

DIRECT-TO-CONSUMER GENETIC TESTING: GATEKEEPING THE PRODUCTION OF GENETIC INFORMATION

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ABSTRACT

Traditionally, the practice of genetic testing was governed by the Diagnostic Paradigm. Under the Diagnostic Paradigm an individual tested for a disease that was prevalent in his family and a medical professional guided the testing process. Yet, recently, a new genetic testing paradigm has emerged—the Consumer Paradigm. Under the Consumer Paradigm, direct-to-consumer genetic testing companies are offering online packages of multiple genetic tests that are bundled together. The individual purchases the package and undergoes testing for a large battery of tests usually without the guidance of a medical practitioner.

This Essay argues that the emergence of the Consumer Paradigm signals a new step in the genetic revolution and creates a need for an additional policy focus. While in the past legal discourse focused on the removal of barriers for innovation and access, it should now also consider the need to regulate and filter the production of genetic information. Specifically, this Essay underscores the necessity of having a medical professional as a gatekeeper of the production of genetic information.

This Essay argues for the need for a law mandating the guidance of a medical professional not only at the interpretation stage but also at the outset of the process—to guide individuals through the selection of tests. Not all genetic information is made equal and not all test results are similarly desirable for all people. A medical practitioner can guide individuals in selecting the genetic tests that reflect their preferences and produce the genetic information that is beneficial for them.

I. INTRODUCTION

Over the last decade, the media dedicated significant attention to the promise of the genetic revolution. The legal and popular debate reacted to the excitement accompanying progress in genetics and focused on ways to eliminate barriers to innovation in the science of genetics and access to genetic technology.

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Primarily, the debate centered on the effect of gene patents on subsequent research in genetics, and consequently on the affordability of the developed products.¹ At the same time, scholars and legislators raised concerns about genetic discrimination and its deterrent effect on the use of genetic testing.²

While the debate focused on the need to facilitate the proliferation of genetic science and technology, another important transformation was taking place. The nature of genetic testing, currently genetics' most prominent clinical application,³ was changing from a diagnostic to a consumer model. Originally, genetic testing was solely a medical endeavor. A patient would undergo testing, usually for a specific condition, and would receive pre-testing and post-testing consultations from a medical professional ("The Diagnostic Paradigm").⁴ Yet, over the last couple of years, genetic testing is increasingly offered on the Internet, through sites such as 23andMe.com.⁵ Moreover, recently Walgreens planned to sell a genetic testing kit in its stores.⁶ Under this model, testing is generally bundled up and the consumer purchases testing for a large number of conditions without choosing which tests to undergo. Genetic testing is marketed not primarily as a diagnostic tool but in a more playful manner to satisfy curiosity or to give as a gift ("the Consumer Paradigm"). Under the Consumer Paradigm, a medical professional is usually not involved at the beginning of the process

¹ See, e.g., Gaia Bernstein, *In the Shadow of Innovation*, 31 CARDOZO L. REV. 2255 (2010) [hereinafter *In the Shadow of Innovation*] (discussing the inhibiting effects of gene patents on the diffusion of genetic testing technology); Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RES. L. REV. 691, 728, 730 (2004) (describing scholars' concerns and academic proposals to resolve the effects of patenting on genetic science innovation); Michael A. Heller & Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 699-700 (1998) (arguing that the large number of patents on upstream products increases the costs of research).

² See generally Gaia Bernstein, *The Paradoxes of Technological Diffusion: Genetic Discrimination and Internet Privacy*, 39 CONN. L. REV. 241, 261-62 (2006) [hereinafter *The Paradoxes of Technological Diffusion*]; Mark A. Hall & Stephen S. Rich, *Genetic Privacy Laws and Patients' Fear of Discrimination by Health Insurers: The View from Genetic Counselors*, 28 J.L. MED. & ETHICS 245, 246 (2000); Jessica L. Roberts, *Preempting Discrimination: Lessons from the Genetic Information Nondiscrimination Act*, 63 VAND. L. REV. 439, 480-83 (2010).

³ Two additional areas of clinical genetics' applications are gene therapy and pharmacogenetics. Despite years of research and trials, gene therapy has so far attained few successes. See NINDS, Gene Therapy Page, http://www.ninds.nih.gov/research/parkinsonsweb/gene_therapy.htm (last visited Dec. 20, 2010). Pharmacogenetics is currently a very promising clinical application, but is far less developed than genetic diagnostic testing. See U.S. FOOD & DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: PHARMACOGENOMIC DATA SUBMISSIONS (2005), <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126957.pdf>.

⁴ See generally Wylie Burke, *Genetic Testing*, 347 NEW ENG. J. MED. 1867 (2002); Muin Khoury, Linda McCabe & Edward R.B. McCabe, *Population Screening in the Age of Genomic Medicine*, 348 NEW ENG. J. MED. 50 (2003).

⁵ 23andMe.com, <https://www.23andme.com> (last visited Dec. 20, 2010).

⁶ See Andrew Pollack, *Start-Up May Sell Genetic Tests in Stores*, N.Y. TIMES, May 11, 2010, at B2. Following FDA intervention, Walgreens withdrew its plan. Rob Stein, *Walgreens Won't Sell Over-the-Counter Genetic Test After FDA Raises Questions*, WASH. POST, May 13, 2010, <http://www.washingtonpost.com/wp-dyn/content/article/2010/05/12/AR2010051205156.html>.

when the individual decides to undergo testing, nor does he play a role in helping the individual interpret the results.

In this Essay, I argue that the proliferation of the Consumer Paradigm, which now stands side-by-side with the Diagnostic Paradigm, signals a need for a change in the legal discourse concerning genetic testing. Instead of focusing exclusively on eliminating barriers to innovation and access, the debate should also address the need to regulate and constrain the production of genetic information.⁷ Although genetic information can help control and improve health outcomes, not all genetic information is made equal and not all test results are similarly desirable for all people. Some individuals may prefer not to know certain genetic information about themselves because there are no significantly effective preventive measures and they do not desire to live with the knowledge that they have a high likelihood of incurring certain diseases. In addition, some genetic test results convey little information. Certain positive test results indicate only a slightly higher probability of incurring the disease than the likelihood in the general population. Other genetic tests simply lack solid scientific validity. Hence, some individuals may prefer to filter the package of tests at the outset to facilitate focusing on the important findings at the interpretation stage.

Regulating the production of genetic information requires a knowledgeable gatekeeper. Medical organizations and scholars have lamented the absence of a medical professional at the interpretation stage, arguing that laymen cannot appropriately understand genetic information, leading to potentially harmful results.⁸ In this Essay, I underscore the need for the medical professional, who may be a physician but preferably is a genetic counselor, as the gatekeeper of the production genetic information. The medical professional has an important role to play not only after testing, at the interpretation stage, but at the beginning of the process to guide individuals through the selection of tests. I highlight the need for a law requiring an independent medical professional, engaged by the individual, to guide her throughout the testing process of disease risks, drug reactions, trait and carrier status genetic tests.⁹ Instating the medical professional as a gatekeeper would merge the Diagnostic and Consumer paradigms, retaining the proliferation of genetic testing offered by the Consumer

⁷ I am using the terms “production” and “creation” loosely. One’s genetic sequence is of course created at conception and the testing merely produces the sequencing in the form of readily accessible information.

⁸ See, e.g., Cynthia Marietta & Amy L. McGuire, *Currents in Contemporary Ethics: Direct-to-Consumer Genetic Testing: Is it the Practice of Medicine?*, 37 J.L. MED. & ETHICS 369, 372-73 (2009) (arguing that genetic testing should be performed only under the care of qualified health care professionals); AM. C. OF MED. GENETICS BOARD OF DIRECTORS, ACMG STATEMENT ON DIRECT-TO-CONSUMER GENETIC TESTING (2008), http://www.acmg.net/StaticContent/StaticPages/DTC_Statement.pdf [hereinafter ACMG STATEMENT]; EDWARD LANGSTON, CHAIR, AM. MED. ASS’N, REPORT OF THE BOARD OF TRUSTEES: DIRECT-TO-CONSUMER ADVERTISING AND PROVISION OF GENETIC TESTING 1 (2008), <http://www.ama-assn.org/ama1/pub/upload/mm/471/bot7.doc>.

⁹ I do not argue for requiring a medical professional to accompany genetic testing for ancestry.

Paradigm with the regulated control of genetic information currently offered solely under the Diagnostic Paradigm.

The Essay proceeds as follows: Part II describes the Diagnostic Paradigm and the Consumer Paradigm of genetic testing. Part III argues for the need to focus on regulating and constraining the production of genetic information, specifically, analyzing the need for the medical professional as a gatekeeper at the outset of the testing process. Part IV describes state law regulation of medical testing and argues for the need for a law requiring an independent medical professional to guide the testing process from its outset to completion.

II. FROM A DIAGNOSTIC TO A CONSUMER PARADIGM FOR GENETIC TESTING

Under the Diagnostic Paradigm, genetic testing includes pre-testing and post-testing consultations with medical professionals. Patients usually test for a disease that is prevalent in their family or among their ethnic group. For example, a woman whose mother and sister were inflicted with breast cancer would undergo genetic testing for BRCA1/BRCA2—a breast cancer genetic mutation. Similarly, an Ashkenazi Jewish couple seeking to conceive would undergo genetic testing for genetic diseases that are common among Ashkenazi Jews. The patient undergoing the test would consult before testing with her own physician or with a genetic counselor to determine which test is required. After testing, she would receive the results from the physician or genetic counselor who would explain the significance of the result, including the probability that the individual who carries the mutation will become sick, the range of manifestations of the disease, and whether there are any preventative measures.¹⁰

Direct-to-consumer (“DTC”) genetic testing created a new paradigm for genetic testing, which provides the public with a vast amount of unfiltered genetic information and turns the patient into a consumer.¹¹ Under the Consumer Paradigm, DTC testing offers the individual a relatively cheap option to test for a broad array of genetic conditions. For as little as several hundred dollars a consumer can test for a battery of health conditions, drug reactions, traits and even test for carrier status for multiple diseases in order to plan for a pregnancy.¹²

¹⁰ On the current practice of genetic counseling, *see generally* Burke, *supra* note 4; Khoury, McCabe & McCabe, *supra* note 4.

¹¹ Genetic testing is even offered as a gift. *See, e.g.*, 23andMe.com, How do I give this service as a gift?, <https://www.23andme.com/you/faqwin/beforeyoubuygift/> (last visited Dec. 10, 2010) (describing how to give genetic testing as a gift).

¹² For example, 23andMe offers a genetic report of ninety-five disease risk, twenty-four carrier conditions, eighteen drug responses, and forty-eight traits for \$199 plus a subscription of five dollars per month for updates. 23andMe.com, Health Reports: Complete List, <https://www.23andme.com/health/all/> (last visited Feb. 7, 2011); 23andMe.com, Order the Service, <https://www.23andme.com/store/cart/> (last visited Feb. 7, 2011). deCODEme offers a scan for forty-seven health conditions and an ancestry report for \$2000, a cancer scan for seven cancers for

Recently, Walgreens planned to offer a DNA testing kit for the enticing price of \$20-\$30; once the consumer bought the kit she would pay an additional \$79-249 depending on the tests ordered.¹³ DTC testing is structured to sell the consumer a package which includes many genetic conditions selected by the company. But, paradoxically, the consumer under the Consumer Paradigm has less choice than the patient under the Diagnostic Paradigm. DTC testing usually does not provide the consumer with an option to select a specific test or choose not to test for a specific condition. Instead, multiple tests are bundled together. As a result, the Consumer Paradigm significantly increases the amount of genetic information that an individual receives. In lieu of receiving information about a specific disease, under the Consumer Paradigm, the individual receives information about a wide-range of conditions. She is not given the real option of selecting which genetic information she wants to receive. Furthermore, the lack of choice is exacerbated by the absence of a medical professional as a gatekeeper who can suggest which tests would be most useful and desirable for the individual to undergo.¹⁴

DTC testing also influences the quality of genetic information received by the consumer. Individuals receive the test result on an Internet Web site.¹⁵ Although companies usually provide an option to discuss the results with a genetic counselor, there is no requirement to do so. Normally, the consumer would go online and view her results.¹⁶ Thus, while under the Diagnostic Paradigm, the patient would know what test results she is expecting and would receive the results from a medical professional who would explain their implications, under the Consumer Paradigm, the consumer receives little guidance to help her navigate through the implications of the vast genetic information she receives.

III. REGULATING THE CREATION OF GENETIC INFORMATION: A GATEKEEPER AT THE POINT OF PRODUCTION

To this point, the legal discourse concerning genetic testing has focused mainly on the removal of barriers to innovation in genetic testing technology and to use of genetic information. One important part of the debate focused on the inhibiting effects of gene patents on innovation in the science of genetics.

\$500, and a cardioscan for \$500. deCODEme, <http://www.decodeme.com/genes-and-health> (last visited Feb. 7, 2011).

¹³ Pollack, *supra* note 6.

¹⁴ There are some exceptions to the Consumer Paradigm. For example, Navigenics requires signing up through a physician or corporate wellness program. However, the results are still received individually online. Navigenics, How our services work, http://www.navigenics.com/visitor/what_we_offer/how_it_works (last visited Dec. 20, 2010).

¹⁵ *Id.*

¹⁶ There are some exceptions, such as Knome, which offers complete sequencing of one's DNA for significant sums of money and requires an in-person meeting to receive the results. Knome, Frequently asked questions, <http://www.knome.com/faq.html> (last visited Dec. 20, 2010).

Scholars raised concerns that the grant of patents on the building blocks of genetic science, such as DNA sequencing, would increase the cost of developing diagnostic testing and therefore inhibit scientific progress.¹⁷ Furthermore, in a recent case, which received significant publicity, *Association of Molecular Pathology v. U.S. Patent and Trademark Office*, the court invalidated Myriad Genetics' patent over the breast cancer genetic mutations BRCA1 and BRCA2 on subject matter grounds.¹⁸ The court emphasized the detrimental effect of the patent holder actions on access to genetic testing for breast cancer.¹⁹ Another major part of the debate concerned fears that genetic testing would result in insurance or employment discrimination.²⁰ Studies showed that fears of genetic discrimination prevented use of genetic testing.²¹ These concerns partly motivated the enactment of the Genetic Information Non-Discrimination Act of 2008.²²

Promoting progress in genetic technology and facilitating use of genetic information was, doubtless, an important step in enabling the genomic revolution. Yet, the advent of DTC genetic testing signals a new step in the genomic revolution and creates a need for an additional policy focus. Legal discourse should consider not only the removal of barriers for innovation and access but also the need to regulate and filter the production of genetic information. Of particular importance is the role of the medical professional as a gatekeeper in regulating the creation of genetic information.

Scholars and medical organizations alike have noted the absence of a medical professional as an overseer of the DTC genetic testing process.

¹⁷ See, e.g., Burk & Lemley, *supra* note 1 (describing scholars' concerns and academic proposals to resolve the effects of patenting on genetic science innovation); Heller & Eisenberg, *supra* note 1 (arguing that the large number of patents on upstream products increases the costs of research). *But see* David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1680-84 (2007) (arguing that the effect of the growth in biotechnology patenting on innovation is more limited than believed); Robert P. Merges, *A New Dynamism in the Public Domain*, 71 U. CHI. L. REV. 183, 183-85, 186-91 (pointing out that private actors are acting to alleviate the biotech anticommons problem).

¹⁸ *Ass'n of Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d. 181 (S.D.N.Y. 2010). See also John Schwartz & Andrew Pollack, *Judge Invalidates Human Gene Patent*, N.Y. TIMES, Mar. 29, 2010, at B1.

¹⁹ *Ass'n of Molecular Pathology*, 702 F. Supp. 2d. 181. See also Bernstein, *In the Shadow of Innovation*, *supra* note 1 (discussing the inhibiting effects of gene patents on the diffusion of genetic testing technology).

²⁰ See generally Hall & Rich, *supra* note 2, at 246; Kathy L. Hudson et al., *Genetic Discrimination and Health Insurance: An Urgent Need for Reform*, 270 SCI. 391 (1995); Gina Kolata, *Advent of Testing for Breast Cancer Genes Leads to Fears of Disclosure and Discrimination*, N.Y. TIMES, Feb. 4, 1997, at C1; National Human Genome Research Institute, *Health Insurance in the Age of Genetics*, <http://www.genome.gov/10000879> (last visited Dec. 20, 2010). See also Bernstein, *The Paradoxes of Technological Diffusion*, *supra* note 2.

²¹ Bernstein, *The Paradoxes of Technological Diffusion*, *supra* note 2.

²² See Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (2008); Jessica L. Roberts, *Preempting Discrimination: Lessons from the Genetic Information Nondiscrimination Act*, 63 VAND. L. REV. 439, 480-83 (2010) (discussing fear as a basis for law).

Particularly, they noted the importance of having a medical professional interpret the results of the tests and emphasized the need for a law that would protect individuals from receiving their genetic test results from DTC companies independently without the guidance of a medical professional.²³ Various reasons support requiring the guidance of a medical professional at the interpretation stage. Genetic information may not be useful, or could even be harmful, if received without appropriate explanations. First, genetic information generally provides probabilities and not a determinate answer. Studies show that individuals are not adept at interpreting probabilities.²⁴ Furthermore, DNA has a profound cultural power. Consequently, people tend to overestimate the importance of genetic information, ignoring other factors that often also play a significant role in causing disease.²⁵ Second, some test results can profoundly affect some recipients' psychological well-being and these individuals would benefit from professional counseling when receiving the results.²⁶ Third, individuals, at times, rely on genetic tests' results to take actions affecting their healthcare. Incomplete understanding of the nature of the results or of the

²³ See, e.g., Marietta & McGuire, *supra* note 8, at 372-73 (arguing that genetic testing should be performed only under the care of qualified health care professionals); ACMG STATEMENT, *supra* note 8; LANGSTON, *supra* note 8.

²⁴ See ACMG STATEMENT, *supra* note 8 (describing the difficulties of interpreting the results of genetic tests); LANGSTON, *supra* note 8. On biases related to estimating probabilities in medical decision-making, see generally Aaron D. Twerski & Neil B. Cohen, *Informed Decision-Making and the Law of Torts: The Myth of Justiciable Causation*, 1988 U. ILL. L. REV. 607 (1988).

²⁵ Sarah E. Gollust, Sara Chandros Hull & Benjamin S. Wilfond, *Limitations of Direct-to-Consumer Advertising for Clinical Genetic Testing*, 288 J. OF THE AM. MED. ASS'N 1762, 1763 (2002) (stating that a positive result does not always indicate a definitive clinical manifestation because of incomplete penetrance, variable expressivity, and environmental phenotype influences); Marietta & McGuire, *supra* note 8, at 370 (stating that a positive result does not establish the exact risk of developing the disease because most diseases tested for are multifactorial and the test does not consider other factors such as family history or environmental exposures). On the cultural power of genetic information, see DOROTHY NELKIN & M. SUSAN LINDEE, *THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON* 2 (1995); Jacquelyn Ann K. Kegley, *Genetic Information and Genetic Essentialism: Will We Betray Science, the Individual and the Community*, in *GENETIC KNOWLEDGE: HUMAN VALUES AND RESPONSIBILITY* 41, 41, 48-49 (Jacquelyn Ann K. Kegley ed., 1998).

²⁶ See Judith L. Benkendorf et al., *Impact of Genetic Information and Genetic Counseling on Public Health*, in *GENETICS AND PUBLIC HEALTH IN THE 21ST CENTURY* 361, 376 (Muin J. Khoury et al. eds., 2000); Caryn Lerman et al., *Genetic Testing: Psychological Aspects and Implications*, 70 J. CONSULTING & CLINICAL PSYCHOL. 784, 793 (2002). While a recent study focusing on DTC genetic testing found that the majority of individuals testing (ninety percent) indicated no test-related distress, it also found that ten percent of the subjects did exhibit test-related distress. Furthermore, the study's findings that the majority of subjects had no test related distress are limited in two ways. First, the study's subjects were individuals who voluntarily purchased DTC genetic testing and, therefore, represent a self-selected early adopters group which may not represent the general population. Secondly, forty-four percent of the subjects who underwent testing did not complete the follow up. These subjects may have been adversely affected from the testing and their failure to follow up may be related to these effects. Cinnamon S. Bloss, Nicholas J. Schork & Eric J. Topol, *Effect of Direct-to-Consumer Genomewide Profiling to Assess Disease Risk*, *NEW ENG. J. MED.*, Jan. 12, 2011, at 5, 7, 10, <http://www.nejm.org/doi/pdf/10.1056/NEJMoa1011893>.

effectiveness of preventive measures can result in erroneous and even harmful actions. People receiving negative test results indicating that they are not at an increased risk for a disease may not realize that there are also lifestyle effects that can cause a disease, such as obesity for diabetes, and act irresponsibly thinking they are risk-free. At the same time, certain decisions about preventive measures, such as getting a mastectomy following a positive breast cancer genetic test, can be complicated and require proper assessment of the result of the genetic test.²⁷

The guidance of a medical professional is no doubt important at the interpretation stage. However, it is also vital at an earlier stage—when an individual decides what tests to undergo and in essence what genetic information to produce. Not all genetic information is of equal value. The production of certain genetic information may, in fact, not be desired for some, and other genetic information may not be as useful. A medical professional can help an individual tailor the panel of tests to his needs.

First, under the Consumer Paradigm, individuals usually purchase packages of tests containing many conditions. The packaged offerings decrease the likelihood that individuals will stop and assess whether they want to test for all the conditions offered. The shift toward a Consumer Paradigm, in which the tests can even be purchased as a gift, serves to obscure the significance and potentially life-changing nature of the results. In fact, some of these tests may contain information individuals may prefer not to know. These preferences vary from one individual to another. For example, early detection of a genetic mutation for Alzheimer's disease may help control the disease, but Alzheimer's disease is a devastating and unpreventable disease and many individuals may actually prefer not to know they carry the mutation, especially for early-onset Alzheimer's disease.²⁸ At the same time, a woman whose mother incurred Alzheimer's at an early age and who lived for years fearing she will suffer the same fate may want to test and finally put her mind at rest.²⁹ A medical professional can provide individuals with information regarding the nature of the conditions for which they are testing, whether there are effective preventive

²⁷ Rose Geransar & Edna Einsiedal, *Evaluating Online Direct-to-Consumer Marketing of Genetic Tests: Informed Choices or Buyers Beware*, 12 GENETIC TESTING 13, 14 (2008) (warning of wrong choices based on misinterpretation of genetic information).

²⁸ See U.S. National Institutes of Health, Alzheimer's Disease Treatment, <http://www.nia.nih.gov/Alzheimers/AlzheimersInformation/Treatment> (last visited Dec. 20, 2010). See also U.S. National Institutes of Health, Alzheimer's Disease Fact Sheet, <http://www.nia.nih.gov/Alzheimers/Publications/adfact.htm> (last visited Dec. 20, 2010) (describing genetic testing for Alzheimer's disease).

²⁹ A recent study showed that the willingness to undergo and pay for testing depended on the disease. Inclination to take the test was lowest for Alzheimer's disease (70-74%) and highest for prostate cancer (85-88%). See Peter J. Neumann et al., *Willingness-to-Pay for Predictive Tests With No Immediate Treatment Implications: A Survey of US Residents*, 20 HEALTH ECON. 6 (2011).

measures, and help each person determine the panel of tests he would like to undergo.

Secondly, some genetic information conveys little clinically useful information.³⁰ In certain tests, a positive result merely means that the person has a slightly higher percentage of incurring the disease than the general population. For example, for Alzheimer's disease, certain variants in the APOE gene are associated with only a moderately heightened risk of contracting the disease.³¹ In other tests the likelihood of incurring a disease is so remote that even a positive test result for a mutation associated with the disease indicates a very slight probability of getting sick. For example, the probability in the general population of incurring Lou Gehrig's disease ("ALS") is 1 in 100,000 while a positive test result at most indicates that an individual has the probability of 1.3 in 100,000 of incurring the disease.³² To compare, one out of eight women in the general population will develop breast cancer during her lifetime.³³ Finally, some genetic tests, whether due to the state of the science or the effect of many mutations and environmental factors, carry little scientific validity. This is the case for both disease and particularly trait information. For example, the tests currently offered for Asthma and for Pain Sensitivity are based on preliminary research that needs to be confirmed by the scientific community.³⁴

A medical professional can help an individual filter the information. Filtering information at the outset is significant for facilitating the latter stage of interpreting the results. The inclusion of unnecessary tests burdens the interpretation task and detracts attention from the important findings. While some individuals engage in testing out of general curiosity, many may do so in order to improve their health, engage in preventive measures, and control outcomes. These individuals would benefit from focusing on the information that is pertinent to their health instead of being detracted by insignificant information.

IV. LOOKING FORWARD

³⁰ See generally Scott D. Grosse & Muin J. Khoury, *What is the Clinical Utility of Genetic Testing?*, 8 GENETICS IN MED. 448 (2006) (defining clinical utility for genetic testing).

³¹ See Stuart Hogarth, Gail Javitt & David Melzer, *The Current Landscape for Direct-to-Consumer Genetic Testing: Legal, Ethical and Policy Issues*, 9 ANN. REV. OF GENOMICS AND HUM. GENETICS 161, 168 (2008).

³² 23andMe.com, Lou Gehrig's Disease (ALS)—Sample Report, <https://www.23andme.com/health/Lou-Gehrigs-Disease-ALS> (last visited Dec. 20, 2010). The 23andMe site further indicates that subsequent studies failed to support the association between the mutation and the disease. *Id.*

³³ Imaginis, Breast Cancer: Statistics on Incidence, Survival, and Screening, <http://www.imaginis.com/breast-health/breast-cancer-statistics-on-incidence-survival-and-screening-2> (last visited Dec. 20, 2010).

³⁴ 23andMe.com, Asthma, <https://www.23andme.com/health/Asthma/> (last visited Dec. 20, 2010); 23andMe.com, Pain Sensitivity, <https://www.23andme.com/health/Pain-Sensitivity> (last visited Dec. 20, 2010).

Currently, state law governs who may order a laboratory test and specifies to whom the results may be sent. While some states provide that only health care professionals, licensed physicians, or persons authorized by law may order lab tests and some states require that the results should be reported only to the person ordering the test, many are silent on the issue and therefore these states are viewed as permitting DTC genetic testing. Furthermore, states have varied in how strictly they interpret the requirements and whether they view them as prohibiting DTC.³⁵

Operating under a patchwork of uncertain state law, DTC genetic testing companies usually do not require a consultation with a medical professional before and after testing. In addition, while many DTC companies offer genetic counseling, the medical professional is a representative of the company. Although a medical professional representing the company would have good knowledge of the tests,³⁶ he does not have a complete picture of the consumer's health and family history.³⁷ Moreover, at the outset when determining which genetic information to produce, the medical professional employed by the DTC company is likely to find himself in a conflict of interest. Generally, physicians have a fiduciary duty toward their patients and may not place their interests above the interests of their patient.³⁸ A medical professional employed by the DTC company, however, represents his employer. The DTC company's goal is to maximize its sales of genetic tests. However, this goal may often be in conflict with the individual's interest to narrow the tests she undergoes, whether in order not to receive information she does not wish to know or to prevent detraction by information that is of little utility.

³⁵ See Katherine Drabiak-Syed, *Baby Gender Mentor: Class Action Litigation Calls Attention to A Deficient Federal Regulatory Framework for DTC Genetic Tests, Politicized State Statutory Construction and Lack of Informed Consent*, 14 MICH. ST. J. MED. & LAW 71, 78-82 (2010); THE GENETICS AND PUBLIC POLICY CENTER, SURVEY OF DIRECT-TO-CONSUMER TESTING STATUTES AND REGULATIONS (June 2007), <http://www.dnapolicy.org/resources/DTCStateLawChart.pdf>.

³⁶ This is an important advantage because although genetic counselors are knowledgeable about tests, studies have shown that physicians often lack the necessary understanding of genetic information. See generally Joseph D. McNerny, *Genetics Education for Health Professionals: A Context*, 17 J GENETIC COUNSELING 145 (2008); L. Wideroff & S.T. Vadaparampil et al., *Hereditary Breast/Ovarian and Colorectal Genetics Knowledge in National Sample of US Physicians*, 42 J. MED. GENETICS 749 (2005).

³⁷ Marietta & McGuire, *supra* note 8, at 373.

³⁸ See generally Maxwell J. Mehlman, *Dishonest Medical Mistakes*, 59 VAND. L. REV. 1137, 1144-53 (describing ethical and legal sources for a fiduciary duty between physician and patient). *But see, e.g.*, Frances H. Miller, *Secondary Income from Recommended Treatment: Should Fiduciary Principles Constrain Physician Behavior?*, in THE NEW HEALTH CARE FOR PROFIT: DOCTORS AND HOSPITALS IN A COMPETITIVE ENVIRONMENT 153 (Bradford H. Gary ed., 1983) (questioning whether physicians should be regarded as fiduciaries for their patients). It should be noted, however, that it is still debatable as to whether a physician-patient relationship is established when an individual seeks the services of a DTC company and requests to engage a company physician for the purposes of ordering and interpreting the result. See Marietta & McGuire, *supra* note 8, at 372-73.

A law mandating that individuals seeking genetic testing engage an independent medical practitioner for pre-testing and post-testing consultations, would establish unbiased gatekeepers who can regulate the creation of genetic information.³⁹ This requirement should be limited to medical genetic tests (including disease risks, drug reactions, carrier status, and trait tests) and should not encompass ancestry testing offered by many DTC genetic testing companies. The medical practitioner would preferably be a genetic counselor who is trained in understanding genetic tests. It should be accompanied by an additional change in the Consumer Paradigm that would allow the unbundling of the testing packages. Unbundling the tests would enable the individual with the help of the medical professional to tailor the tests to his needs and goals.⁴⁰ Consequently, the Diagnostic and Consumer paradigms would merge, allowing the proliferation of genetic testing offered by the Consumer Paradigm with the regulated control of genetic information currently offered only under the Diagnostic Paradigm.

V. CONCLUSION

³⁹ Settling the question of the appropriate legal authority to legislate a requirement mandating the supervision of an independent medical practitioner is beyond the scope of this Essay. Scholars have debated whether the FDA, FTC, or the states have the authority to regulate DTC genetic testing. See generally Jennifer A. Gniady, *Regulating Direct-to-Consumer Genetic Testing: Protecting the Consumer Without Quashing a Medical Revolution*, 76 *FORDHAM L. REV.* 2429, 2471-72 (2009) (proposing combined regulation by the FDA, FTC, and the states); Gregory Katz & Stuart O. Schweitzer, *Implications of Genetic Testing for Health Policy*, 10 *YALE J. HEALTH POL'Y L. & ETHICS* 90, 123 (2010) (explaining that the FDA and the Clinical Laboratory Improvement Amendments do not regulate most genetic tests); Marietta & McGuire, *supra* note 8, at 371-72 (discussing whether DTC genetic testing constitutes the "practice of medicine" as regulated by the states); Andrew S. Robertson, Note, *Taking Responsibility: Regulations and Protections in Direct-to-Consumer Genetic Testing*, 24 *BERKELEY TECH. L.J.* 213, 238-39 (2009) (arguing that the FDA should extend its oversight to genetic tests, which are laboratory developed tests, as medical devices).

⁴⁰ A major objection to my proposal to require a medical professional to accompany the DTC genetic testing process is that the proposal is paternalistic. One version of the paternalistic argument would assert that requiring individuals to engage a medical practitioner impacts their ability to attain genetic information, particularly because of the increased cost incurred by adding a medical professional as a gatekeeper. See Allen Buchanan, *Medical Paternalism*, 7 *PHIL. & PUB. AFF.* 370, 372 (1978) ("Paternalism is interference with a person's freedom of action or freedom of information, or the deliberate dissemination of misinformation, when the alleged justification of interfering or misinforming is that it is for the good of the person who is interfered with or misinformed.") While a full exploration of the paternalistic objections and the counter-arguments is beyond the scope of this Essay, I would like to suggest that the guidance of a medical practitioner in effect enhances individuals' autonomy by adding information about the genetic testing process and enabling them to make more informed choices. See Michael D. Greenberg, *Information, Paternalism and rational Decision-Making: The Balance of FDA New Drug Approval*, 13 *ALB. L.J. SCI. & TECH.* 663, 671-74 (2003) (arguing that while FDA regulation may be viewed as paternalistic it can in fact enhance autonomy interests by providing the information needed to support meaningful decision-making).

In this Essay, I presented a transformation in the practice of genetic testing. The practice of genetic testing is now dominated by two paradigms: the Diagnostic Paradigm and the Consumer Paradigm. Under the Diagnostic Paradigm, a patient, guided by a medical professional, usually undergoes testing for a specific condition. Conversely, under the Consumer Paradigm, the consumer, often motivated by curiosity, purchases or receives a package of bundled tests, and undergoes the testing process usually without the guidance of a medical professional.

To address the increasing prominence of the Consumer Paradigm, I argued for an expansion of the policy debate on genetic testing to address the need to regulate the production of genetic information. The Essay underscored that while DTC genetic testing companies offer large packages of bundled tests, not all the produced genetic information is desired by all individuals and not all information is, in fact, useful information. Hence, I highlighted the importance of a medical professional who will serve as a gatekeeper to regulate the production of genetic information. I suggested that a law requiring an independent medical professional who will oversee the genetic testing process from its outset will result in merging the two testing paradigms, retaining the advantage of enhanced diffusion offered by the Consumer Paradigm while incorporating the regulated control, which is an integral part of the Diagnostic paradigm.