV outlines a selection of regulatory

23. Pauline C. Ng et al., *An Agenda for Personalized Medicine*, 461 NATURE 724, 724 (Oct. 8, 2009), available at http://www.gis.a-star.edu.sg/internet/site/data/sup_data/2249/an_agenda_for_personalized_medicine.pdf.

24. See, e.g., *Store*, 23ANDME, <https://www.23andme.com/store/cart> (last visited Jan. 20, 2012) (a single \$99 test, plus \$9.95 shipping).

25. GENETICS & PUB. POL'Y CTR., *supra* note 1. Excluded from the study were companies "not offering testing for at least one medical condition, one pharmacogenomic test, or one nutrigenomic test," meaning "companies that sell only fetal sex tests, ancestry tests, and/or paternity/identity tests." *Id.*

26. *Id.* For example, additional costs associated with obtaining genetic counseling via 23andMe can go up to \$375. See *Comprehensive Clinical Genetic Counseling Session*, INFORMED MED. DECISIONS, <http://informeddna.com/index.php/23andme.html> (last visited Nov. 9, 2012).

27. See *GPPC List*, *supra* note 1.

28. This Note will focus on these predictive genome-wide DTC genetic tests rather than pharmacogenetic/pharmacogenomic testing. Pharmacogenomic testing is a growing field that examines the small inherited variations in patients' genes' nucleotide content that dictate drug response and "explores the ways these variations can be used to predict" how a patient will respond or not respond to a certain drug. See *One Size does not Fit All: The Promise of Pharmacogenomics*, NAT'L CTR. FOR BIOTECHNOLOGY INFO. (Mar. 31, 2004), <http://www.ncbi.nlm.nih.gov/About/primer/pharm.html>. This Note will not discuss nutrigenomic testing, which involves genome-wide genetic testing in combination with lifestyle factors, such as diet, exercise, and smoking, of the tested individual to assess his or her potential health risks. Companies offering these tests then present recommendations, often including nutritional supplements sold by the testing company. See Katrina A.B. Goddard et al., *Awareness and Use of Direct-to-Consumer Nutrigenomic Tests, United States, 2006*, 9 GENETICS IN MED. 510, 510 (Aug. 2007), available at http://www.cdc.gov/genomics/update/file/print/goddard_dtc.pdf.

recommendations published by various American and international genetics organizations and governmental agencies. Part V then examines Germany's regulatory approach, which results in an effective ban on DTC genetic testing. Ultimately, after addressing some proposed solutions, Part VI advocates for a regulatory approach in the United States comparable to Germany's, though less strict and more nuanced.

I. POTENTIAL BENEFITS OF DIRECT-TO-CONSUMER GENETIC TESTING

Proponents of DTC testing, including scholars and the DTC companies themselves, cite numerous benefits that could result from genetic testing. These DTC testing services make genetic testing more accessible, because they are relatively affordable and not dependent on an individual's geographic location or ability to meet with a physician or geneticist.²⁹ Moreover, DTC testing companies and some scholars highlight the benefits of individual autonomy and the right of individuals to access their own personal genetic information—part of their identity—without the involvement of a physician.³⁰ Proponents believe this autonomy leads to greater consumer empowerment because it allows individuals to make proactive, preventive lifestyle changes in response to test results indicating predispositions to various conditions.³¹ Such a development, in theory, should ultimately lead to improved overall health in those consumers.³²

This “personalized medicine” approach, according to proponents of DTC testing, gives individuals the ability to make more informed medical decisions, focusing on prevention, prediction, and targeted intervention earlier than was possible before genomic testing.³³ If an individual's results indicate a significantly higher risk for a certain disease or condition, he or she may begin screening for that disease early in order to

29. See Norrgard, *supra* note 17, at 1–2; see also CTR. FOR JEWISH GENETICS, *supra* note 22.

30. *Policy Forum*, 23ANDME, <https://www.23andme.com/about/policy/> (last visited Oct. 1, 2012) (“Genetic information is a fundamental element of a person's body, identity and individuality. As such, the rights that people enjoy with regard to financial, medical and other forms of personal information should apply to genetic information as well.”); see also ROBERT W. KOLB, *THE ETHICS OF GENETIC COMMERCE* 58–60 (2007) (the policy presupposition favoring individual autonomy—the right to be free to make self-regarding decisions without coercion or manipulation—favors allowing people to choose to access their own genetic information via DTC testing).

31. Norrgard, *supra* note 17, at 4.

32. *Id.*

33. *Personalized Medicine*, U.S. NEWS & WORLD REPORT, <http://health.usnews.com/health-conditions/cancer/personalized-medicine#2> (last updated Jan. 1, 2011) (“Personalized medicine is about making the treatment as individualized as the disease. It involves identifying genetic, genomic, and clinical information that allows accurate predictions to be made about a person's susceptibility of developing disease, the course of disease, and its response to treatment.”).

detect the disease and prevent it from progressing significantly.³⁴ There is no clear indication, however, that individuals actually change their lifestyle or behavior once they receive the genetic predisposition results.³⁵

Proponents also emphasize increased privacy as a major benefit of DTC testing. Without the involvement of a physician, test results do not become part of an individual's medical records, which can leave them vulnerable to discrimination by employers or insurers based on their genetic predispositions.³⁶ This was more of a concern before the 2008 passage of the Genetic Information Nondiscrimination Act ("GINA"),³⁷ but DTC testing companies still emphasize complete security, privacy, and individual control over access to the genetic information.³⁸ Proponents note, however, that should an individual choose to share his or her DTC testing results, the educational value of such genetic information could be highly beneficial to family members and would increase public awareness of genetic diseases in general.³⁹ DTC testing might also challenge health care providers to become better educated about genetics and heritability.⁴⁰ Finally, DTC testing proponents argue that there is public enthusiasm for genetic testing and information, and testing companies provide for this unmet need.⁴¹

34. *See id.*

35. *See* Bridget M. Kuehn, *Risks and Benefits of Direct-to-Consumer Genetic Testing Remain Unclear*, 300 J. AM. MED. ASS'N 1503, 1503-04 (2008), available at http://web.mit.edu/writing/2009/June/Risks_and_Benefits_of_Direct_Genetic_Testing.pdf. Thus, further study of the behavior of those who undergo predictive genetic testing would be useful to evaluate the purported merits of DTC testing and personalized medicine.

36. *See* Norrgard, *supra* note 17, at 1-2; Adam J. Wolfberg, *Genes on the Web—Direct-to-Consumer Marketing of Genetic Testing*, 355 NEW ENG. J. MED. 543, 543 (2006); *Policy Forum*, 23ANDME, *supra* note 30.

37. The Genetic Information Nondiscrimination Act of 2008 (GINA), Pub. L. No. 110-233, 122 Stat. 881 (2008), prohibits health insurers from requesting or requiring genetic information of an individual or the individual's family members or from using the genetic information for decisions regarding coverage, rates, or preexisting conditions. The law also prohibits most employers from using genetic information to make employment decisions. It provides a basis for state nondiscrimination laws. However, GINA does not apply to life insurance, disability insurance, or long-term care insurance. *See Information for Researchers and Health Care Professionals*, DEP'T OF HEALTH AND HUMAN SERVS. (Apr. 6, 2009), <http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf>.

38. *See, e.g., Policy Forum*, 23ANDME, *supra* note 30.

39. *Id.*; *see also* CTR. FOR JEWISH GENETICS, *supra* note 22.

40. *See* Norrgard, *supra* note 17, at 4.

41. *See* Stuart Hogarth et al., *The Current Landscape for Direct-to-Consumer Genetic Testing: Legal, Ethical, and Policy Issues*, 9 ANN. REV. OF HUMAN GENETICS 161, 168 (2008), available at http://step.berkeley.edu/Journal_Club/paper1_04212009.pdf ("[T]here is a public appetite for information about the fruits of the Human Genome Project, and that lack of clinical uptake of new tests can be addressed by DTC advertising and test provision.").

II. POSSIBLE DRAWBACKS OF DIRECT-TO-CONSUMER GENETIC TESTING

Despite these asserted benefits, many scientists and scholars harbor serious concerns about the clinical validity,⁴² analytical validity,⁴³ and clinical utility⁴⁴ of predictive DTC testing. In addition, some in the genetics field fear that DTC testing may result in negative psychological and social consequences and problematic ethical issues related to informed consent. These concerns underlie the numerous cautionary public policy recommendations outlined in Part IV of this Note.

A. Clinical and Analytical Validity Concerns

Though most scholars agree that the raw data obtained via DTC genetic testing is accurate, some are concerned about the clinical validity of such tests.⁴⁵ Genetic testing is generally more susceptible to laboratory problems than other types of testing, including less laboratory vigilance, since most genetic testing results do not indicate abnormalities.⁴⁶ DTC companies handle a high volume of tests and often contract the actual genetic testing out to a third party company, which increases the risk of mix-ups between tests.⁴⁷ In fact, in June 2010, 23andMe announced that up to ninety-six individuals may have received and viewed results that were not their own, due to human error in the processing of their saliva samples by the laboratory 23andMe employed to conduct their tests.⁴⁸

42. *Id.* at 169. Clinical validity means that the test result correlates with the presence or absence, or heightened risk of a specific disease.

43. *Id.* Analytical validity means that the test consistently and correctly shows that a specific gene mutation is present or absent.

44. See Audrey Huang, *Who Regulates Genetic Tests?*, GENETICS & PUB. POL'Y CTR., http://www.dnapolicy.org/images/issuebriefpdfs/Who_Regulates_Genetic_Tests_Issue_Brief.pdf (last updated May 30, 2008) ("Clinical utility refers to whether using the test has a positive impact on a patient's health and wellbeing.").

45. See, e.g., Ng et al., *supra* note 23.

46. See LORI B. ANDREWS ET AL., ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY 116–17, 127 (1994), available at http://www.nap.edu/catalog.php?record_id=2057.

47. See Jennifer A. Gniady, Note, *Regulating Direct-to-Consumer Genetic Testing: Protecting the Consumer Without Quashing a Medical Revolution*, 76 FORDHAM L. REV. 2429, 2447 (2008), available at <http://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?article=4354&context=flr>.

48. Turna Ray, *UPDATE: 23andMe Says LabCorp Incorrectly Processed 96 Samples, Mixing up Customer Data*, PHARMACOGENOMICS REPORTER (June 9, 2010), <http://www.genomeweb.com/dxpgx/23andme-says-labcorp-incorrectly-processed-96-samples-mixing-customer-data>.

23andMe said it is considering implementing various safeguards to ensure this type of error does not happen again, including removing manual steps at the lab, completely automating the sample analyses, and implementing further data checks before uploading it to customer accounts. . . . Additionally, 23andMe said it will collect data regarding sex for all new

Moreover, there are often disparities in results between different genetic testing companies.⁴⁹ This occurs, at least in part, because companies use different population definitions when determining the average population disease risk⁵⁰ and different sets of clinically validated genetic markers in calculating relative disease risk.⁵¹ For example, one small study comparing 23andMe and Navigenics DTC test results found that only two-thirds of relative risk predictions between the two companies qualitatively matched.⁵² Similarly, for seven diseases, fifty percent or less of the predictions of the two companies agreed.⁵³ Finally, since the markers discovered and used by DTC testing companies do not explain the majority of the genetic heritability of disease, the test results can be inherently misleading.⁵⁴ If two different DTC testing companies present the consumer with inconsistent results, the consumer may be left wondering which results to believe.

B. Clinical Utility Concerns

Since genomic test results, for most people, do not reveal a significantly increased risk for many genetic diseases, physicians or patients do not usually have a clear course of action to take.⁵⁵ This results

customers prior to laboratory processing as an additional quality check ahead of uploading data.

Id.

49. See Ng et al., *supra* note 23, at 724.

50. *Id.* For example, some DTC companies distinguish between men and women when determining average population disease risk, while others distinguish populations primarily based on age. Because of these definitional differences, consumers could receive disparate results when their risk is compared to that of the greater population.

51. *Id.*

Risk markers are determined from genome-wide association studies. . . . Each marker has different possible alleles. Alleles that occur more frequently in disease patients are designated as risk alleles and have odds ratios greater than 1. . . . DTC companies harness the same publicly available research to decide which markers to include, and for the most part, could use the same or similar markers. Yet no disease has an identical set of markers between the two DTC companies because each company has its own criteria for accepting a genome-wide association result into its relative risk calculation.

Id.

52. *Id.*

53. *Id.*

54. See *id.* at 725; see also CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 11 (“Despite the many scientific advances in genetics, researchers have only identified a small fraction of the genetic component of most diseases. Therefore, genetic tests for many diseases are developed on the basis of limited scientific information and may not yet provide valid or useful results to individuals who are tested.”).

55. See Kuehn, *supra* note 35, at 1505.

in limited clinical utility for most DTC test results.⁵⁶ Clinical utility is further limited because most tests do not mandate sufficient genetic counseling.⁵⁷ Consumers might be confused or have difficulty understanding the often-nuanced results.⁵⁸ If the individual does not interpret his or her results correctly, he or she cannot take the appropriate preventive measures and may even make adverse medical decisions.⁵⁹ For example, an individual may undergo unnecessary preventive testing or unnecessary procedures such as a prophylactic mastectomy in response to a genetic test showing an increased risk of breast cancer.⁶⁰ They might also cease using prescribed medications.⁶¹ These unnecessary procedures and tests could drain the health care system, using physicians' time and health care funds that would otherwise be used for proven and necessary medical reasons.⁶²

C. Psychological Consequences

Due to the lack of thorough, face-to-face genetic counseling, there are concerns about the possible negative psychological effects of DTC testing results. Though not empirically proven, many scholars and practitioners have discussed psychological and social consequences such as reinforcement of deterministic attitudes, serious self-identity difficulties, strained familial relationships, and increased anxiety and depression.⁶³ Since many DTC test consumers will not receive meaningful genetic

56. *Id.* at 1504–05.

57. Even those DTC companies that do offer or require some form of genetic counseling usually only provide “telephone or on-line counseling,” which at least some scholars and many clinicians believe to be an unsatisfactory substitute. Sivan Tamir, *Direct-to-Consumer Genetic Testing: Ethical-Legal Perspectives and Practical Considerations*, 18 MED. L. REV. 213, 219 (2010); see also Adam J. Wolfberg, *supra* note 36, at 544.

58. See Hogarth et al., *supra* note 41, at 168 (using the example of BRCA genes to show the importance of understanding the nuances and context of test results).

59. Tamir, *supra* note 57, at 219.

60. *Id.*

61. *Id.*

62. Amy L. McGuire & Wiley Burke, *An Unwelcome Side Effect of Direct-to-Consumer Personal Genome Testing*, 300 J. AM. MED. ASS'N. 2669, 2669 (2008) (highlighting the need to protect the “medical commons” and resolve the clinical utility problems of DTC genomic testing).

63. See Gabrielle Kohlmeier, *The Risky Business of Lifestyle Genetic Testing: Protecting Against Harmful Disclosure of Genetic Information*, 2007 UCLA J.L. & TECH. 5, 24 (2007), available at http://www.lawtechjournal.com/articles/2007/05_071230_kohlmeier.pdf. These negative psychosocial effects are especially applicable when DTC testing shows near certain probability of an untreatable genetic disease, such as Huntington's disease or Familial Adenomatous Polyposis (inherited colorectal cancer where existence of the gene translates into a nearly one hundred percent chance of developing colon polyps and colorectal cancer). See *Diseases & Conditions—FAP*, CLEVELAND CLINIC, <http://www.clevelandclinic.org/registries/inherited/fap.htm> (last visited Sept. 25, 2012).

counseling and, consequently, may misinterpret their DTC test results, these psychological reactions may be founded upon a faulty understanding of these test results.⁶⁴ Moreover, misinterpretation of DTC test results may lead to a false sense of security if results show a lower probability of disease than anticipated.⁶⁵

D. Ethical Problems

The possibilities of non-consent or a lack of informed consent worry many medical and genetics professionals. DTC testing companies have no definitive way of knowing if the individual requesting the test sends in his or her *own* DNA sample.⁶⁶ In other words, an individual could collect the genetic material of another person without that person's consent and subsequently obtain and use the genetic information received from the DTC testing company.⁶⁷ This could amount to a violation of human dignity and a serious breach of privacy.⁶⁸

Even when an individual consents to DTC genetic testing, this consent might not be informed, completely autonomous consent.⁶⁹ Misleading advertising by DTC testing companies minimizes the risks and overstates the possible benefits of genomic testing.⁷⁰ The advertisements may "induce vulnerable consumers to purchase the tests, thereby diminishing their autonomy."⁷¹ The advertisements also tend to delude consumers into thinking that their genetic traits alone determine their risk of developing a

64. See Hogarth et al., *supra* note 41, at 168. Test results can be nuanced and complex, leading to misinterpretation and mistaken belief that one has an increased genetic risk of developing certain diseases.

65. See Norrgard, *supra* note 17, at 3 (discussing the possible false sense of security if a woman tests negative for genetic mutations causing breast and ovarian cancer, BRCA 1 and 2). Absence of those genetic mutations alone does not preclude the possibility that a woman will develop such cancers, which can be caused by a myriad of factors. This false sense of security might ultimately be detrimental if a woman forgoes screening and preventative measures as a result. *Id.*

66. Tamir, *supra* note 57, at 221.

67. *Id.*

Non-consensual use of genetic testing pertains to unlawful actions, where genetic material (i.e. saliva left on a glass, hair follicles, etc.) is obtained, through collection or removal, without the consent of the (involuntary) 'source' and consequently, the genetic information derived is used, without the source's consent, to his or her detriment, or to benefit others.

Id. The article provides three examples of situations when non-consensual genetic testing might occur.

68. *Id.* at 222 ("[A]n intrusion on basic human dignity and autonomy, a violation of the source's bodily integrity, a breach of information privacy, and essentially deprives the source of the opportunity to exercise his right not to know particular genetic information.").

69. See Deepthy Kishore, *Test at Your Own Risk: Your Genetic Report Card and the Direct-to-Consumer Duty to Secure Informed Consent*, 59 EMORY L.J. 1553, 1576, 1590-93 (2010).

70. *Id.* at 1590, 1592-93.

71. *Id.*

disease when heredity is actually only one factor.⁷² In 2006, as a result of this misleading advertising, the Federal Trade Commission (“FTC”) issued a consumer fact sheet detailing suggested guidelines for individuals considering DTC genetic testing.⁷³ Ultimately, the FTC urged consumer caution.⁷⁴

III. THE UNITED STATES REGULATORY FRAMEWORK

Despite the disagreement and risks associated with DTC genetic testing, the United States federal government exerts only minimal control over genetic testing laboratories and the DTC testing industry.⁷⁵ Currently, federal regulatory authority over DTC testing falls within the province of the Food and Drug Administration (“FDA”), the Centers for Medicaid and Medicare Services (“CMS”) under the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”), state governments and agencies, and the FTC.⁷⁶ None of the regulatory bodies, however, have clear authority over the accuracy, design, and application of DTC genetic tests.⁷⁷

Currently, the FDA regulates in vitro diagnostic devices (“IVDDs”)⁷⁸ as medical devices, via the Medical Device Amendment of the Federal Food, Drug, and Cosmetic Act (“FDCA”).⁷⁹ However, the vast majority of

72. *Id.* at 1593 (“One study showed that 95% of websites for DTC genetic testing services lacked information about the significance of lifestyle, family history, or routine screening.”).

73. *Facts for Consumers—At-Home Genetic Tests: A Healthy Dose of Skepticism May Be the Best Prescription*, U.S. FED. TRADE COMM’N (FTC) (July 2006), <http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea02.shtm>.

74. *Id.* Recommendations for consumers include pre-test consultation with their physician and/or genetic counselor and post-test discussion of the results to aid in interpretation and next steps or prevention. The FTC also warns consumers that DTC tests are not subject to FDA approval. *Id.*

75. Hogarth et al., *supra* note 41, at 170.

76. See Andrew S. Robertson, Note, *Taking Responsibility: Regulations and Protections in Direct-to-Consumer Genetic Testing*, 24 BERKELEY TECH. L.J. 213, 221 (2009), available at <http://www.btlj.org/data/review/24-213-243.pdf>; see also Gniady, *supra* note 47, at 2452–53 (discussion of the FTC’s somewhat limited regulatory authority, which extends only to prohibiting false or misleading advertising related to DTC genetic testing).

77. Robertson, *supra* note 76, at 221.

78. Genetic tests are IVDDs (“test kits”) if the components are bundled, labeled, and sold to a laboratory as a unit. IVDDs must undergo premarket review of safety, accuracy, and utility before they may be distributed commercially. Audrey Huang, *FDA Regulation of Genetic Tests*, GENETICS & PUB. POL’Y CTR., http://www.dnapolicy.org/policy.issue.php?action=detail&issuebrief_id=11 (last updated May 30, 2008).

79. *Id.* Congress passed the Federal Food, Drug, and Cosmetic Act in 1938 “after a legally marketed toxic elixir killed 107 people” *Regulatory Information: Legislation*, U.S. FOOD & DRUG ADMIN. (FDA), <http://www.fda.gov/RegulatoryInformation/Legislation/default.htm> (last updated July 9, 2012). The legislation “overhauled the public health system and authorized the FDA to [require proof] of safety for new drugs, issue standards for food, and conduct factory inspections.” *Id.* The

DTC genetic tests are not IVDDs or “test kits,” but rather laboratory developed tests (“LDTs”).⁸⁰ In fact, “test kits” subject to FDA review make up only about one percent of the commercially available genetic tests.⁸¹ The only exceptions are in vitro diagnostic multivariate index assays (“IVDMIAs”), which use laboratory data and an algorithm to generate a result with the purpose of diagnosing, treating, or preventing diseases such as breast cancer, prostate cancer recurrence, and cardiovascular disease.⁸² Thus, because the FDA exercises its enforcement discretion,⁸³ LDTs and DTC tests exist in a loophole, and most are not subject to any analysis to gauge their clinical validity before marketing and use.⁸⁴

LDTs and DTC testing do fall under CMS’s power to implement and enforce the CLIA, which “applies to all clinical laboratories that operate or provide testing services in the United States.”⁸⁵ Genetic testing is not, however, subject to proficiency testing requirements for high-complexity laboratory tests.⁸⁶ This has led to some concern among genetics scholars and professionals about the lack of CLIA oversight over genetic testing and a lack of transparency in the enforcement process.⁸⁷ To address these concerns, many have called for laboratory guidelines specifically tailored to genetic testing.⁸⁸

Medical Device Amendments of 1976 applied effectiveness standards and safety precautions to newer devices. *Id.*

80. See Robertson, *supra* note 76, at 221. LDTs are “genetic tests that are designed and produced within a clinical laboratory”

81. See Gniady, *supra* note 47, at 2438 (citing Huang, *supra* note 44).

82. These types of tests, according to draft guidelines, are considered medical devices and are subject to FDA premarket review. See FDA, DRAFT GUIDANCE FOR INDUSTRY, CLINICAL LABORATORIES, AND FDA STAFF: IN VITRO DIAGNOSTIC MULTIVARIATE INDEX ASSAYS (July 26, 2007), available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071455.pdf>.

83. The FDA may exercise discretion when deciding whether or not to promulgate and enforce certain non-legislative rules and regulations, and they may enforce them in the manner they see fit. These rules are interpretative. See 5 U.S.C. § 553(b)(A)(2006).

84. Robertson, *supra* note 76, at 224.

85. See Hogarth et al., *supra* note 41, at 170.

86. *Id.*

CMS issued final regulations that implemented CLIA in 1992. These regulations created “specialty areas” for laboratories that perform high-complexity tests, which specified personnel, quality assurance, and proficiency testing requirements for tests such as toxicology and immunology. Genetic testing, which was in its infancy at the time, was not included in these specialty areas. As a result, proficiency testing was never mandated for genetic testing laboratories.

Id. (internal citation omitted).

87. *Id.*

88. *Id.*

The FTC, another federal regulatory body, has the power to enforce a prohibition of misleading or deceptive advertising for DTC genetic tests.⁸⁹ In combination with the FDA, the FTC could ensure that consumers have correct information about claims made by DTC testing companies and manufacturers who do not have FDA approval for their products.⁹⁰ The FTC could also enforce a mandatory disclaimer stating that the tests are not FDA approved or subject to FDA approval.⁹¹

Finally, many states have exercised their authority to regulate DTC testing via laboratory regulations that are more stringent than CLIA requirements.⁹² Others have exercised authority to regulate who may order genetic tests and receive the results from the testing laboratories.⁹³ In fact, as of 2007, thirteen states specifically prohibited DTC genetic testing.⁹⁴ Other states significantly limit the DTC testing industry by requiring physician referral or specifying that only certain tests are permissible for DTC marketing and sale.⁹⁵ Meanwhile, twenty-five states and the District of Columbia remain silent on the issue and allow DTC testing without restrictions.⁹⁶

89. See Gniady, *supra* note 47, at 2452. However, “the extent of the FTC’s regulatory authority extends only to prohibiting false or misleading advertising.” *Id.*

90. *Id.* at 2453.

91. *Id.* at 2472.

92. See Robertson, *supra* note 76, at 224 (citing Gail H. Javitt et al., *Direct-to-Consumer Genetic Tests, Government Oversight, and the First Amendment: What the Government Can (and Can’t) Do to Protect the Public’s Health*, 57 OKLA. L. REV. 251, 274 (2004)). Both New York and Washington have opted out of the CLIA program in favor of state-supervised alternatives, which are more stringent than CLIA. *Id.*

93. *Id.*

94. *Id.*; see also Aruna Prabhala, *Center Releases Analysis of State DTC Laws*, GENETICS & PUB. POL’Y CTR. (July 2007), http://www.dnapolicy.org/news.eneews.article.nocategory.php?action=detail&newsletter_id=24&article_id=100; GENETICS & PUB. POL’Y CTR., SURVEY OF DIRECT-TO-CONSUMER STATUTES AND REGULATIONS (June 2007) [hereinafter GENETICS & PUB. POL’Y CTR., SURVEY], <http://www.dnapolicy.org/resources/DTCStateLawChart.pdf>. States that completely prohibit DTC testing without physician involvement are Alabama, Connecticut, Georgia, Hawaii, Idaho, Kentucky, Michigan, New Hampshire, Pennsylvania, Rhode Island, South Carolina, Tennessee, and Wyoming. GENETICS & PUB. POL’Y CTR., SURVEY, *supra*.

95. GENETICS & PUB. POL’Y CTR., SURVEY, *supra* note 94. For example, California allows DTC tests, but only those which test for “pregnancy, glucose level, cholesterol, occult blood, and any other test for which there is a test for a particular analyte approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit.” *Id.* at 1. Essentially, this constitutes a de facto ban on DTC genetic testing. Similarly, New York effectively bans DTC testing via its provision stating that “[t]est results cannot be sent directly to patients except with written consent of the physician or authorized person . . .” *Id.* at 9.

96. See *id.*

IV. RECOMMENDATIONS FROM U.S. AND EUROPEAN GOVERNMENTAL, MEDICAL, AND GENETICS ORGANIZATIONS

The U.S. Government Accountability Office (“GAO”), the FDA, and several domestic and European medical and genetics professional organizations have issued recommendations regarding DTC testing. Despite these recommendations, U.S. government regulation remains lax. In 2010, the GAO published testimony before the Subcommittee on Oversight and Investigations of the House Energy and Commerce Committee, highlighting the deceptive DTC testing advertising claims.⁹⁷ The GAO conducted an analysis of several DTC testing companies’ results and asserted that the test results were misleading and had limited utility for consumers.⁹⁸

The FDA’s summary from its March 2011 Molecular and Clinical Genetics Panel Meeting also includes several recommendations related to DTC testing.⁹⁹ The recommendations include only permitting pre-symptomatic tests with high predictors for a disease¹⁰⁰ and allowing pharmacogenetic DTC tests through either a prescription or a health care professional.¹⁰¹ The FDA also suggested that DTC testing companies employ a “knowledge test prior to providing the DTC clinical genetic test to assess whether the consumer understands the meaning and

97. U.S. GOV’T ACCOUNTABILITY OFFICE, DIRECT-TO-CONSUMER GENETIC TESTS: MISLEADING TEST RESULTS ARE FURTHER COMPLICATED BY DECEPTIVE MARKETING AND OTHER QUESTIONABLE PRACTICES, GAO-10-847T (July 22, 2010), *available at* <http://www.gao.gov/new.items/d10847t.pdf>. The GAO undertook this study in response to the *Time* article and the increasing availability and visibility of DTC testing. They

[p]urchased 10 tests each from four companies, for \$299 to \$999 per test. GAO then selected five donors and sent two DNA samples from each donor to each company: one using factual information about the donor and one using fictitious information, such as incorrect age and race or ethnicity. After comparing risk predictions that the donors received for 15 diseases, GAO made undercover calls to the companies seeking health advice . . . To assess whether the tests provided any medically useful information, GAO consulted with genetics experts. GAO also interviewed representatives from each company. To investigate advertising methods, GAO made undercover contact with 15 DTC companies, including the 4 tested, and asked about supplement sales, test reliability, and privacy policies. GAO again consulted with experts about the veracity of the claims.

Id.

98. *Id.* at 4.

99. See FDA, SUMMARY FROM THE MOLECULAR AND CLINICAL GENETICS PANEL MEETING—MARCH 8 AND 9, 2011 (2011) [hereinafter FDA, SUMMARY], *available at* <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetings/Meetings/Committees/MolecularandClinicalGenetic/UCM246907.pdf>.

100. Some examples include Huntington’s disease and Adenomatous Polyposis. See CLEVELAND CLINIC, *supra* note 63; Kohlmeier, *supra* note 63.

101. See FDA, SUMMARY, *supra* note 99.

consequences of test results.”¹⁰² Finally, the FDA discussed requiring consumers to participate in qualified, professional genetic counseling with the purchase of a DTC genetic test.¹⁰³

Various medical and genetics organizations have issued policy statements and recommendations regarding DTC testing.¹⁰⁴

The Board of Directors of the American College of Medicine Genetics recommends that genetic testing should only be provided to the public through health care professionals, who should order the tests, interpret the results, and provide pre- and post-test genetic counseling to the individual.¹⁰⁵ In addition, the American Society of Human Genetics (“ASHG”) recommends increased transparency and information accessibility in order to allow consumers to make informed decisions about DTC genetic testing.¹⁰⁶ ASHG also calls for more education for health care providers about the risks and benefits of DTC testing,¹⁰⁷ laboratory regulations specifically targeting DTC genetic testing,¹⁰⁸ and cooperation between the FDA, FTC, and CMS/CLIA to increase overall regulation of DTC testing.¹⁰⁹

102. *Id.* This addresses the aforementioned ethical concerns about lack of informed consent among those who obtain DTC testing.

103. *Id.*

104. Policy statements are not binding upon consumers, DTC companies, or genetics professionals. They are professional guidelines and suggestions for professionals and policymakers to take into consideration. *See, e.g.*, Letter from Eleanor D. Kinney, Section Chair, American Bar Ass’n Section on Admin. Law and Regulatory Practice, to Lisa Jones, Office of Mgmt. and Budget 3 (Dec. 15, 2005), http://www.whitehouse.gov/sites/default/files/omb/assets/inforeg_good_guidance/c-aba.pdf (“[s]ince policy statements are not legally binding”); Admin. Conference of the U.S., Recommendation 92-2, at 2–3 (June 18, 1992), <http://www.acus.gov/best-practices/wp-content/uploads/2011/09/92-2.pdf>.

105. *See* AM. COLL. OF MED. GENETICS BD. OF DIRS. (ACMG), *ACMG Statement on Direct-to-Consumer Genetic Testing*, 6 GENETICS MED. 60 (2004), available at http://www.acmg.net/StaticContent/StaticPages/Direct_Consumer.pdf.

106. *See* AM. SOC’Y OF HUMAN GENETICS (ASHG), *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, 81 AM. J. HUMAN GENETICS 635, 636 (2007), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1950839/> (“To promote transparency and to permit providers and consumers to make informed decisions about DTC genetic testing, companies must provide all relevant information about offered tests in a readily accessible and understandable manner.”).

107. *Id.* at 636–37.

To ensure that providers are aware that genetic tests are being provided DTC and that some of these tests may lack analytic or clinical validity, professional organizations should educate their members regarding the types of genetic tests offered DTC, so that providers can counsel their patients about the potential value and limitations of DTC testing.

Id.

108. *Id.* at 637 (“To ensure the analytic and clinical validity of genetic tests offered DTC and to ensure that claims made about these tests are truthful and not misleading, the relevant agencies of the federal government should take appropriate and targeted regulatory action.”).

109. *Id.* ASHG also calls for a CDC study of “the impact of DTC testing on consumers” *Id.*

European genetics organizations have also issued policy statements. In 2010, for example, the United Kingdom's Human Genetics Commission ("HGC") issued a framework of principles regarding DTC testing.¹¹⁰ These principles include accurate, transparent advertising and provide information for consumers in an understandable and accessible way.¹¹¹ The HGC also recommended pre- and post-test counseling conducted by a qualified genetic counselor, standardized testing methodologies and regulated laboratory processes, and reasonable efforts to ensure actual consent.¹¹² The Council of Europe issued an additional protocol to the Convention on Human Rights and Biomedicine, which stated, "[a] genetic test for health purposes may only be performed under individualised medical supervision."¹¹³ The statement emphasized the need for genetic counseling before and after testing to ensure informed consent¹¹⁴ and clinical utility.¹¹⁵ These recommendations represent the views of many other similar medical and genetics organizations, as well as some European governments.¹¹⁶

V. THE GERMAN APPROACH

With the passage of the Human Genetic Examination Act, Gesetz über genetische Untersuchungen bei Menschen [Gendiagnostikgesetz] ("GenDG"), in 2009, the German government enacted many of these recommendations.¹¹⁷ The legislation requires genetic testing laboratory accreditation, fully informed consent, and genetic counseling for all genetic testing.¹¹⁸ Moreover, it makes anonymous paternity tests illegal,¹¹⁹

110. See HUMAN GENETICS COMM'N. (U.K.), *A Common Framework of Principles for Direct-to-Consumer Genetic Testing Services*, BRIT. SOC. FOR HUMAN GENETICS (July 2010), <http://www.sashg.org/documents/HGC-UK-Policy-on-DTC-testing.pdf>.

111. *Id.* at 6–7.

112. *Id.* at 4, 7, 9–11.

113. Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Genetic Testing for Health Purposes art 7, ¶ 1 (2008), available at <http://conventions.coe.int/treaty/en/treaties/html/203.htm>.

114. *Id.* arts. 9, 10.

115. *Id.* art. 6.

116. Countries with federal legislation regulating and limiting genetic testing and DTC testing include Austria, Belgium, France, Norway, the Netherlands, and Sweden. See Hogarth et al., *supra* note 41, at 172.

117. See Untersuchungen bei Menschen [Gendiagnostikgesetz—GenDG] [Human Genetic Examination Act], July 31, 2009, Bundesgesetzblatt [BGBl] at 2529 (Ger.) [hereinafter GenDG], available at http://www.eurogentest.org/uploads/1247230263295/GenDG_German_English.pdf (contains original German version and English translation).

118. *Id.* §§ 5, 13.

prohibits parents from using genetic testing to determine the sex of their unborn children,¹²⁰ and prohibits genetic discrimination.¹²¹ The GenDG also establishes the independent Genetic Diagnostic Commission, which develops guidelines and reviews new developments in science and technology.¹²² Most importantly for the DTC testing industry, the legislation states that predictive genetic examinations may only be ordered through medical doctors that have specialized genetics training and that provide genetic counseling services.¹²³ In other words, all potential providers of DTC genetic testing would need to persuade German regulatory authorities that their services provide educational and/or informational products rather than medical or clinical services.¹²⁴ The provision, in essence, amounts to a complete ban of DTC genetic testing kits ordered directly by consumers.¹²⁵

The legislation's stated purpose is "to protect human dignity and ensure the individual right to self-determination via sufficient information."¹²⁶ According to the Deutsches Referenzzentrum für Ethik in den Biowissenschaften, the GenDG's requirements for predictive genetic testing are based on the individual right to "informational self-determination"¹²⁷ and concerns about genetic discrimination for insurance

119. *Id.* Some misdemeanor violations are punishable by fines up to five thousand euro. *Id.* § 26(2). Other violations can be punishable with fines of up to five-hundred thousand euro. *Id.*

120. *Id.* § 15(1) ("A prenatal genetic examination may *only* be conducted for *medical purposes* and to the extent it is targeted at determining certain genetic characteristics of the embryo or foetus which, according to the generally accepted status of science and technology, might impair its health before or after birth or if treatment of an embryo . . .") (emphasis added). The section goes on to say that if a fetus's sex is determined during medical prenatal testing, the parents may find out the results.

121. *Id.* § 1. The GenDG prohibits employers and insurance companies from demanding genetic testing of employees and individuals, subject to narrow exceptions.

122. *Id.*

123. *Id.* After having received written information on the contents of the counseling, an individual may waive their right to genetic counseling in writing. *Id.* § 10. Additionally, after counseling, the person concerned shall be allowed adequate time for consideration before undergoing the test. *Id.*

124. David Clark, *Genetic Exceptionalism and Paternalism Themes in New German Legislation*, GENOMICS L. REP. (Sept. 2, 2009), available at <http://www.genomicslawreport.com/index.php/2009/09/02/genetic-exceptionalism-and-paternalism-themes-in-new-german-legislation/>.

125. *Id.*

126. GenDG, *supra* note 116, § 1.

127. See Birte Herrfurth-Rödiger et al., *Predictive Genetic Testing*, GER. REF. CTR. FOR ETHICS IN THE LIFE SCI. [DRZE] (Nov. 2011) (Ger.), available at <http://www.drze.de/in-focus/predictive-genetic-testing>.

Genetic data can touch upon the core areas of an individual's personality. It can therefore be considered to be generally accepted that as far as their own genetic constitution is concerned every individual is entitled to a "right to know" as well as a "right not to know." Both are commonly subsumed under the concept of 'informational self-determination'. Problems arise in cases where one person's right not to know collides with another person's right to know.

Id.

and employment purposes.¹²⁸ Concerns about family conflict, stress due to positive test results, and the danger of “geneticising the living world,”¹²⁹ also contributed to the development of the GenDG.¹³⁰ The requirement that genetic tests be ordered by physicians aims to prevent the commercialization of genetic tests, to guarantee appropriate consultation prior to genetic testing and the correct interpretation of test results, and to protect the results with medical confidentiality requirements.¹³¹ The GenDG’s mandated involvement of qualified genetics health care providers and strict informed consent requirements endeavor to protect consumers of genetic testing from both intrinsic and extrinsic ethical, psychological, and medical consequences.¹³²

Despite these admirable goals, many critics believe the German legislation’s provisions are misguided and overly paternalistic. It is argued that the GenDG is an overly extreme attempt to control German citizens’ access to and use of their own genetic information and is based too heavily on the idea of “genetic exceptionalism.”¹³³ Others argue that the prohibition of employee genetic testing may harm German companies in the international market and may be detrimental to insurance companies.¹³⁴ Conversely, some contend that the GenDG has too many loopholes and does not go far enough to regulate the genetic testing industry.¹³⁵

VI. PROACTIVE REGULATION OF DTC TESTING THE U.S.: FOLLOWING GERMANY’S LEAD, BUT FORGING A MODERATE PATH

Considering the questionable validity and utility of DTC genetic tests, combined with the potentially serious negative consequences, the United States should follow Germany’s example of proactively regulating DTC genetic testing. Though the GenDG, taken as a whole, may appear overly

128. *Id.*

129. *Id.* (available at <http://www.drze.de/in-focus/predictive-genetic-testing/ethical-aspects>). “Geneticising” refers to the reduction of individuals solely to their DNA. *Id.*

130. *Id.*

131. *Id.*

132. *Id.*

133. Clark, *supra* note 124. Genetic exceptionalism is “the belief that genetic information is qualitatively different from other forms of personal or medical information.” *Id.*; see also Caroline Wright, *Update on Genetic Non-Discrimination Legislation*, PHG FOUNDATION (Aug. 10, 2009), <http://www.phgfoundation.org/news/4752/>.

134. See, e.g., Peter Singer, *German Genetics Law a Double-Edged Sword*, JAPAN TIMES (July 18, 2009), available at <http://www.japantimes.co.jp/text/eo20090718a1.html>.

135. See *New German Law Restricts Genetic Testing*, DEUTSCHE WELLE (Apr. 24, 2009), <http://www.dw-world.de/dw/article/0,,4201588,00.html>.

paternalistic, specifically when considering the provisions on prenatal genetic testing that ban seemingly innocuous testing for fetal sex, the provisions related to predictive genetic testing are positive steps in regulating DTC testing. The legislation does not hamper genetic advances—it still gives people the autonomy to choose predictive genetic testing.¹³⁶ The GenDG merely requires the involvement of a physician to ensure fully informed consent and to increase clinical utility of the results.¹³⁷

The United States should, through a single regulatory body (rather than the current fragmented and ineffective regulatory framework), adopt regulations similar to the GenDG, though with some notable differences. Theoretically, the German approach makes sense, but in effect amounts to a total ban of DTC testing.¹³⁸ Requiring the involvement of physicians specializing in genetics would likely be problematic and could severely limit an individual's ability to undergo genome-wide genetic testing.¹³⁹ Therefore, rather than adopting a physician-only approach to DTC testing, the U.S. should enact pre- and post-test genetic counseling requirements by certified professionals and promulgate standardized laboratory and methodological requirements to ensure clinical and analytical validity of the results.¹⁴⁰ Because empirical results are inconclusive as to negative effects, the United States should not completely preclude the possibility of DTC predictive genetic testing and individual choice to pursue that avenue.¹⁴¹ Concerns about individual autonomy and the right to access one's own genetic information persist, so it is doubtful that a complete ban of DTC genetic testing would be politically feasible in this country.

Since 2012, several DTC testing companies have moved to a physician only business model, as prescribed in the German legislation and most policy recommendations.¹⁴² Most physicians, however, lack specialized knowledge of genetics and genetic testing.¹⁴³ Physicians may be ill

136. *Id.*

137. See Herrfurth-Rödiger et al., *supra* note 127.

138. See Clark, *supra* note 124.

139. See Heidi Carmen Howard & Pascal Borry, *Is There a Doctor in the House? The Presence of Physicians in the Direct-to-Consumer Genetic Testing Context*, 3 J. COMMUNITY GENETICS 105, 109 (2012), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3312941/>.

140. See Hogarth et al., *supra* note 41.

141. See, e.g., Cinnamon S. Bloss et al., *Direct-to-Consumer Personalized Genetic Testing*, 20 HUM. MOL. GENET. R132 (2011), available at <http://hmg.oxfordjournals.org/content/early/2011/08/24/hmg.ddr349.full>.

142. See Howard & Borry, *supra* note 139, at 107–08. For a list of DTC companies now employing the physician-only model, see *GPPC List*, *supra* note 1.

143. See Howard & Borry, *supra* note 139, at 107–08 (pointing out the shortcomings of the physician-only approach and the need for further physician education on genetics). For example, the

equipped to fully inform patients about genome-wide predictive genetic testing.¹⁴⁴ Since genetic testing capabilities have progressed rapidly, resulting in a shortage of genetics specialists, state boards and medical associations should institute continuing physician education programs to encourage effective physician involvement in the DTC genetic testing process.¹⁴⁵ To that end, the National Human Genome Research Institute has called for enhanced genetics education in undergraduate and graduate medical programs, as well as continuing professional education.¹⁴⁶ At this point in time, however, requiring the involvement of physicians specializing in genetics would be problematic and may severely limit an individual's ability to undergo genome-wide genetic testing.¹⁴⁷ Mandating physician involvement would likely fail to solve the problems of misinformation and uninformed consent, while restricting individual access.¹⁴⁸

Balancing the need to combat these problems with the desire for personal autonomy, requiring genetic counseling for all DTC tests seems to be the best solution. The American Medical Association emphasized the importance of genetic counseling in their February 2011 letter to the FDA.¹⁴⁹ By mandating quality, thorough genetic testing, the U.S. regulatory body would continue to allow people to access their genetic information, while ensuring that they can fully understand it and cope with it.

United Kingdom's National Health Service instituted a program in 2009 to educate physicians on genetics. See *NHS Starts Pilot Program to Increase Doctors' Genetics Knowledge*, GENOME WEB DAILY NEWS (July 30, 2009), <http://www.genomeweb.com/nhs-starts-pilot-program-increase-doctors-genetics-knowledge>.

144. Howard & Borry, *supra* note 139, at 109–11.

145. *Id.*; see also AM. ACAD. PEDIATRICS, COMM. ON BIOETHICS, *Ethical Issues With Genetic Testing in Pediatrics*, 107 PEDIATRICS 1451, 1454 (2001), available at <http://pediatrics.aappublications.org/content/107/6/1451.full.pdf> (“The number of genetic counselors and geneticists is insufficient for these professionals to take primary responsibility for managing this technology. As a result, primary care physicians will need to expand their knowledge of genetics and the benefits and risks of genetic testing.”).

146. *Improving Providers' Understanding of Genetic Testing*, NAT'L HUMAN GENOME RESOURCE INST., <http://www.genome.gov/10002396> (last updated Apr. 2006).

147. *Id.*

148. *Id.*

149. *AMA to FDA: Genetic Testing Should Be Conducted by Qualified Health Professionals*, AMERICAN MED. ASS'N (Feb. 23, 2011), <http://www.ama-assn.org/ama/pub/news/news/genetic-testing-qualified-professionals.page> (“Without the benefit of proper medical counseling, patients may spend money on direct to consumer genetic tests needlessly or misinterpret the results of the tests, causing them to make unnecessary or unhealthy lifestyle changes”); see also *FDA Recognizes Role of Genetic Counselors in DTC Testing: A Statement from the National Society of Genetic Counselors*, NAT'L SOC'Y GENETIC COUNSELORS (Mar. 9, 2011), http://www.nsgc.org/Portals/0/Press%20Releases/x110309%20Statement%20on%20FDA%20Panel%20-%20FINALv3%20%20_2_.pdf.

Many call for a transparency-focused approach to the DTC testing dilemma, rather than regulating DTC genetic tests through traditional channels (like FDA premarket review and approval for medical devices), to improve consumers' awareness of what information is obtainable and useful.¹⁵⁰ Steps to increase transparency would include making participation in the forthcoming National Institutes of Health Genetic Testing Registry mandatory rather than voluntary,¹⁵¹ increasing FDA transparency efforts, and involving the FTC.¹⁵²

Another approach discussed by some scholars is to rely on private tort liability to regulate this type of genetic testing.¹⁵³ It remains to be seen, however, if consumers will take action in large enough numbers to actually effectuate change.¹⁵⁴ Moreover, consumers often may not be able to prove the requisite harm for recovery, especially if they are claiming only emotional harm.¹⁵⁵ Causation would, in many cases, be difficult to prove, and many are concerned that relying solely on tort liability could

150. See, e.g., Dan Vorhaus, *Transparency First: A Proposal for DTC Genetic Testing Regulation*, GENOMICS LAW REPORT (May 24, 2010), <http://www.genomicslawreport.com/index.php/2010/05/24/transparency-first-a-proposal-for-dtc-genetic-testing-regulation/>.

151. See *Genetic Testing Registry*, NAT'L INST. OF HEALTH (NIH), <http://www.ncbi.nlm.nih.gov/gtr/> (last updated Oct. 6, 2011). The registry, launched in February 2012, provides access to information about genetic tests for inherited genetic variations and is based on voluntary data submissions by test developers and manufacturers. *Genetic Testing Registry*, NIH (Feb. 29, 2012), http://oba.od.nih.gov/oba/gtr/GTR_Fact_Sheet_2-28-12.pdf.

152. Vorhaus, *supra* note 150.

[C]reating greater DTC transparency can be most efficiently accomplished *without* the application of regulations that would be onerous for early-stage DTC companies and their investors, restrictive for consumers interested in the broadest access to their genetic information and expensive and time-consuming for regulators to enforce. Over the next 6–9 months, the DTC genetic testing industry and regulators, working together, should take three key steps to enhance transparency industry-wide, ensure that customers, regulators and healthcare professionals are better able to understand and evaluate the products offered, and encourage the DTC industry to grow responsibly without more traditional regulation.

Id.

153. Hogarth et al., *supra* note 41, at 175 (these product liability claims would generally allege that misleading advertising caused financial or physical harm to the consumer); see also Pilar N. Ossorio, *Product Liability for Predictive Genetic Tests*, 41 JURIMETRICS J. 239, 242 (2001) (other feasible claims could be breach of express or implied warranty and negligence).

154. Ossorio, *supra* note 153. These cases are subject to the inherent limitations of consumer litigation. Consumers may not know or understand their rights, and may have comparably limited resources and time to devote to lengthy, complex litigation. *Id.*

155. Hogarth et al., *supra* note 41, at 175 ("For example, the consumer would need to show that the test result led to some harmful action, and that the action was a foreseeable result of the misleading information. Emotional harm, such as added anxiety from being told one was at greater likelihood of developing a disease, would likely be an insufficient basis for receiving damages in the absence of more concrete injury.").

have a chilling effect on the DTC testing industry and predictive genetic testing in general.¹⁵⁶

Considering the possible policy approaches to the problem of regulating DTC testing, the U.S. should follow Germany's example and favorably consider the goals underlying the GenDG. However, the U.S. government should take a more balanced, politically feasible course of action. One regulatory body should have the power to mandate thorough, satisfactory genetic counseling and stricter, tailored laboratory standards and methodologies.

CONCLUSION

As genome-wide predictive testing becomes more integrated into the health care scheme,¹⁵⁷ DTC testing will only become more prominent if left unregulated. Some argue that this would be a positive development for personalized medicine, prevention, genetic education and awareness, and individual autonomy to access one's own genetic information.¹⁵⁸ However, considering the many ethical concerns and possible negative consequences of predictive DTC genetic testing, such as lack of clinical and analytical validity, possible psychological strain, and little clinical utility,¹⁵⁹ it is in the United States' interest to limit the unfettered growth of this industry. Germany heeded the advice of countless international medical and genetics organizations and enacted legislation that protects consumers from the possible harms of unregulated predictive genetic testing. The United States should follow Germany's example by requiring satisfactory genetic counseling and enacting standardized laboratory procedure requirements.¹⁶⁰ However, for practical reasons and in order to maintain the autonomy that DTC testing gives consumers, the United States should stop short of Germany's physician-only requirement.

156. See Gniady, *supra* note 47, at 2468–69.

157. See Kenneth P. Tercyak et al., *Parents' Attitudes Toward Pediatric Genetic Testing for Common Disease Risk*, 127 PEDIATRICS 1288, 1289 (2011), available at <http://pediatrics.aappublications.org/content/127/5/e1288.full.pdf>.

158. See *supra* Part I, notes 30–41.

159. See *supra* Part II, notes 42–65.

160. See Press Release, Coll. Am. Pathologists, CAP Urges Increased Oversight of Direct-to-Consumer Laboratory Tests Citing Potential Risk to Patients (July 22, 2010), available at http://www.cap.org/apps/cap.portal?_nfpb=true&cntvwrPtlActionOverride=%2Fportlet%2FcontentViewer%2Fshow&_windowLabel=cntvwrPtl&cntvwrPtl{actionForm.contentReference}=media_resources%2Fnews_rel_direct_to_consumer.html&_state=maximized&_pageLabel=cntvwr. The letter stated that “direct-to-consumer testing is clinical laboratory testing and should be . . . required to meet all applicable requirements as defined by CLIA.” Moreover, individuals may need a medical professional to interpret the test results and recommend any future steps or treatment.

Recent steps taken by the FDA and other regulatory agencies in this country, including letters sent by the FDA to several DTC companies¹⁶¹ and the March 2011 Molecular and Clinical Genetics Panel Meeting, have led many to wonder whether the end of the DTC testing industry is imminent.¹⁶² It remains to be seen what the regulatory result of the FDA's March 2011 meeting might be, if any. But while the risks of DTC genetic testing remain possible, the United States would certainly benefit from adopting the basic principles of Germany's protective approach.

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161. *In Vitro Diagnostics*, FDA, <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/default.htm> (last updated Feb. 19, 2013).

162. See, e.g., Emily Singer, *The End for Direct-to-Consumer Genetic Testing?*, MIT TECH. REV. (Mar. 11, 2011), <http://www.technologyreview.com/blog/editors/26499/>; see also Bruce Japsen & Sandra M. Jones, *Walgreens Postpones Carrying Pathway Genomics Genetic Test Kit*, L.A. TIMES (May 13, 2010), available at <http://articles.latimes.com/2010/may/13/business/la-fi-dna-kits-20100513> (reporting on the FDA's enforcement letter to Pathway Genomics giving them fifteen days to respond to a request for information regarding the product and its lack of FDA approval, and Walgreen's subsequent decision to delay plans to sell the DTC test kits in their drug stores).

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