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Direct-to-Consumer Genetic Testing: Perceptions, Problems, and Policy Responses

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Abstract

Direct-to-consumer (DTC) genetic testing has attracted a great amount of attention from policy makers, the scientific community, professional groups, and the media. Although it is unclear what the public demand is for these services, there does appear to be public interest in personal genetic risk information. As a result, many commentators have raised a variety of social, ethical, and regulatory issues associated with this emerging industry, including privacy issues, ensuring that DTC companies provide accurate information about the risks and limitations of their services, the possible adverse impact of DTC genetic testing on healthcare systems, and concern about how individuals may interpret and react to genetic risk information.

INTRODUCTION

Genetic tests sold directly to the public (direct-to-consumer or DTC testing), especially those that utilize next-generation sequencing technologies to test for susceptibility to hundreds of diseases and traits, have stirred interest and generated much excitement. But they have also stimulated intense policy debate in the United States and abroad (see **Table 1** for examples of policy recommendations). A wide range of scholars, professional organizations, and governmental entities have weighed in on the array of ethical, legal, and social issues raised by DTC genetic testing (1–5).

Although it is not known how many people have actually purchased these services, data are beginning to emerge about what motivates consumers to get tested and how they respond to the information received (6). These data are helping to inform policy makers who are struggling to determine the most appropriate way to regulate a product that has multiple purposes, that is sold to consumers internationally and over the internet, and that has been found by federal investigation to have questionable validity and unproven utility (7, 8). In this article, we review the current state of DTC genetic testing, existing data on public interest in these tests, and some of the many ethical and legal issues associated with offering health-related test results directly to consumers.

CURRENT STATE OF DTC GENETIC TESTING

Although DTC genetic testing has been around for a long time, it is a phenomenon that has gained prominence in just the past few years, largely as a result of improved testing and sequencing technologies. Not long ago, the sequencing of a single genome cost billions of dollars. Now it can be done for a few thousand, and it seems likely that, in the near future, the sequencing of a whole genome will cost less than $1,000 (9). DTC companies rarely sequence entire genomes [however, there are exceptions (10)], but the efficiency in sequencing technology has enabled some companies to genotype hundreds of thousands of SNPs across the genome for less than $100. This technological advance has transformed the DTC genetic testing industry and has led to the emergence of companies like 23andMe (**http://www.23andme.com**) and Navigenics (**http://navigenics.com**). These companies capitalize on the recent explosion of genome-wide association studies to test individuals for thousands of variants across the genome that are associated with common traits and complex diseases.

The tests provide a wide range of information, some ostensibly offering little more than a genetic curiosity (e.g., a gene variant that determines ear wax characteristics) while others relate to serious medical conditions. For example, DTC genetic testing can now provide individuals with information about their genetic predisposition to a variety of diseases, including heart disease, diabetes, cancer, Alzheimer's disease, and mental illness. They can also learn about genetic factors that may influence their body's reaction to certain foods, alcohol, pharmaceuticals, and caffeine, as well as genes associated with eye color, male pattern baldness, and athletic performance.

In general, DTC companies market testing by suggesting that it will allow individuals to make more informed health care decisions and to personalize healthy lifestyle choices. For example, the website for 23andMe states that you can "live well at any age by understanding your health risks." The Navigenics website says that the company's "goal is to empower you with genetic insights to help motivate you to improve your health."

Despite the health claims made by many of these companies, the health value of these services remains questionable. Most of the variants tested for have relatively low penetrance, and compared to other genetic tests that have moved into clinical use, the utility of the information gleaned from DTC services is largely unproven. As Janssens et al. have noted, the "scientific evidence for most associations between genetic variants and disease risk is

Table 1 Examples of policy recommendations for direct-to-consumer (DTC) genetic testing

Organization	Report	Key recommendations				
Secretary's Advisory Committee on Genetics, Health, and Society, 2010 (U.S.)	*Direct-to-Consumer Genetic Testing*	Improve federal oversight of DTC genetic tests	Federal test registry should include DTC tests	Federal task force should evaluate DTC company claims	Address gaps in privacy and research protections	Develop genetics education initiative for consumers and health professionals
Human Genetics Commission, 2010 (U.K.)	*A Common Framework of Principles for Direct-to-Consumer Genetic Testing Services*	Marketing claims must be accurate and disclose evidence base for tests and advice	Consumers' informed consent requires details of company practices and test benefits, risks and limits	Qualified professional should interpret and explain results and provide counseling for heritable disorders	Sample handling and lab procedures must comply with appropriate standards	Genetic information requires highest level of confidentiality
European Society of Human Genetics, 2010 (E.U.)	*Statement of the ESHG on Direct-to-Consumer Genetic Testing for Health-related Purposes*	Clinical utility is key criterion for offering DTC tests	Testing laboratories must meet accepted quality standards	Marketing claims must fairly and accurately explain test purpose and predictability	Provide genetic counseling appropriate to test and disease	Safeguard confidentiality of sensitive genetic information
American College of Medical Genetics, 2008 (U.S.)	*ACMG Statement on DTC Genetic Testing*	Knowledgeable professional should be involved in testing	Consumers should be informed about benefits and limits of tests	Scientific basis of tests should be clearly stated	Testing laboratories must be accredited by a relevant authority	Privacy issues must be discussed before testing
American Medical Association, 2008 (U.S.)	*Direct-to-Consumer Marketing and Availability of Genetic Tests*	Genetic testing should be supervised by qualified health professional	Consumers should seek advice of health professional before buying tests	AMA will provide input on acceptable marketing of DTC tests	Federal authorities should ensure company claims are fair and truthful	AMA will inform members about DTC issues to support patient education
American Society of Human Genetics, 2007 (U.S.)	*ASHG Statements on Direct-to-Consumer Genetic Testing*	Companies must be transparent about scientific basis for tests and advice	Federal government should take regulatory action to ensure test and lab quality	Health professional organizations should educate members about DTC tests	Companies must protect privacy and explain compliance with applicable law	Further research is needed on evidence base for tests and impact of DTC access on consumers

insufficient to support useful applications" (p. 598) (11).

Indeed, much of the risk information that is provided is of limited predictive value. For example, one variant related to cardiovascular disease is reported to increase risk from 1% to 1.6%. While this could be called a 60% increase in risk, it is, in truth, practically meaningless from a health perspective (12). Many scholars have begun to question the public health value of genetic testing more broadly, especially in the context of common chronic diseases (13, 14). In order to avoid inappropriate hype, it has been suggested that "[h]uman genetics and genomics researchers should avoid generating too high expectations of the applications of their results for diagnosis, treatment and prevention" (p. 381) (15).

Despite these calls for caution, however, DTC companies continue to market and sell their services. Some companies, especially 23andMe, have used a variety of innovative marketing strategies, such as hosting celebrity "spit parties" (16) and introducing a social networking feature for customers who wish to connect with genetically similar "friends." These efforts seem to have paid off; 23andMe's retail genetic test was selected by *Time Magazine* as the invention of the year in 2008 (17).

PUBLIC INTEREST IN GENETIC TESTING

Despite the great deal of attention this field has received, it is unclear how much public interest there is in DTC genetic testing services. Some commentators have claimed that the market could be quite large—a 2007 Forbes article put the current annual market at around $730 million with a projected annual growth of 20% (18)—but there is, in fact, little robust evidence on the actual uptake of DTC tests. One interesting 2010 analysis, done by Wright & Gregory-Jones, used Internet traffic and public statements by the relevant companies to estimate the size of the DTC market (19). They concluded that only 20,000–30,000 individuals, worldwide, purchased a test from one of the three top companies (23andMe, Navigenics, and deCODEme) in 2009. Given that the price for the tests at the time of their analysis ranged from $400 to $1,000, Wright & Gregory-Jones estimate that the size of the market is a much more modest $10–$20 million. They speculate that "current demand for genomic profiling tests for susceptibility to common complex diseases is fairly small. As such, the impact of these tests on health systems must also be small, although not negligible" (p. 594) (19). It is worth noting that since the Wright & Gregory-Jones analysis, DTC companies have reduced their prices significantly. The 23andMe test, for example, can now be purchased for $99 ("was $499," as the company website declares). This marketing strategy also hints at a less than strong demand for DTC services.

On the other hand, several studies have found that considerable public interest in knowing genetic risk information. In a 2010 survey of Americans, 70%–80% of respondents (depending on the exact scenario presented) indicated willingness to pay for DTC testing (20). The survey also found that this interest was sustained even if the results did not have immediate clinical value. The study authors concluded that "people desire information for its own sake" and often for nonhealth reasons. A study of the Canadian public found a more moderate level of interest. This could be because Canadians have a sense that the public system should pay for health-related testing services. That said, the study still found a slight majority of the surveyed population (51%) willing to pay for testing for serious and unpreventable diseases (21). Other studies, using different survey methods, have found a similar degree of stated interest. A 2009 online survey of more than 1,000 social networking users found that 64% would consider using DTC genetic testing, primarily for the purpose of obtaining useful health information (22).

History tells us that a stated interest in a testing technology will not necessarily translate into an actual demand, and the current market is clearly weaker than originally envisioned by many in the industry. There is also some

evidence of reluctance to use genetically informed personalized medicine, especially among racial minorities (23). But the emerging public opinion data do reveal a public that seems relatively comfortable with the idea of DTC testing. Given the ubiquity of the services and the decreasing cost of the testing technology, it seems inevitable that a large number of people will have access to information about their genetic risks and traits.

LEGAL, ETHICAL, AND SOCIAL CHALLENGES

Since the inception of the DTC genetic testing industry, concerns have been raised about its ethical and legal implications. Some countries (e.g., Germany) have even banned the use of DTC genetic testing services. In the United States, DTC companies have been criticized for making false claims, engaging in the unlicensed practice of medicine, and selling a medical device without appropriate regulatory oversight. Concerns have also been raised about potential harm to consumers, the health system implications of DTC testing, and privacy issues related to the commercial storage of genomic data.

Marketing DTC Genetic Tests

Access to accurate and truthful information is essential for informed decision making. In 2006, the U.S. Government Accountability Office (GAO) investigated a subset of DTC companies offering genetic testing coupled with nutrigenomic advice and sale of supplements. The GAO reported that "[t]he results from all of the tests GAO purchased mislead consumers by making predictions that are medically unproven and so ambiguous that they do not provide meaningful information to consumers" (7). In 2010, the GAO conducted a second investigation, this time expanding its scope to more mainstream DTC companies like 23andMe, Navigenics, and Pathway Genomics. Again it found the results to be "misleading and of little or no practical use" (8). Despite the fact that all of these companies go to great lengths to ensure that their product is grounded in the newest and best science, the GAO investigation found a great deal of variance in test results obtained through different companies. It also found that "10 out of the 15 companies [it] investigated engaged in some form of fraudulent, deceptive, or otherwise questionable marketing practices" (8).

In the United States, the Federal Trade Commission (FTC) is responsible for consumer protection, including protection against deceptive advertising. In 2006, the FTC warned consumers to interpret at-home genetic tests with "A Healthy Dose of Skepticism" and to "[b]e wary of claims about the benefits these products supposedly offer" (24). The FTC could regulate against cases of deceptive marketing more rigorously, but up to now they have reserved their policing authority for more egregious cases. Although many DTC companies strive to provide not only accurate but also educational information to their consumers, some continue to mislead with false claims and gross exaggerations. This leaves unwitting consumers vulnerable to inaccurate and untruthful claims and has led some critics, including the Secretary's Advisory Committee on Genetics, Health, and Society, to call on federal agencies to enhance regulation of DTC genetic testing companies (4, 5). As van El & Cornel have noted: "Special attention is necessary regarding advertising for direct-to-consumer tests to ensure adequate information is given and truthful claims are made about the test and possible interventions" (p. 380) (15).

Psychosocial Impact of Testing

One of the longest held and central concerns associated with DTC genetic testing is that the results will cause anxiety or lead to an inappropriate behavioral response, either because individuals will overinterpret the significance of a positive result or gain a false sense of security from a negative result (25, 26). This concern has been echoed in a wide range of policy reports, including that of the 2000 Secretary's Advisory

Committee on Genetic Testing, National Institutes of Health (27).

However, the few studies that have looked at individuals' response to test results have found that people generally adapt well to the information provided (28). For example, a recent study that explored the reaction of individuals to commercially available genetic tests found that "testing did not result in any measurable short-term changes in psychological health, diet or exercise behavior, or use of screening tests" (p. 524) (29).

A few studies have hinted at the possible existence of a fatalistic response to genetic risk information. Claasen et al., for example, found that patients were more inclined to perceive their risk of cardiovascular disease as something outside their control when the risk was presented in a manner that included DNA testing (30). However, in total, there appears to be little evidence that people respond fatalistically. A 2011 systematic review of available research on the fatalism question concluded that the limited available evidence suggests that the "feedback of genetic risk information may have little impact on [fatalistic] beliefs" (p. 273) (31).

In fact, there is little evidence to suggest any sustained behavior change, good or bad, as the result of genetic risk information (29). There have been some well-publicized stories suggesting that genetic testing may motivate at least some people to engage in healthy behavior change; for example, Francis Collins himself has touted the health benefits of DTC testing, relating how information about his genetic susceptibility to diabetes motivated him to lose weight and exercise more (31, 32). Yet, more systematic studies suggest that genetic test results have a limited impact on healthy behavior change. A 2010 systematic review, published as part of the Cochrane Collaboration, concluded thus: "Claims that receiving DNA-based test results motivates people to change their behavior are not supported by evidence" (p. 2) (33).

Integration with Medical Practice

Direct-to-consumer genetic testing bypasses the involvement of a licensed health care professional. In some jurisdictions and for some professional groups, this has been deemed unacceptable—primarily because of concern about misinterpretation of results. For example, as noted above, DTC testing has been banned in Germany (34), and the Australian Medical Association supports a ban (35). It has not been banned in the United States, but several professional organizations, including the American College of Medical Genetics (ACMG) and the American Medical Association (AMA), suggest that genetic testing should not be performed without involvement of a licensed health care provider (36, 37). The U.K. Human Genetics Commission and the European Society of Human Genetics both allow DTC testing but recommend that it not be provided without appropriate genetic counseling (3, 38). Some companies provide genetic counseling services to their consumers, but a recent survey found that only ~10% of consumers reported using these services (29).

In 2008, two U.S. states sent cease-and-desist letters to DTC companies, claiming that they were violating state laws, including laws against the unlicensed practice of medicine (39). Although state laws vary, the practice of medicine generally encompasses diagnosing and/or treating a disease, condition, or injury (40). Thus, the question of whether DTC companies are engaged in the practice of medicine turns on whether predictive genetic information is considered a diagnosis. Although an unsettled legal issue, research has shown that many of the people who access DTC testing believe it is akin to health information or a medical diagnosis (22).

Health Systems Implications

Although consumers have been encouraged by DTC companies, federal agencies, and professional societies to discuss their results with a health professional, doing so raises additional concerns about the potential adverse impact of DTC testing on the broader health care system, particularly in countries with publicly funded systems. Specifically, it has been suggested that

DTC testing could lead to unnecessary visits to health care providers and inappropriate follow-up tests (41). These could, in turn, lead to iatrogenic injuries that cause further harm and social costs (5). Some research supports this concern. For example, one study found that of those who expressed an interest in getting tested, 78% said that they would ask their physicians for help interpreting their results, and 61% thought that physicians have a professional obligation to provide such help (22). These results are consistent with other research studies that have found that the public views the results as health information that should be taken to a health care provider. In one survey of 1,463 Americans, 59% said they would take their results to a physician or specialist for a second opinion (20).

Given that the clinical and health-promoting value of these tests remains highly questionable, this trend seems unlikely to have much social utility—especially because few primary care physicians are likely prepared to respond to questions about the genetic risk information found in DTC test results. One recent study of U.S. physicians, for example, found that only 10% felt prepared to handle pharmacogenetic testing (42).

However, this concern might be overstated. As noted above, the current market for DTC testing is relatively small. Also, a stated intention to do something does not necessarily translate into action. Individuals who report an intention to take test results to a physician will not necessarily do so. In a recent survey of actual DTC test users, only 10.4% of those surveyed reported discussing their results with a company-employed genetic counselor, and 26.5% reported sharing their results with their physician (29).

Privacy Concerns

Research has shown that concern for privacy is one of the top issues for the general public in the context of genetic testing (29). And numerous studies have found that many in the public view genetic information to be among the most sensitive and personal. A 2001 survey of the Canadian public found that 90% either strongly agree (61%) or agree (29%) that rules governing access to genetic information should be stricter than for other forms of personal information (43). Academic commentators and professional groups have also touched on the privacy issues specific to DTC genetic testing (2, 44), noting that consumers may assume, incorrectly, that the traditional rules of confidentiality that exist in the physician-patient relationship apply to DTC companies (45). This may give a false sense of security to the consumers of DTC services. In fact, there are no uniform standards that are applicable to DTC companies regarding the collection and storage of samples and personal information (44). For example, the American Society of Human Genetics noted in its 2007 Statement that "DTC companies are not necessarily subject to the health privacy regulations issued pursuant to the Health Insurance Portability and Accountability Act (HIPAA), leaving consumers vulnerable to having their information used or disclosed in a manner that would be impermissible in the health care system" (p. 635) (2).

A 2010 study gives some support to the existing apprehension about privacy protection (44). In its analysis of the privacy practices of 32 DTC companies, the study found significant variation in the ways in which companies deal with the protection of personal information and DNA samples. Only seven of the companies had a reasonably comprehensive privacy policy that was accessible for viewing by the general public on the company website.

Privacy issues may also arise if the ownership of a DTC company changes hands or if the company goes out of business. For example, if a company is sold, the new owner may not feel bound by previous privacy arrangements or may reside in a jurisdiction with less strict or comprehensive privacy protection rules (44). It could be even more problematic if a company simply goes bankrupt or out of business (45), as did deCODE Genetics, Inc. in 2009. The company's assets were sold, and this raised numerous concerns about what would happen

to the highly sensitive information stored in the company's biobanks (46).

Governmental Oversight

Genetic tests are largely unregulated in the United States. Laboratories that provide testing services are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (47). CLIA ensures that laboratories follow procedures that minimize the risks of laboratory error. Most DTC companies now run their tests in a CLIA-certified lab. However, this does not guarantee the analytic validity of tests, as exemplified by a laboratory processing error at 23andMe that resulted in 96 consumers receiving test results that did not belong to them (48). Fortunately, the error was caught quickly and consumers were informed of the mistake immediately, minimizing potential harm from receiving incorrect test results.

The U.S. Food and Drug Administration (FDA) provides heightened regulation for medical drugs and devices. The FDA has jurisdiction to regulate genetic tests but has not traditionally done so. It has not, to date, exercised its enforcement discretion over all tests that are developed in-house, as are most DTC genetic tests. However, in July 2010, partly in response to the DTC company Pathway Genomics' announcement that it planned to sell its test kit through Walgreens drugstores, the FDA sent letters to several DTC companies indicating its intention to assert its jurisdiction over them (49). The FDA is still deliberating about the best regulatory approach and has held several public meetings to solicit input (50). One of the problems is that since DTC genetic tests have multiple purposes with varying degrees of associated risk, no one regulatory approach will be appropriate for all (51). The Secretary's Advisory Committee on Genetics, Health, and Society has therefore recommended a stratified approach so that high-risk test results are subject to greater scrutiny than lower-risk results (4). McGuire and colleagues have also suggested a stratified approach, but because of the challenges of collecting efficacy data for predictive genetic tests, they advocate premarket review of higher-risk tests followed by enhanced postmarket surveillance as safety and efficacy data are collected (5). This allows for greater oversight to protect consumers without regulating DTC testing out of existence.

THE FUTURE

There are myriad other issues associated with DTC testing that are important to consider as the technology continues to advance and the industry expands. For example, despite the fact that most medical associations (e.g., the American Academy of Pediatrics) discourage the testing of children for adult-onset diseases, many DTC companies either explicitly market the testing of children or have no way of preventing it. In some cases, companies are marketing directly to parents, encouraging them to test their children to find out whether they are genetically predisposed to particular traits, such as athletic ability (52). Emerging evidence hints that many parents are interested in getting their kids tested, not only for athletic predispositions but for disease genes (53). Other companies are beginning to offer preconceptional DTC genetic testing (54). The implications of both the DTC testing of minors and the use of testing to inform reproductive decisions intensify many of the above-noted policy dilemmas, heightening the need to ensure appropriate oversight and the provision of accurate information (54).

As sequencing technologies continue to advance at unprecedented speed, new businesses are sure to emerge that seek to capitalize on the human curiosity that drives us all to learn more about ourselves. With these developments, new social challenges seem certain to appear. For example, it is inevitable that cheap whole-genome sequencing will soon be available. When this happens, consumers will be able to access more than risk-susceptibility information about themselves. Whole-genome sequencing will provide access to information about rare and novel variants that are present in everyone and may or may not be deleterious to one's health or the health of one's offspring. This will

further complicate the issues discussed above and potentially raise new issues as consumers, company employees, and health care professionals all struggle to understand the meaning of the information generated and disclosed. It is essential that as this industry grows, adequate attention is given to exploring ethical, legal, and social issues that arise, creating innovative oversight mechanisms, and ensuring accountability so that consumers are protected and, at a minimum, guaranteed to receive accurate and truthful information in a way that facilitates understanding and informed decision making.

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