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Direct-to-Consumer Genetic Testing: Is It The Practice of Medicine?

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Understanding of the human genome and its functional significance has increased exponentially since the completion of the Human Genome Project (HGP) in 2003. The HGP fueled the discovery of more than 1,800 disease genes and paved the way for researchers to identify and test for genes suspected of causing inherited diseases. Currently, there are more than 1000 genetic tests for human diseases and conditions on the market.¹ These tests can play an integral role in the delivery of health care by providing information that could potentially form the basis for profound life decisions, such as whether to undergo a prophylactic mastectomy, whether to terminate a pregnancy, or whether to take a particular drug or medication dose.²

Traditionally, genetic tests were available only through healthcare providers. There is an increasing trend, however, for genetic test companies to market and sell their genetic test products directly to consumers.³ Direct-to-consumer (DTC) genetic testing provides a consumer with access to his or her genetic information without necessarily involving a doctor in the process.

Over the past year there has been much debate about the legality of DTC genetic testing. At least two states have sent “cease and desist” letters to companies, arguing that they were in violation of state law regulating the unlicensed practice of medicine.⁴ DTC genetic testing has become more controversial as the number of available single gene tests has increased and particularly with the introduction of personal genome testing services, which provide risk assessment information for many diseases, traits, and conditions by genotyping thousands of gene loci in each individual. The variety of genetic information tested for complicates the issue of whether these companies are providing information for recreational purposes only or whether they are also providing medical diagnostic information. The pertinent legal issue relates to whether the services offered by DTC genetic testing companies fall within the scope of medical practice, and if so, to what extent must a physician or other health care provider be involved?

Types of DTC Genetic Testing Services Available

Currently, there are approximately thirty-five (35) DTC genetic testing companies doing business via the internet.⁵ These companies collectively offer a broad range of DNA testing services directly to consumers. The types of information tested for can be grouped into four general categories: (1) susceptibility to disease (e.g., age-related macular degeneration, Celiac disease, Crohn’s disease, Parkinson’s disease, prostate cancer, diabetes); (2) nutritional and metabolic assessments (e.g., oxidative stress tests, caffeine metabolism, metabolizing certain nutrients, skin health), (3) individual traits or characteristics (e.g., athletic performance, bitter taste perception, earwax type), and (4) ancestry information. A few companies market a single gene test, while others market an entire genome scan that includes one or more of these categories of information.

As Prainsack and Reardon point out, personal genome testing blurs the boundaries of when the performance of a genetic test constitutes the practice of medicine.⁶ It may be clear that

some genetic information is not medical per se (e.g., ancestry information and information about certain traits or characteristics like bitter taste perception) while other information clearly is (e.g., results of a test for a single gene Mendelian disorder such as Huntington disease). It is much less clear, however, whether the provision of genetic risk assessment information for common and complex disorders constitutes the practice of medicine or how to treat companies that provide genome scans that provide both medical and non-medical information to consumers.

Benefits and Risks of DTC Genetic Testing

Proponents of DTC genetic testing believe that it will empower consumers to take more personal responsibility for their health by providing them risk assessment information and allowing them to proactively search for specific genetic variants of interest.⁷ It may also lead to an increased use of genetic testing services since individuals do not have to go through a licensed physician to order the test and receive the results. A recent survey that we (ALM) conducted of social networkers' attitudes toward DTC personal genome testing suggests that at least some potential consumers will see this as a major benefit of DTC genetic testing.⁸ It is not clear why consumers would prefer to receive genetic information without the involvement of a physician, but it may be that they are concerned about their privacy. Research shows that members of the public are concerned about their genetic privacy and worry about being discriminated against because of their genetic susceptibility to disease.⁹ The recent passage of the Genetic Information Nondiscrimination Act (GINA),¹⁰ a federal law that prohibits the use of genetic information for employment and health insurance coverage decisions may help alleviate these concerns, but it is still too soon to tell. It is also not clear that DTC genetic testing protects privacy any better, since there is wide variation in company privacy policies and issues of who owns the data if the company is bought out or goes bankrupt are not resolved.

Advocates of DTC genetic testing also argue that individuals have a right to personal genetic information and worry that too much regulation will unjustifiably limit this right.¹¹ While we agree that competent adults generally have a right to purchase available information about themselves and their DNA, if that information is related to an individual's health or susceptibility to disease and would warrant additional follow-up from a licensed health care provider then there is an obligation to ensure that the information is accurate and that the consumer is well-informed about the potential clinical implications of the information and the risks and benefits of receiving it.

While the growing market for DTC genetic testing may promote awareness of genetic diseases and allow consumers to take a more proactive role in their health care, these "at-home" genetic tests also pose significant risks and limitations. The results of genetic tests are not always straightforward, imposing a challenge for interpretation. A positive test result means the laboratory found a variance in a particular gene, chromosome, or protein of interest. Depending on the purpose of the test, this result may confirm a diagnosis, identify an increased risk of developing a disease in the future, indicate the person is a carrier of a particular genetic mutation, or suggest a need for further testing.¹² If a genetic test finds a variance in DNA that has not been associated with a disorder in other people, it may be difficult to tell whether it is a harmless polymorphism or a disease-causing mutation. In some situations, positive test results are simply uninformative or indeterminate because everyone has common, natural variations in their DNA that do not affect health.¹³ Finally, a positive result on a predictive or presymptomatic genetic test does not necessarily establish the exact risk for developing a disorder because most diseases tested for are multifactorial and the genetic test does not consider additional factors, such as family history or environmental exposures when assessing

individual risk. This explains why health professionals cannot and should not use a positive test result to predict the course or severity of a condition.¹⁴

A negative test result, on the other hand, means the laboratory did not find a variance in the gene, chromosome, or protein under consideration. A negative result may indicate the person is not affected by a particular disorder, does not have an increased risk of developing a certain disease, or is not a carrier of a specific genetic mutation. Or, a negative result may mean the test failed to detect genetic changes that could cause a particular disorder.

The complexity of test results and the complicated interaction between genes and the environment (e.g., lifestyle choices, nutritional diet, and environmental elements, such as sunlight and tobacco) and its effect on health and disease has enabled DTC genetic testing companies to claim that they are not providing medical information to consumers, but rather, that they are only providing information for educational purposes.¹⁵ They encourage consumers to discuss this information with their physician, who should use his or her professional judgment to interpret it in light of other risk factors in order to derive a diagnosis and/or plan for surveillance.¹⁶ However, physicians have been advised not to provide counsel on the basis of DTC test information because of concerns about the validity and utility of test results.¹⁷ Without the benefit of interpretive guidance from a healthcare provider, vulnerable “at home” genetic test consumers may be misled by the results of unproven or invalid tests and potentially could make important decisions about treatment or prevention based on inaccurate, incomplete, or misunderstood information about their genetic health.

Professional Guidelines

Over the course of the past few years, several professional medical organizations and health oversight governmental agencies have recognized the potential vulnerability of “at home” genetic test consumers and the detrimental effects if consumers are left to self-interpret the results of “at home” tests. Specifically, in 2004, the American College of Medicine Genetics (ACMG) issued a policy statement opposing DTC genetic testing and stating that genetic testing should be provided to the public only through the services of appropriately qualified health care professionals, who would be responsible for both ordering and interpreting the genetic tests, as well as pre-test and post-test counseling regarding the medical significance of the test results and the need, if any, for follow-up.¹⁸ The ACMG recognized that, due to the complexities of genetic testing and counseling, the self-ordering of genetic tests by patients over the telephone or Internet, and their use of “at home” test kits, is potentially harmful. Potential harms could include inappropriate test utilization, misinterpretation of test results, and lack of necessary follow-up.¹⁹

Several governmental organizations and agencies, including the Secretary’s Advisory Committee on Genetics, Health, and Society (SACGHS), the Food and Drug Administration (FDA), the Federal Trade Commission (FTC), and the Centers for Disease Control and Prevention (CDC)²⁰ embraced the ACMG’s policy, which subsequently led to the FTC’s issuance of a fact statement for consumers in 2006, titled, *At Home Genetic Tests: A Healthy Dose of Skepticism May Be the Best Prescription*.²¹ The FTC maintains the firm position that, because of the complexities involved in both genetic testing and the interpretation of results, genetic tests should be performed in a specialized laboratory and the results should be interpreted by a doctor or trained counselor who understands the value of genetic testing for a particular situation.²² In 2008, the American Medical Association (AMA) took a similar stance recommending DTC genetic testing should be carried out under the supervision of a health care professional.²³

These policy statements, which oppose DTC genetic testing and collectively call for qualified health care professionals to order, supervise, and interpret genetic tests, impliedly raise the

question of whether the practice of DTC genetic testing falls within the scope of the practice of medicine? If so, should the practice of ordering and interpreting genetic tests be limited to the confines of the physician-patient relationship?

Does DTC Genetic Testing Falls Within the Scope of the Practice of Medicine?

There is no universal definition of the “practice of medicine.” The medical licensing authority within each state defines the “practice of medicine” for that given state. Thus, the issue of whether DTC genetic testing constitutes the “practice of medicine” would logically fall within the purview of each state’s medical licensing authority.

Each state maintains its own regulatory definition for the “practice of medicine.”²⁴ A cursory survey reveals that most states include some combination of the following words within their regulatory definition: diagnosis, treatment, cure, disease, disorder, and/or injury.²⁵ From a historical perspective, over one century ago, courts recognized that the “practice of medicine” encompasses three things: (1) judging the nature, character and symptoms of the disease; (2) determining the proper remedy for the disease; and (3) giving or prescribing a remedy for the disease.²⁶ Simply put, the medical practitioner is concerned with determining what afflicts his or her ailing patients -- making a diagnosis -- and then determining what remedy he or she should administer to his patient.²⁷

Medical Diagnoses and DTC Genetic Testing

There has been little case law defining what constitutes a medical diagnosis.²⁸ Under the rules of statutory construction, when a word in a statute is clear and unambiguous, courts generally will give the word its plain and ordinary meaning.²⁹ Webster’s dictionary defines “diagnosis” as the “art or act of identifying a disease from its signs and symptoms.”³⁰ However, when there is no manifestation of disease or symptoms, does the act of providing information about the probability of developing a particular condition constitute a medical diagnosis? No state has directly addressed this issue. As Nunnally points out, “[e]ven the most recent iterations of state statutes, ... do not contemplate diagnostic genetic testing for the potential onset of genetic disorders at a pre-symptomatic stage. Hence, determination of whether genetic testing constitutes medical practice is a matter of interpretation that has not yet come before the courts.”³¹

It could be argued that testing asymptomatic persons for disease risk does not constitute a diagnosis and is not within the scope of the practice of medicine precisely because no disease or pathology exists. However, as Han has argued, this “assumes a limited view of medicine and the role of genetic tests. Multivariate genetic tests are valuable precisely because they provide additional information as to a patient’s disease risk.”³²

If a DTC genetic test company is exercising medical judgment by rendering health care advice on the basis of genetic test results then it is probably engaged in the unlicensed practice of medicine.³³ Several DTC genetic test companies not only sell genetic tests online but also provide nutritional advice on the basis of test results and sell expensive supplements or provide lifestyle recommendations directly to the consumer. The United States Government Accountability Office (GAO) investigated four of these companies in 2006 and issued a report titled, *Nutrigenetic Testing: Tests Purchased from Four Web Sites Mislead Consumers*.³⁴ During its investigation, the GAO purchased genetic tests for 14 fictitious consumers from companies through the Internet. After receiving the 14 written test results, the GAO concluded the results contained health-related predictions that a consumer could potentially interpret as diagnoses. Although the Internet genetic testing companies provided disclaimers stating the information was not intended to diagnose disease or a pre-disposition to disease, the GAO

found the results misleading because they indicated the fictitious consumers were at risk for developing a myriad of medical conditions.³⁵

A survey of the web sites for several current Internet genetic test companies reveals disclaimer language consistent with that found in the GAO report.³⁶ Most DTC genetic testing companies do not provide specific medical or lifestyle advice and do not sell supplements or products based on test results. Yet a recent survey that we (ALM) conducted found that 38% of social networkers who would consider using these DTC genetic testing services and 60% of those who reported having used these services consider the information obtained to be a diagnosis of a medical condition or disease.³⁷ This substantiates the GAO's concerns and raises serious questions about the safety of consumers who might make important health care decisions on the basis of this information without any interpretive guidance from a licensed health care provider.

Consumer Protection and Company-Employed Physicians

The underlying purpose of medical licensing laws is to prevent fraud and to protect the public from "unscrupulous and untrained providers."³⁸ Thus, from a public policy perspective it is most important that consumers of DTC genetic testing are adequately protected. At a minimum, this requires stricter regulation to ensure truth-in-marketing and to prevent fraud.³⁹ It should also require that the test is valid (that it tests for what it says it is testing for). The Center for Medicare and Medicaid Services (CMS) regulates laboratory testing through the federal Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). The objective of CLIA is to ensure quality laboratory testing which, in theory, should include test validity through a laboratory certification process.⁴⁰ However, the CLIA certification process has been criticized as not providing adequate oversight of laboratories conducting genetic tests.⁴¹ Additional regulation may be warranted to ensure the safety and efficacy of test products,⁴² but even with heightened federal regulation, according to state law, if consumers are receiving medical services then they must be provided through a licensed health care provider.

Several companies have responded by hiring a physician to order and interpret tests for all consumers. For example, Navigenics, a popular DTC personal genome testing company, provides consumers with an opportunity for pre- and post-test counseling with a board-certified genetics counselor. It also employs a physician to order tests and receive results, but specifies that this is simply "to satisfy the laws of certain states" and it is "not intended to create, nor [does it] create, any doctor-patient relationship."⁴³ The ACMG, AMA, and FTC policy statements call for a qualified health care provider to supervise genetic testing, yet none of these entities specify whether the health care provider should be the consumer's personal physician as opposed to a laboratory-employed physician.

Physicians have a fiduciary obligation to act competently and to use their expert knowledge and skills primarily for the benefit of their patient.⁴⁴ The genetic test consumer's interests are best served by involving a licensed professional who can help interpret test results and who can advise about the clinical utility of those results as well as recommend medically indicated follow-up. Company-employed physicians can be utilized for this purpose as long as they are able to appropriately manage real and perceived conflicts of interest that might arise. However, if a physician is employed by the company to act for the benefit of the patient, neither the company nor the physician can avoid the establishment of a physician-patient relationship by simply declaring it not to exist.

The question of whether a DTC company physician establishes a physician-patient relationship with on-line consumers is complex. Ultimately, it is a matter of state law and will be left to individual state legislators or courts to decide. Typically, the question of whether a physician-patient relationship has been formed arises in the context of medical malpractice lawsuits and

when analyzing whether the physician owes a duty to the patient. Absent this relationship, there is no duty.⁴⁵

According to most states, the physician-patient relationship is a consensual relationship, in which the patient knowingly seeks the physician's services and the physician knowingly accepts the person as his patient.⁴⁶ This consensual relationship may be either express or implied and may exist where others have contracted with the physician on the patient's behalf.⁴⁷ The key in determining whether the relationship is a consensual one is not who contracted for the services, but whether the services were contracted with the express or implied consent of the patient or for his or her benefit.⁴⁸

The physician does not have to establish direct physical contact or deal directly with the patient to establish a physician-patient relationship.⁴⁹ In fact, this relationship may exist between a patient and a physician, such as a radiologist or pathologist, who had no actual contact with the patient, but nevertheless, performed a service for the benefit of the patient.⁵⁰

There is no clear case law directly on point to suggest that a DTC genetic testing company-based physician and an on-line consumer have an implied physician-patient relationship. However, if the consumer knowingly seeks testing services from the DTC company, and the DTC company requests the physician's services for purposes of ordering and interpreting the test for the benefit of the consumer, then arguably, the physician impliedly established a physician-patient relationship with the consumer by ordering the test (and interpreting the same) for the consumer's benefit even though the physician never spoke with or directly dealt with the consumer. If this relationship exists, then the physician owes the duty to treat the consumer with proper professional skill, which conceivably would include deciding whether it would be in the consumer's best interest to order a particular genetic test or set of tests and ensuring that the consumer-patient receives accurate and unbiased information about the benefits and risks of genetic testing and the clinical utility, or lack thereof, of test results. This duty should supersede any economic interest or benefit the physician could potentially receive from the company.

The Physician's Role: Clinical Utility and the Free Market

Sound clinical principles dictate that, before genetic tests can be generally accepted in clinical practice, data must be collected to demonstrate the benefits and risks that accrue from both positive and negative effects.⁵¹ In other words, the physician must determine what benefits can be gained from performing a genetic test before ordering it. Usually, a screening or diagnostic test alone does not have utility; rather, it is the therapeutic and preventive interventions that influence health outcomes.⁵² However, some test results may provide personal meaning to the consumer-patient, which is a benefit that must be carefully considered.

The utility of a test should be defined as the balance between the benefits and harms (clinical as well as personal) of testing and the ensuing follow-up evaluation, treatment, or prevention.⁵³ It must be evaluated within a specific context, including clinical variables, availability of resources, acceptability, and values and patient preference.⁵⁴

Currently, the degree to which clinical utility is established for different genetic tests varies widely and often depends on the type of test offered and the populations or conditions with which they are associated.⁵⁵ Incomplete knowledge of clinical utility can lead to wasted resources and jeopardize patient care.⁵⁶

The current state of complexity and uncertainty surrounding DTC genetic testing suggests that physicians have a limited but important role to play. The advantage of using a company-employed physician is that he or she will be familiar with the test products and can provide

accurate and detailed information about them. The disadvantage is that the company-employed physician does not usually have a complete picture of the consumer's health and family history and should therefore not make predictions about disease risk or severity and should not render advice regarding health behaviors or clinical follow-up, other than to provide referral to a physician or genetics counselor who can perform a complete history and provide comprehensive follow-up care.

Consumers should be free to purchase information, whether it is predictive information regarding their astrological future or their biological future, in a free market economy. If consumers understood and could fully appreciate the limitations of this information then minimal regulation may be justified. However, the little available evidence suggests that, despite disclaimers of DTC genetic test companies, consumers are likely to misinterpret the clinical significance of test results and to make misinformed and potentially harmful health care decisions on the basis of those results. Medical licensure laws were originally created to protect patients from unscrupulous and untrained providers. Non-medical employees of DTC genetic testing companies may not be deceitful or even dishonest, but they are not trained providers and therefore should not be providing medical information or advice directly to consumers without the assistance of a licensed professional.

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