 PRIVACY AT A PRICE: DIRECT-TO-CONSUMER GENETIC TESTING & THE NEED FOR REGULATION

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I. INTRODUCTION

Have you been longing to find out your earwax type or your predisposition to avoidance of errors? Who, genetically speaking, is your one true love? Are you going to have hair-loss like your father, who has not had a full head of hair since college? What regions of the world are your long-lost ancestors from? Perhaps, more seriously, you are curious about your predisposition towards diabetes, cancer, age-related muscle degeneration, or Lou Gehrig’s disease? It is your lucky day. For the low price of around $400 U.S. Dollars and a swab from your cheek, you can discover these things plus much, much more. Best of all, you can do this completely from the comfort of your own home and without ever having to take that dreaded trip to the doctor’s office.

However, this convenience does not come without other non-monetary costs. Many of these tests lack any substantial involvement by a physician, which has given rise to discussion over the safety and effectiveness of allowing genetic testing to be done without the direct supervision of a physician or other medical technician. For example, the results of genetic tests are susceptible to different interpretations and meanings, which may be beyond the knowledge of the average recipient of direct-to-consumer (“DTC”) genetic test results. There is concern over allowing this consumer unfettered access to their genetic

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1. 23AndMe, How It Works, https://www.23andme.com/howitworks/ (last visited Mar. 12, 2009). Although prices vary by company and service provided, this DTC genetic testing company (23andMe, Inc) offers genetic testing for $399 per test kit.


3. See id.

testing results for numerous reasons, which are presented later in this Note.5

While genetic testing has been used in many different ways for years,6 DTC testing is a more recent phenomenon.7 Lending to DTC testing popularity is the fact that consumers can test for many things, from “single-gene disorders, such as cystic fibrosis, to tests for predisposition to complex, multifactorial diseases.”8 DTC genetic testing allows an individual to take a genetic test at home, with results sent to them directly, bypassing any direct contact between physician and patient.9 According to the National Institute of Health (“NIH”), “this form of testing, which is also known as at-home genetic testing, provides access to a person’s genetic information without necessarily involving a doctor or insurance company in the process.”10 The FDA11 and CDC12, among others, feel that these genetic tests should only be performed by trained individuals.13

The popularity of DTC testing appears to rest on how easy it is for the average consumer to obtain and use them. These tests can be obtained in a number of ways, such as ordering via telephone. They can also be obtained through a seller’s website.14 Genetic tests, as medical tests, were administered or overseen by a trained professional such as a physician or genetic counselor. Given the sensitive nature of genetic testing and its results, there is concern over the impact on the consumer, both physical and mental, of the lack of trained healthcare professional, particularly physicians or similar, involvement in the genetic testing process. There are also concerns regarding the claims that are made about genetic tests that are being sold, for example via advertising. This, however, is regulated at the federal level and is beyond the scope of this Note.15

Naturally, this is likely where the legislature, at the state or federal level, may decide to step in to determine what is in the best interest of society and create uniform regulations governing physician involvement in DTC testing.

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5. See discussion of potential issues infra, Part III.A.
6. For example, using genetic testing to determine paternity of a child.
9. See, e.g., Williams, supra note 7 (“Some companies that advertise tests directly to consumers require that they see their doctors in order to have the tests performed, while others allow individuals to send samples directly to the laboratory and receive the results at home.”).
11. The FDA is the widely used acronym for the U.S. Food & Drug Administration.
12. Similarly, CDC is the acronym for the U.S. Center for Disease Control.
14. There are many websites which market direct-to-consumer tests on the Internet. Some examples of these companies are 23andMe, Navigenics, and Scientific Match. See Stuart Hogarth et al., The Current Landscape for Direct-to-Consumer Genetic Testing: Legal, Ethical, and Policy Issues, 9 ANN. REV. OF GENOMICS & HUM. GENETICS 161, 166-67 (2008) (summarizing DTC testing companies and their services).
15. Williams, supra note 7. See also Peter Lurie, DTC Advertising Harms Patients and Should be Tightly Regulated, 37 J.L. MED. & ETHICS 444 (discussing DTC testing advertisements and their pitfalls).
Currently, there is a patchwork of state laws and only weak federal regulation of DTC testing in the United States. Since it is left to state legislatures to regulate, each state is free to, and subsequently does, deal with this type of genetic testing as they see fit. While some states have statutes regulating DTC testing, other states have no pertinent statutes and have little to say on the matter. Not only could uniform regulation protect consumers, but it could potentially avoid confusion on the part of the sellers of these tests, who are often selling via the Internet to consumers in multiple states. The state actions by California and New York, beginning in mid-2008, attempting to regulate or cease the business of Internet providers of direct-to-consumer genetic testing, again stirred up controversy about these at-home tests. Due to the fact that the Internet-based selling of genetic tests is regulated in a patchwork fashion by each state, there are many concerns about its safety, value, and consequences to society.

This Note will discuss the issues surrounding DTC genetic testing primarily conducted via the Internet and its regulation. Part II will discuss the background of genetic testing, the current technology, and current events in the field. Part III will present and analyze benefits and drawbacks of DTC testing, as well as the current legal framework. It also presents possible solutions to the issue of regulation, or lack there-of. Part IV gives a recommendation for resolving the legal issue. Part V will offer some concluding remarks on this concern going forward.

II. BACKGROUND

In today’s world, scientists are furiously working to further understand the human genome. Genes hold the explanation for many traits and diseases which are still a mystery to the scientific community. Some genes, those that are more fully understood, are the subject of the genetic testing. Genetic testing is the process of detecting changes in three things: chromosomes, ribonucleic acid (“RNA”), and deoxyribonucleic acid (“DNA”). A basic description of these building blocks may help in understanding what happens in genetic testing.

17. See, e.g., 210 ILL. COMP. STAT. 257-101 (2008) (requiring that tests be ordered directly by physicians or other qualified healthcare providers).
A. The Science behind Genetic Testing

Trillions of cells comprise the human body, and within each cell are a number of different parts. One such part of the cell is the nucleus, which is protected by a membrane and contains the majority of a person’s DNA. DNA, in its most basic terms, is a long strand of hereditary material. DNA takes the form of the ladder-like, double helix structure, which is comprised of nucleotides. Genes, which are simply smaller, operational segments of the long strand of DNA, are the basic unit of inheritance. Genes are responsible for guiding a cell’s activities, such as building bone or carrying a nerve signal. Through the creation of different proteins, genes can guide cells in these activities. Causing different cells to carry out different tasks can be done because the protein each gene creates is guided by the unique DNA sequence of the gene. Genes create thousands of different proteins. Further complicating the matter is that the human body likely contains somewhere between 20,000 and 25,000 genes. Some genetic tests look directly at these genes to see if the person is a carrier or has a predisposition to a disease.

When there is a predisposition to a disease or a person is a genetic carrier, there are a number of things that may have gone wrong in terms of genetic variations. In attempting to understand genetic variations, it is helpful to consider a basic literary analogy where a strand of DNA is the paragraph, genes are the words of the paragraph and nucleotides are the letters that make up the words in the paragraph. With this analogy in mind, in scientific terms, “genetic variations can be classified into different categories: stable genetic variations, unstable genetic variations, silent genetic variations, and other types.” In laymen’s terms, this means that the DNA sequence may be different than what is considered normal (i.e. be “misspelled”). Stable

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26. Id. There are four DNA bases: Adenine, Guanine, Cytosine, and Thymine. These bases pair up and attach to sugars and phosphates, forming a unit called a nucleotide. Strands of nucleotides create the double helix structure of DNA.
29. Id.
30. Id.
31. Id. The human body can create somewhere around 100,000 different proteins.
32. Genetics Home Reference, supra note 27.
33. Collins, supra note 22.
35. Id. Misspelled is a way of saying that the sequence of the bases is out of order, which can lead to disease. For example, if a sequence should be spelled AAACCGT, but is instead spelled ACACCGT, this would constitute a misspelling. THOMAS H. MCCONNELL, THE NATURE OF DISEASE: PATHOLOGY FOR THE HEALTH PROFESSIONS 91 (Lippincott Williams & Wilkins, 2006).
genetic variations are changes (insertions, deletions, or substitutions) in single nucleotide sequences. Unstable genetic variations are those mutations in which nucleotides repeat themselves many times. Silent genetic variations are those which cause no noticeable changes. Other genetic variations include things such as replications of entire genes.

With these many avenues for genetic variation, there are an endless number of genetic variations, some of which lead to disease and others which make no detectable difference. DNA tests are done from “cellular material,” which can be collected from skin, blood, urine, saliva, and hair, amongst other things. These samples are then placed in a container, on tubes or swabs, possibly frozen, and tested. RNA, which is essentially a copy of a short DNA sequence, is also a source of genetic material and can be tested from the same cellular materials as DNA.

The other important structure to be familiar with is the chromosome. A chromosome is made of the long strands of DNA which are tightly coiled around a central point, called a centromere. Generally, humans have a total of 46 chromosomes, with 23 coming from each parent. Of course, there are individuals whose chromosomes vary from this standard, which is a chromosomal abnormality. Because humans have two sets of chromosomes, and chromosomes are made up of DNA which contains genes, this means they have two of every gene. Some genetic conditions, which are genetically tested for by looking directly at the chromosomes, are caused by mutations in or an abnormal number of chromosomes. Together, these structures make up the human DNA that carries the genetic answers that individuals seek to discover through genetic testing.

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36. Id. “An example of this is in sickle cell anemia, in which one nucleotide is substituted for another. The genetic variation in the gene causes a different amino acid to be added to a protein, resulting in a protein that does not do its job properly and causes cells to form sickle shapes and not carry oxygen.”

37. Id. “An example of a disease caused by an expanded repeat is Huntington disease, a severe disorder of a part of the brain that is marked by dementia, hydrocephalus, and unusual movements.”

38. Id.

39. Id.

40. Id.


42. Collins, supra note 22, ¶ 2.


46. Id.


B. The Process of DTC Testing

Genetic tests are used for numerous purposes, but are frequently used to predict a person’s risk of a disease (predictive/pre-symptomatic testing) or to diagnose a disease they already possess (diagnostic testing). Genetic tests are performed in all stages of life, from prenatal testing of embryos to posthumous testing of remains. There are a number of prevalent genetic tests used by parents on their children including carrier screening, newborn screening and prenatal testing. There are also other widely used genetic tests, such as paternity tests. Genetic tests are performed on a sample of genetic material from the patient—blood, skin, hair, amniotic sac fluid, or other tissues, depending on the purpose of the test.

Although many genetic tests are done directly through genetic counselors or physicians, of particular interest in this article are DTC genetic tests, as defined in the Introduction. Generally, a DTC genetic test is easily available as it bypasses the use of a physician or genetic counselor. An individual can, for example, order a test kit directly from the Internet and receive his or her results directly from the company. This is a deviation from normal practice since genetic tests historically have been ordered by someone such as a physician.

These tests make it so that anyone with the Internet or telephone can simply call the company or fill in an online form, order a test, and have it sent directly to their home. Once the kit is in the individual’s possession, they take a swab from their cheek, which contains DNA, and send it back to the company. When the results are sent back to the company, they are processed and interpreted in a laboratory. The user can then generally access their information via an Internet portal. Recent developments have forced some DTC genetic testing companies to change this model, now using physicians to receive the tests, perform the sample collection, and relay the results.

C. Companies Offering DTC Testing

In terms of DTC genetic testing companies, there is a wide array of services. It is not restricted to the common-place genetic tests such as

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49. Lab Tests Online, The Universe of Genetic Testing, http://www.labtestsonline.org/understanding/features/genetics-3.html (last visited Mar. 2, 2010). Generally, there are four reasons that physicians conduct genetic testing: pre-symptomatic testing, diagnostic testing, carrier testing, and fetal testing. Id.


51. See generally id. (discussing a variety of available tests that provide information about an individual’s genes).


54. See supra, Part I.

55. Williams, supra note 7.

56. See infra Part II.D.

57. See generally Hogarth, supra note 14, at 166–67 (summarizing DTC testing companies and their
paternity testing; these tests are far more imaginative and far-reaching. These services are focused on predictive and carrier testing.\textsuperscript{58} Otherwise stated, they are meant to show people’s genetic propensities towards developing certain diseases or conditions due to their having certain genetic mutations. Many companies offer general predictive genetic testing, where they take one sample to test for a number of different traits and predispositions.\textsuperscript{59} For example, they may test for genetic mutations related to obesity, eye color, freckling, breast cancer, glaucoma, high blood pressure, ancestry, and eighty other conditions and traits.\textsuperscript{60}

Genetic tests like these are certainly efficient, and when correct, can provide helpful information to someone who knows how to interpret them. It must be noted, however, that genetic predisposition does not mean that a person will get a disease.\textsuperscript{61} Unfortunately, many consumers are not aware of this fact, which leads to much of the debate regarding DTC testing.

Examples of prevalent companies offering DTC genetic testing via the Internet include 23andMe\textsuperscript{62} and DNAdirect.\textsuperscript{63} Other companies, such as HairDX and ScientificMatch, offer more targeted DTC testing services. HairDX tests solely for genetic mutations that cause hair loss (alopecia) in both women and men.\textsuperscript{64} In theory, the individual can then prevent their hair loss before it becomes a problem, as the company claims it is easier to prevent hair loss than to re-grow it once it is already lost.\textsuperscript{65} A further demonstration of the bounds of DTC testing, the company Scientific Match uses a member’s DNA to match them with other individuals who match their “chemistry.”\textsuperscript{66} Essentially, Scientific Match is advertising a genetics-based dating system. This company claims to only look at genes related to your immune system, rather than your whole genetic makeup, in order to find those individuals with whom you will have the greatest “physical chemistry.”\textsuperscript{67} In fact, the founder states that this type of matching brings “increased fertility, healthier kids, [and] less cheating . . . .”\textsuperscript{68} While this may seem to be a stretch to the average consumer, the company has had enough success to expand its business to a number of major metropolitan areas.\textsuperscript{69}

\textsuperscript{58} See, e.g., 23andMe, Health & Traits: Complete List, https://www.23andme.com/health/all/ (last visited March 1, 2010) (listing the potential traits and diseases that can be tested for using their genetic testing service).
\textsuperscript{59} Id.
\textsuperscript{60} Id.
\textsuperscript{61} See Barbara Basler, Are Genetic Tests A Good Idea? It Depends, AARP BULLETIN TODAY, June 2006, available at http://bulletin.aarp.org/yourhealth/diseases/articles/are_genetic_tests.html (“Moreover, even having a gene or genes associated with a disease doesn’t mean a person is predestined to have it.”).
\textsuperscript{62} 23andMe, supra note 58.
\textsuperscript{64} HairDX—Genetic Test for Hair Loss, http://www.hairdx.com (last visited Mar. 2, 2010).
\textsuperscript{65} Id.
\textsuperscript{67} Id.
\textsuperscript{69} Id.
This ease of access, absence of a physician, privacy issues, and effect of the results on the recipient are troubling to many individuals. Coupled with the fact that there has been little regulation at the federal as well as state levels—even to control truthfulness and quality—debate surrounds DTC genetic testing. This debate, and possible solutions, will be explored in the Analysis section of the Note.

D. Recent Events at the State Level

In June 2008, the California Department of Public Health (“CA Health Department”) sent cease and desist letters to approximately thirteen genetic testing companies in the state. The letters ordered the companies to cease their genetic testing and related advertising, offered through their websites, to California consumers until they comply with certain statutory provisions. Two well-known companies targeted by the mailing were 23andMe and Navigenics. Citing numerous violations of the California Business & Professions Code, the CA Health Department stated that the companies had roughly two weeks to submit a plan demonstrating that their laboratories are certified on the state and federal levels, and that their genetic tests are being performed through a certified physician. Should the companies have chosen to not comply with the letters, the penalty would have been civil and/or criminal sanctions, including monetary fines.

Also involved in a battle over DTC genetic testing is the state of New York. Earlier in the year, in April 2008, the New York State Department of Health (“NY Health Department”) sent out similar cease and desist letters to a number of DTC genetic testers, again including the usual suspects, Navigenics and 23andMe, as well as other companies. Over a six month period, the NY Health Department sent out these letters, similar to California, threatening jail time and fines to the non-complying companies.

In the face of the threatened harsh penalties in these states for non-compliance, a number of companies chose to continue offering their services to California and New York residents. Some companies who received these letters, and those who were just fearful they might, argued that their services were not medical, just informational, and thus shouldn’t be subject to the...
regulations.\textsuperscript{77} Other companies, such as Navigenics, said their tests are ordered by a physician, and thus meet the standards.\textsuperscript{78} 23andMe, a prominent DTC genetic testing company mentioned above, was vocal about their refusal to close their virtual doors in these states.\textsuperscript{79}

Yet another option for companies to pursue, for those who were not already doing so, was to switch to only offer their testing through qualified physicians. One such company is California-based HairDX, who sells to customers in 24 states as well as foreign countries.\textsuperscript{80} Before the letters, HairDX offered their testing kits directly to consumers, who could purchase them via the Internet.\textsuperscript{81} Now, however, the company directs customers to certain physicians who will take the necessary cheek swab, send it to the laboratory, and then share the results with the consumer.\textsuperscript{82} This change, namely using a physician throughout the process, was done in direct response to California’s actions,\textsuperscript{83} likely in hopes of avoiding any legal complications. While it appears that the physician involvement was first only required in California and New York after the letters were sent,\textsuperscript{84} the website now directs all users to physicians in their state.\textsuperscript{85} Unfortunately, this may limit the number of individuals that have access to the testing, as there are only a small number of physicians listed in some states; for example, New York only has one listed practice.\textsuperscript{86}

Most recently, California decided to grant licenses to two companies who originally received cease and desist letters to continue operating their direct-to-consumer genetic testing services in the state.\textsuperscript{87} The California health department granted the licenses to the companies Navigenics and 23andMe in August 2008, saying that the department was “very satisfied that they have met the California requirements for licensure.”\textsuperscript{88} Other companies, such as Iceland-based Decode Genetics, are also now seeking licenses in the state to be able to deal with California consumers.\textsuperscript{89}

\begin{itemize}
\item \textsuperscript{77} Id.
\item \textsuperscript{78} Id.
\item \textsuperscript{79} Alexis Madrigal, 23andMe to California: We’re not Ceasing or Desisting, WIRED SCIENCE, June 24, 2008, http://blog.wired.com/wiredscience/2008/06/23andme-were-no.html [hereinafter 23andMe to California].
\item \textsuperscript{80} HairDX, Doctors Offering the HairDX Test, http://hairdx.com/Doctors.aspx (last visited April 4, 2010).
\item \textsuperscript{81} Alexis Madrigal, DNA Testing Company Stops Direct-To-Consumer Sales in California, WIRED SCIENCE, June 23, 2008, http://www.wired.com/wiredscience/2008/06/dna-testing-com/ [hereinafter DNA Testing Company Stops].
\item \textsuperscript{82} Id.
\item \textsuperscript{83} Id.
\item \textsuperscript{84} Id.
\item \textsuperscript{85} HairDX, Doctors Offering the HairDX Test, http://hairdx.com/Doctors.aspx (last visited Nov. 15, 2008).
\item \textsuperscript{86} Id.
\item \textsuperscript{88} Id.
\item \textsuperscript{89} Id.
III. ANALYSIS

As suggested by the nature of genetic testing and the current events, there has long been controversy surrounding DTC testing. Given the sensitive nature of DTC testing and lack of uniform regulation, many agencies and medical-related associations have called for more attention to these tests. This debate is going on not only nationally, but internationally as well. Reactions from these sources appear to be less than positive, giving warnings to be skeptical about its use. This section will deal with the positive and negative aspects at the center of DTC testing, the regulatory schemes governing it, and the possible solutions that have been suggested.

A. Arguments on Both Sides

1. Cons of DTC Testing

There are many concerns surrounding direct-to-consumer genetic tests. These concerns center on the lack of knowledge on the part of the individual consumer. Critics of making these tests available directly to consumers seem to be particularly concerned with the inability of average consumers to interpret the results of a genetic test. Given that the process of genetic testing is beyond the knowledge of the average consumer, they may misinterpret results. This could lead to consumers not only being very emotionally distressed, but also may lead them to take unnecessary, and potentially harmful, actions such as self-treatment or adopting different lifestyle patterns. Perhaps people would make life-altering decisions regarding their bodies or whether they should have children. Although it likely would not happen regularly, there is the more extreme example of a woman feeling the need to get a double mastectomy because she has the breast cancer gene.

Additionally, there is concern over the fact that the testing companies do not have to prove the efficacy of their tests, nor has the FTC been rigorous in stopping them from making misleading claims. Granted the impact of these results on individuals and the weight they may place on them, this is an

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92. See, e.g., supra note 90 at 8 (recommending caution, along with the FDA and CDC, in using DTC testing).

93. See, e.g., Hogarth, supra note 14, at 168 (arguing that “without medical context and qualified counseling, consumers are vulnerable to being misled and to making inappropriate healthcare decisions”); Anny Huang, FDA Regulation of Genetic Testing: Institutional Reluctance and Public Guardianship, 53 FOOD & DRUG L.J. 555, 566 (“Misdiagnosis could lead to unnecessary, painful, and risky treatments, and the failure to diagnosis might discourage diligence in taking care of the body and seeking medical attention.”).


unsettling thought. This issue was brought to the forefront of the controversy in a study conducted by the Government Accountability Office ("G.A.O."), released in 2006.96 The G.A.O. formulated 14 fictitious consumers and submitted DNA samples with these consumer descriptions to different DTC testing companies who “purport[ed] to use genetic information to deliver personalized nutrition and lifestyle guidance.”97 What the G.A.O. found was that all of the tests they purchased provided “predictions that are medically unproven and so ambiguous that they do not provide meaningful information to consumers.”98

The G.A.O. produced a laundry list of other concerns from their study. For example, one company was using the results to suggest that the consumer buy specialized supplements that would cost $1200.99 These specialized supplements were substantially similar to the average vitamin or antioxidant that would cost only $35 a year.100 The concern is that companies could capitalize on the fear generated by (misleading) results to push a particular product or set of products.

Another concern relates to privacy of information.101 With no physician being involved and an individual conducting their business solely via the Internet, there is some chance that this sensitive, private information could fall into unintended hands. For example, while there are only limited protections for certain medical information and communications, such as the patient-physician confidentiality privilege in court proceedings, applicable for the use of medical information communicated between a physician and patient,102 consumers could lose some of these otherwise expected but limited protections by not having a physician involved or communicating with non-physician employees of the DTC testing company. This could also be damaging to a consumer in terms of obtaining insurance coverage or employment.

Due to these concerns, critics of DTC genetic testing feel it should be necessary to not only have the testing performed by a qualified physician, but also to have the results sent to the physician, to share with the patient along with his or her professional interpretation.103 However, some feel that individuals may be deterred by the involvement of a physician in the process,104 perhaps because of increased price or sensitivity about their genetic information. These drawbacks need to be weighed carefully against the

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97. Id.
98. Id.
99. Id.
100. Id.
102. Physician-patient privilege is dictated by state law and is thus not always available. See, e.g. ALASKA R. EVID. § 504 (2010) (recognizing a physician-patient privilege in the state of Alaska).
103. See, e.g., F.T.C., supra note 13 (“Ask your doctor or a genetic counselor to help you understand your test results.”).
positive aspects of DTC testing.

2. **Pros of DTC Testing**

Proponents of easily accessible, DTC testing, including the companies which provide these services, tend to believe that “people have the right to access their personal genetic information.”\(^{105}\) In other words, genetic information belongs to the consumer, like other personal belongings, and they should be able to access it at their will. Arguably, the government should not be able to regulate the consumer’s access to this extremely personal information. This argument is in the vein of a broader “the government acting as big brother” concern, which is very upsetting to many individuals who believe strongly in people’s freedom of choice.\(^{106}\) Proponents believe that a person’s DNA is fundamental to their being, and do not see any major risk in allowing the tests to bypass the use of a physician.\(^{107}\) At the very least, they may believe that the right of access outweighs any risk of no physician involvement.

Giving people access to their personal information, which may lead them to healthier, longer lives, is a positive goal. Having this information accessible to the average person for what many would consider a modest fee allows individuals to predict their predispositions, whether it is regarding their potential for hair loss or their chance of encountering cancer.

In theory, this awareness allows individuals to act preventively. For example, Google co-founder Sergey Brin (who is coincidentally married to the founder of the DTC genetic testing company 23andMe) recently shared his story of being tested for a genetic predisposition towards Parkinson’s disease \(^{108}\) since his mother carries the specific genetic mutation and in fact has Parkinson’s.\(^{109}\) While Mr. Brin does in fact carry the gene, it is likely he will never have to struggle with the devastating disease.\(^{110}\) However, he feels that his knowledge of the predisposition is very positive, as he can take possibly preventative steps, such as exercising, which is thought to decrease the risk of Parkinson’s.\(^{111}\) This sentiment is likely shared by many individuals who chose to undergo genetic testing, especially for diseases that already exist within their family.


\(^{106}\) See, e.g., California Bans Self-Knowledge, Jun. 22, 2008, http://freewill.typepad.com/genetics/2008/06/california-bans.html (stating that “such big brother tactics are an attempt to exclude individuals from understanding our own genetic differences.”).

\(^{107}\) Norrgard, supra note 16.

\(^{108}\) Parkinson’s is an as-of-yet incurable, progressive disease which occurs when certain nerve cells in the brain, that normally produce a chemical that coordinates smooth body movement, die or are impaired. This leads to tremors, severely impaired movement, stiffness, and problems with balance, amongst other things. National Parkinson Foundation – About Parkinson Disease, http://www.parkinson.org/Page.aspx?pdc=225&srcid=226 (last visited Mar. 12, 2009).


\(^{110}\) Id.

\(^{111}\) Id.
There are other issues connected to making it easier for people to obtain their genetic information, including insurance companies using this easily accessible information for purposes of discrimination. \(^{112}\) This ties in with the concern regarding privacy of testing results. Although it is beyond the scope of this Note, the Genetic Information Non-Discrimination Act of 2008 \(^{113}\) is meant to address that concern. This Act was signed in May 2008, and prohibits health insurance companies from using people’s genetic information to discriminate against them. \(^{114}\) This should allay the fears of genetic testing critics who are concerned with the potential non-privacy of genetic testing that is easily obtained and changes hands numerous times in the process of ordering it from the Internet. However, most individuals are painfully aware that even though insurance companies are theoretically unable to use this information, this does not mean it will not happen.

### B. State Laws

Prior to the cease and desist letters sent in June 2008, California had done little to regulate DTC genetic testing companies that were operating within their state. Despite their generally pro-technology stance, \(^{115}\) the state of California finally chose to deal with the DTC testing companies through its state health department laws. \(^{116}\) Many state codes deal with DTC genetic testing, even if they do so indirectly. On the other hand, many states are silent on the subject. \(^{117}\) At one point, a state health department official stated that California was no longer going to tolerate DTC genetic testing. \(^{118}\) As noted above, the cease and desist letters were sent by the CA Department of Public Health and cited eight statutory provisions violated by the companies. \(^{119}\) California falls into a category of states that allow direct to consumer genetic testing but impose certain limitations. \(^{120}\) Others states’ statutes are silent on

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116. See generally Letter from Karen L. Nickel, Cal. Dept. Public Health, to Phil Robinson, Director of DNA Traits (June 9, 2008) available at http://www.wired.com/images_blogs/wiredscience/files/madrigal.PDF (warning Robinson that the testing performed by his laboratory was in violation of several sections of the California state code).

117. See GENETICS & PUBLIC POLICY CTR., SURVEY OF DIRECT-TO-CONSUMER TESTING STATUTES AND REGULATIONS (2007), http://www.dnapolicy.org/resources/DTCSStateLawChart.pdf (noting in the comments column that several state codes are silent on the issue, but state officials are often able to clarify).


120. See generally Genetics & Public Policy Ctr., Survey of Direct-To-Consumer Testing Statutes and Regulations (June 2007), http://www.dnapolicy.org/resources/DTCSStateLawChart.pdf (last visited Mar. 14,
the issue, usually meaning they permit DTC genetic testing without limitation for the time being; other states strictly prohibit any DTC genetic testing.  

1. Regulating States: California and Illinois

The first states up for discussion are those that allow DTC genetic testing, but do so with pertinent regulations limiting the practice. Generally these limiting states restrict which particular tests can be ordered by the consumer without physician involvement, and further may mandate that any other genetic test must be ordered directly by a physician, with the results sent directly from the laboratory to the ultimate consumer. This approach seems to allow states to choose tests that they think need the involvement of a physician while still allowing some DTC genetic testing. Two states representative of this category are California and Illinois, and each of these states will be discussed in turn.

California is generally known for its technology-friendly stances. In fact, it is the state of choice for some DTC testing companies. However, as evidenced by the recent events, California has not been equally warm to DTC testing companies. Although California allows DTC genetic testing, it is limited by the fact that they require that the genetic testing companies apply for licenses since they are effectively operating as “clinical laboratories.” It also is illegal for anyone to offer “clinical laboratory tests” directly to a consumer without the involvement of a physician, unless the test is exempt. “Clinical laboratory tests,” which fairly clearly encompass genetic tests, are defined by the code as:

The detection, identification, measurement, evaluation, correlation, monitoring, and reporting of any particular analyte, entity or substance within a biological specimen for the purpose of obtaining scientific data which may be used as an aid to ascertain the presence, progress, and source of a disease or physiological condition in a human being, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition in a human being, or for the performance of non diagnostic tests for assessing the health of an individual.

2010 [hereinafter Survey of Regulations] (providing a survey of state DTC laws and regulations).

121. See generally id. (providing a survey of state DTC laws and regulations).


123. Survey of Regulations, supra note 120. Other states who fall into the limited DTC testing category currently include Arizona, Colorado, Florida, Maine, Maryland, Massachusetts, Nevada, New Jersey, New York and Oregon. Id.

124. See generally RelocateAmerica.com, Riverside, California, http://www.relocateamerica.com/california/cities/riverside (last visited Mar. 1, 2010) (noting that Riverside, California, is a technology friendly city, which has forty high technology companies).


127. CAL. BUS. & PROF. CODE § 1288 (2008). An argument against this statute tends to be that the DTC genetic tests are not clinical laboratory tests, rather just educational information.

128. Id. at § 1206(a)(4) (West 2008).
Furthermore, the tests that may be provided without the involvement of a physician are restricted by the statute to “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 . . . .”\textsuperscript{129} Therefore, California requires DTC genetic testers to obtain clinical laboratory licenses from the state, which requires the involvement of a physician in the testing.

Illinois is not as clearly in the category of states with limitations, such as California. The pertinent regulation comes from the Illinois Clinical Laboratory and Blood Bank Act.\textsuperscript{130} The Illinois statutes restrict the ordering of genetic tests by consumers by directing clinical laboratories to examine specimens only at the request of certain enumerated individuals.\textsuperscript{131} These individuals include licensed physicians, law enforcement officers, and a number of types of licensed healthcare professionals.\textsuperscript{132} It is a violation of the statute for a clinical laboratory to examine specimens from individuals other than these or to report the information gained from the test to anyone but the referring party.\textsuperscript{133} Essentially, these statutes appear to try and stamp out DTC testing to a large extent.

Putting aside the fact that companies could likely get around these by employing a physician to refer tests to a laboratory and accept the test results, Illinois is still classified as a “limiting” state rather than a “prohibiting” state.\textsuperscript{134} While this remains fuzzy, it is likely due to the fact that there was a “rule” which would allow DTC testing for CLIA-waived tests.\textsuperscript{135} However, that rule was to be approved by the Advisory Board of the Illinois Department of Public Health, which was disbanded.\textsuperscript{136} If nothing else, the rule is indicative of the state’s desire to allow some DTC testing, contrary to the above-discussed statutes.

2. Non-Regulating States

As opposed to states who limit genetic testing through their statutes, numerous states currently have no statutes dealing with DTC genetic testing, at least in the area of who can order and receive genetic tests.\textsuperscript{137} Of interest in this section are those states whose statutes are silent, but still allow DTC testing with little limitation. States included this category include Delaware, Delaware, Delaware, Delaware, Delaware.
Indiana, Louisiana, Minnesota, New Mexico, Oklahoma, Texas, Vermont and West Virginia.\textsuperscript{138} Indiana, for example, a state which is generally known for its conservative leanings, does not appear to have any state statutes dealing with DTC testing.\textsuperscript{139} Individuals at the Indiana State Department of Health, in the past, have confirmed that although the state statutes are silent on the issue, DTC testing is allowed.\textsuperscript{140} The silence on part of these states may be due to the relatively new nature of DTC testing, or perhaps a conscious judgment by the legislature to let DTC testing continue without limitation. Regardless, should there be no forthcoming federal regulation on the issue, it would be beneficial for these states to take stance on DTC testing through their law-making process, so as to give companies more security in their sales.

3. Prohibiting States

Finally, there are states whose statutes, either directly or indirectly, prohibit any form of DTC genetic testing. Included in this category are Alabama, Connecticut, Georgia, Idaho, Kentucky, Michigan, New Hampshire, Pennsylvania, Rhode Island, South Carolina, Tennessee, and Wyoming.\textsuperscript{141} Perhaps states like Illinois belong in this category as well, depending on the status of Health Department rules, but for generalization purposes the states discussed here will be Tennessee and South Carolina.

Tennessee is a prime example of a state that expressly prohibits DTC testing in its statutes and has thus far made no exception to the rule.\textsuperscript{142} According to Tennessee law, “No person . . . shall examine human specimens without the written request of a physician . . . or other health care professional legally permitted to submit to a medical laboratory a written request for tests appropriate to that professional’s practice . . . .”\textsuperscript{143} Therefore, genetic tests must be ordered in writing by a physician or other qualified healthcare professional. Additionally, the law requires that results from the test be reported “directly to the physician . . . or other health care professional who requested it.”\textsuperscript{144} This plainly attempts to exclude any DTC testing where the company orders the tests or has the results sent directly to themselves or the individual consumer. However, DTC testing companies may work around this rule by having a physician on staff in the state order the test and receive the results. Therefore, while DTC testing may be expressly prohibited in theory, companies may still manage to sell within those states.

Other states appear to take a vaguer route to prohibiting DTC testing. South Carolina, although their statutes have historically been silent on the

\textsuperscript{138} Id.
\textsuperscript{140} Id.
\textsuperscript{141} Id. at 1–14.
\textsuperscript{142} Id. at 12.
\textsuperscript{143} Id., quoting TENN. CODE. ANN. § 68-29-121 (2008).
\textsuperscript{144} TENN. CODE. ANN. § 68-29-121(b) (2008).
issue, prohibits DTC testing. The South Carolina Department of Health and Environmental Control has stated that it is “understood in South Carolina that patients cannot directly order laboratory tests.” This understanding rests on the fact that under CLIA, only authorized persons are allowed to order genetic tests and receive test results. While “authorized persons” are not defined by the South Carolina statute, it is understood by laboratories to exclude the average, individual consumer. This approach clearly raises legal questions and concerns, which will be addressed in a later section.

C. Current Federal Regulation

As evidenced by the patchwork state regulations regarding DTC testing, there is very little pertinent federal regulation. Although there are a few regulations that seemingly touch on the subject, there are no laws meant to directly deal with DTC testing, as opposed to regular, physician-administered genetic testing. Despite some regulation in the general area of genetic testing, the important regulation on the matter is left to the states and often leaves much to be desired. The more pertinent regulations come in connection with the Centers for Medicare & Medicaid Services (“CMS”), U.S. Food and Drug Administration (“FDA”) and the Federal Trade Commission (“FTC”). These will be discussed in turn. This brief discussion demonstrates the shortcomings of federal regulation in DTC testing.

Most important to this Note are the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”). CLIA established “quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed.” The implementing regulations for CLIA were passed in 1988. Under this regulation, laboratories must be certified in order to perform “clinical genetic testing.” Under CLIA, a laboratory is defined as “any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health.” However, CLIA is not considered particularly on point for genetic testing as it “does not address clinical validity or claims made by the laboratory regarding the tests.” Interestingly, CMS had

145. Survey of Regulations, supra note 120, at 11.
146. Id.
147. See infra note 150 and accompanying text.
148. Id.
149. Id.
151. Id.
153. ASHG Statement, supra note 8, at 636.
154. CLIA, supra note 135, at 1.
155. ASHG Statement, supra note 8, at 636.
publicly considered creating a specialty area in the regulation for genetic tests, but abandoned that proposal in 2006.\footnote{156}{Id.}

The FDA also plays a role in this regulation, and further demonstrates its shortcomings. In addition to the CLIA not covering aspects of tests that are important in DTC testing, the FDA scrutinizes tests differently depending on whether they are a commercial versus laboratory-developed test kit.\footnote{157}{Id.} Laboratory-developed test kits are given far more leeway, with no need to have them review or report when there is a mishap after it is used,\footnote{158}{No definition is given for what would constitute a “mishap.” Perhaps this means when a test gives an improper result or something similar.} with minimal exceptions.\footnote{159}{ASHG Statement, supra note 8, at 636. This is opposed to commercial test kits, which have requisite pre-market testing and reporting of “adverse events” that happen post-market. The pertinent exception to this is very narrow and relates only to “in vitro diagnostic multivariate index assays.” Id.} As pointed out the American Journal of Human Genetics, this problem extends beyond DTC testing to genetic testing a whole.\footnote{160}{Id.} However, the problems are more acute when it comes to DTC testing being put directly into the hand of consumers.\footnote{161}{Id.} Generally, the FDA likely has the authority to regulate these genetic tests, but as of yet, have done little to take responsibility.\footnote{162}{Huang, supra note 93, at 574.}

The second scheme deserving of comment in this Note comes from the FTC, the independent agency generally dealing with the protection of consumers. While an in depth explanation is outside the scope of this Note, the FTC has the most oversight of DTC testing at the federal level, as it is responsible for regulating the related advertising. Particularly, the FTC should be stepping in where there are any “unfair, deceptive, or fraudulent trade practices including making false or misleading advertising claims” in relation to DTC testing.\footnote{163}{ASHG Statement, supra, note 8, at 636.} Although the FTC has issued a statement on DTC testing that warns consumers to be wary of the likely false claims made by companies,\footnote{164}{F.T.C., At-Home Genetic Tests: A Healthy Dose of Skepticism May Be the Best Prescription (July 2006), http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea02.shtm.} they have taken little to no significant action against them to this date. There are many possible reasons why the FTC has not cracked down, such as members of the FTC staff not being knowledgeable enough about the genetic-testing subject matter to be able to spot misleading claims.\footnote{165}{ASHG Statement, supra note 8, at 636.} A lack of complaints being filed is not one of them.\footnote{166}{Id.}

\section*{D. Possible Solutions}

Even before the events in California and New York, individuals in the legal and science world had proposed a number of viable solutions to the lack
of regulation in the DTC genetic testing arena. In light of those events, however, it seems even more important that a consensus be reached. There are any number of possible solutions for dealing with the unique qualities of DTC testing.

1. State Level Regulation

States have clearly chosen to deal with DTC testing in different ways, from explicitly banning this type of test, to limiting its uses, to leaving the area completely unregulated. This leaves plenty of uncertainty for companies who would wish to operate in every state for obvious economic reasons. Perhaps it is best to let the legislatures of each state decide how they feel about the safety of DTC testing and regulate accordingly. Consumers would be free to live in a state, or travel to a state, where they can have access to DTC testing if that is important to them. Genetic testing, in general, has always been an understandably controversial issue. Undoubtedly, every state has a capable legislature that could deal with the issue, though this process would not necessarily be efficient. Furthermore, this scheme still allows widespread access to DTC testing. There would still be a market for DTC genetic tests in some states, even if not in a majority.

On the other hand, state-level regulation has led to non-uniform laws that cause problems for companies and individuals trying to access these services in certain areas. It may leave dangerous gaps in regulation, possibly allowing problems such as misleading advertising, misinterpretation of tests, and involvement of unqualified individuals without consequences in some states. Second, it is more difficult for all involved parties to navigate the surrounding law when each state has its own regulations, some of which are unclear, non-existent or easily circumvented. This is especially true given the nature of DTC testing. These tests are being sold via the Internet, in many cases across state lines. While it is not unrealistic to expect companies to abide by different genetic testing laws in different states, it may be more efficient and better for the public welfare to have a more overarching and uniform regulation which makes DTC testing safer and easier for both consumers and companies. There is an argument that companies will simply move states to more easily circumvent rules, to the states with the most relaxed or non-existent rules. States, in turn, may want to relax their DTC laws to draw in the headquarters of more DTC testing companies. This phenomenon would hardly beneficial for the trusting consumer, who likely relies on regulation of genetic tests purchased via the internet, just as they would tests performed in person by their physician. Regardless of the reason, many of these regulations that are set out by a patchwork of states are being simply disregarded or circumvented. The

167. See generally Gniady, supra note 94 (advocating improving regulation through the Food and Drug Administration as well as other mechanisms to protect consumers).
168. Supra Part III.B.
169. Id.
unique qualities of DTC genetic testing seems to call for more than generic, state-by-state laws, although these laws may provide insight into drafting appropriate legislation.

2. Federal Regulation

Given the scattered nature of the state level regulation and the issues that have already arisen under the current regulatory scheme, an alternative that needs to be considered is regulation at the federal level. Although physician-administered genetic tests have arguably been efficiently regulated under state laws, DTC tests have the added complications of being sold directly to consumers and without physician contact. This calls for a specialized scheme to deal with its potentially harmful qualities. Under more uniform laws, companies could know what standards they have to meet when selling via the Internet to individuals in many different states and would be theoretically less able to circumvent the requirements. It would be a small sacrifice on the part of the states, but could result in a more useful, accessible, and safe DTC testing industry.

Although it may be relatively obvious, DTC tests being sold via the Internet are products which are appropriately overseen on the federal level. Congress could likely derive its power to regulate DTC tests from the Commerce Clause. DTC testing companies, by necessity, generally set up a headquarters in a certain state, such as California. Their tests are then marketed and sold to consumers in other states. Given that the tests are sold over the Internet and can reach consumers in nearly every state, these transactions should fall squarely within the category of interstate commerce.

Additionally, it would be beneficial to have a registry at the national level for DTC genetic tests to help monitor their quality and consistency. While the FTC could more aggressively pursue false and misleading claims, a federal database would help consumers, who are purchasing their genetic tests through the Internet, to quickly and painlessly discover any negative information regarding the test kits they are considering using. If nothing else, it would deter companies from selling poor quality test kits with the threat of possible mass disgrace on the Internet where potential customers can easily access it. Although some scholars feel the database must be a formal and mandatory one, created by the FDA, even a less formal database might be sufficient. While

171. U.S. CONST. art. 1, § 8, cl. 3.
173. Huang, supra note 93, at 574–79.
174. See, e.g., Gail H. Javitt, In Search of a Coherent Framework: Options for FDA Oversight of Genetic Tests, 62 FOOD & DRUG L.J. 617, 646 (2007) (submitting that the FDA should create a database for genetic tests where companies would be required to submit information about the validity of their tests); S.H. Katsanos et al., A Case Study of Personalized Medicine, 320 SCI. MAG. 53, 54 (2008) (proposing that companies must “submit information about the test and data supporting the intended use of the tests to a registry that would be accessible to the public”).
it is important to have information submitted by the company regarding the validity of their test, even a more interactive registry where physicians and patients can share their experiences and concerns would be useful. Given the widespread access to the Internet and the fact that DTC tests are sold via the Internet, an online database of this nature would be targeted to those individuals who are most interested in the tests. The FDA or other agency may still need to oversee the registry, in order to keep companies and individuals from abusing the database.

Given the fact that DTC companies operate via websites, an alternative to having a database would simply be to require the companies to prominently display statements regarding the validity of their tests. While companies tend to have descriptions of the science behind their tests,\cite{176} it is not necessarily within the understanding of the average consumer ordering the test. Therefore, the language would need to be in plain terms which a layperson could understand, prominently displayed on their website. Companies understandably might be resistant to this, but it would be the most accessible, efficient way for consumers to know what they are purchasing, without having to spend copious amounts of time searching for information. In fact, it may spur consumers to do more research on a company; whereas without the prominently placed statement, the consumer may assume that these tests are FDA approved and will live up to the companies claims. This would also help lower a consumer’s unreasonable expectations about genetic testing.

The tougher questions lie in where the bar should be set for physician involvement and an individual company’s responsibilities in DTC testing. Is it enough to just send swabs to a physician through a middle-man company or do you need a physician to be more actively involved in ordering, collecting, and giving the results? Should companies have to make sure that consumers are given correct, sound information on how to interpret the results? Must companies disclose all possible risks of this unique service? A number of scholars have offered their opinions on these questions and the broader question of how to regulate DTC testing in scientific journals.\cite{177}

The American Society of Human Genetics (“ASHG”) offers a persuasive 3-pronged approach to dealing with DTC testing: transparency, provider education, and test and laboratory quality.\cite{178} For transparency, every DTC company “must provide all relevant information about offered tests in a readily accessible and understandable manner.”\cite{179} This would mean that a company

\begin{itemize}
\item 177. See generally, ASHG Statement, supra note 8, at 636 (generally discussing government oversight of genetic testing and recommending the promotion of transparency); Gniady, supra note 94 (generally discussing direct-to-consumer genetic testing while protecting the consumer); Hogarth, supra note 14 (discussing direct-to-consumer genetic testing comparing the United States and Europe); Huang, supra note 93 (discussing the FDA regulation of genetic testing); S.H. Katsanis et al., A Case Study of Personalized Medicine, 320 Sci. Mag. 53, 53–54 (2008) (discussing how genetic testing could be used to improve drug safety information).
\item 178. ASHG Statement, supra note 8, at 636–37.
\item 179. Id. at 636.
\end{itemize}
would have to provide the average consumer with accessible information on the scientific value of the test, strength of the scientific evidence, any risks associated with the test, CLIA status of their laboratories, and clinical evidence. For provider education, “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.”

Finally, for quality, the ASHG recommends that the FTC, FDA, and CMS become more actively involved in regulating this area. The FTC needs to more aggressively pursue false and misleading claims. The FDA needs to become involved in developing guidelines for DTC testing companies. CMS needs to create a specialty area in the CLIA for DTC tests. Most importantly, the ASHG recommends that “the federal government [...] take steps to ensure the clinical validity of DTC tests that make health-related or health care–affecting claims.”

However, we need to be careful not to strangle the DTC testing industry. DTC testing has benefits to the consumer in both its accessibility and types of tests. Imposing unrealistic requirements on these companies, even regarding disclosure, or forcing them to have a physician present every step of the way would essentially move us back to physician-administered genetic testing as the sole option. These companies are not the consumer’s keeper and should only be held responsible up to a certain point for a consumer’s misunderstandings of what they order. Requiring a registry or plain statement on a company website would go far in helping address this issue. However, if an informed individual wants access to their personal information, the medical industry should encourage this curiosity, rather than try to hinder their efforts.

A proper scheme of regulation by the federal government, which protects the consumer by requiring certain standards, certifications and disclosures as discussed broadly by the ASHG, but does not strangle the DTC testing industry, could be an ideal situation. Such a scheme would certainly require the cooperation of many agencies, including the FDA, CMS, and FTC.

IV. RECOMMENDATION

DTC testing has many positive aspects that should not be abandoned because of issues with regulation. In light of the issues associated with the patch-work of state regulations, the best idea would be federal regulation focused not just on genetic testing, but specifically on DTC testing and its unique qualities. Consumers are not being afforded the appropriate protection from DTC genetic testing companies who potentially have the power to

180. Id.
181. Id. at 637.
182. ASHG Statement, supra note 8, at 637.
183. Id.
184. Id.
185. Id.
186. Id.
187. See text accompanying Part III.A.
significantly alter people’s lives. This power needs to be checked on the federal level, although not to the point that it makes it difficult for people to access these tests, as ease of access is the essence of DTC testing. This regulation should be achieved through efforts by the FDA, CMS, and FTC, who are already involved in the oversight of genetic testing, in line with the quality suggestions of the ASHG. 188

As for the necessity of physician involvement in the process, while it is desirable for a company to have a physician on staff in a given state, the seemingly most important physician-involvement would be with the interpretation of the testing results. Given the sometimes exorbitant prices, claims made by DTC testing companies, and possible impact of undesirable results, companies should have physicians or other qualified healthcare professionals that are capable of interpreting and disclosing the meaning of a given test result in plain language. Additionally, companies should disclose the certification status of their laboratories, as well as the scientific strength of any of the claims that are made to the consumer, preferably in an easily accessible online format. While, in theory, it seems beneficial to require a physician to order the tests, the initial ordering of a test from a certified laboratory is not as concerning as subsequent events that are done without physician involvement. Furthermore, a national, federally overseen database should be set up for easy consumer tracking of the claims and issues arising from each DTC company.

A scheme that required these few things would provide greater protection to the consumer without squashing the industry. Requiring these disclosures as well as physician involvement on the back-end of the process would not result in any extra hassle to the consumer nor would it decrease the ease of access to DTC testing. Consumers could still order directly from the Internet, without ever having to deal with a physician, and thus would not be discouraged from seeking such tests. At the same time, consumers are more protected, at manageable cost to the company. Both consumers and companies would be better off with this overarching regulation. Consumers would be less likely to be harmed by the advertising and results, and companies would be more likely to be able to sell to a broader audience with fewer issues from individual states.

V. CONCLUSION

DTC testing, its shortcomings, and corresponding regulatory scheme have been discussed in this Note. As we continue to push the boundaries of medical testing and make it more accessible to the individual consumer, the law often seems to struggle to adapt. The accessibility of direct-to-consumer genetic testing has brought with it tremendous benefits to the individual, like its accessibility to the general public. Its accessibility, however, has also brought new risks that were not at issue with strictly physician-administered genetic tests. The current patchwork of state laws, with some states even choosing not

188. Supra text accompanying notes 127–34; ASHG Statement, supra note 8, at 637.
to regulate the issue, is doing a poor job of maximizing the practice’s benefits and minimizing its risks to the consumer. An overarching federal framework, particularly dealing with physician involvement, is the most efficient way to bring about these results.