Direct-to-Consumer Genetic Testing: Personalized Medicine in Evolution

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Overview: **Genetic testing has been one of the cornerstones of personalized cancer care for a decade. However, direct-to-consumer (DTC) marketing of genetic tests has led to a rapid evolution of how testing is viewed by scientists, consumers, businesses, health care providers, and regulatory bodies. The advent of high-throughput genetic technologies has created an opportunity for large-scale genomic evaluation of individuals at a relatively affordable price. This article discusses the potential for use and abuse of these technologies from the perspectives of the various stakeholders. DTC genetic testing platforms are reviewed with respect to methodology and quality of tests currently available to the consumer. The pros and cons of DTC genetic testing are reviewed from the consumers' perspective. What is known about how consumers understand, interpret, and implement this new knowledge is discussed. The potential positive and negative impacts of DTC genetic testing on oncologic practice are reviewed. The rapid evolution of DTC genetic testing has made regulation of these services a moving target, and the current regulatory status of DTC testing is described. In sum, DTC genetic testing has the potential to launch personalized medicine to a height never before anticipated if technologic, social, and ethical issues are effectively addressed.**

DTC GENETIC testing is intimately entwined with the personal genomics movement. Certainly, DTC genetic testing represents a powerful mechanism for providing comprehensive genomic information to a large number of individuals, but several DTC tests have now moved toward use of a physician or counselor intermediate to help provide and interpret the test results, making it no longer a DTC test. The purpose of this review is to compare tests that are currently on the market and provide insights into issues associated with provision of this information to patients. Therefore, we will not adhere strictly to the requirement that the tests be ordered by or provided directly to consumers, but rather that they are being marketed to or for the general public. In this review we provide first a summary of the technology that is currently available along with a discussion of the meaning and validity of the results obtained from these tests. Next, we discuss DTC genetic testing from the perspective of the consumer, including attitudes and behaviors that may result from the testing process. Another important issue with respect to DTC genetic testing is how this will affect health care, doctor-patient relationships, and genetic education of patients. We include a section on implications for health care providers to address this concern. Finally, the vast potential for gain of genetic knowledge, juxtaposed with the fear of ethical and privacy issues, has created a heated debate on the regulatory front. Our final section highlights regulation of DTC personal genomics.

Technology

Modern DTC genomics includes a wide range of products (Table 1), but these can be broadly grouped into three classes[1]: targeted analysis ("genotyping") of a small number of specific genetic variants[2]; the use of "single nucleotide polymorphism (SNP) chips" (pronounced "snip chips") to simultaneously examine thousands of small changes found across the genome[3]; or the use of DNA sequencing to determine the precise sequence of bases either across small regions of the genome, or across the entire genome (whole-genome sequencing [WGS]).

Targeted Genotyping of Specific Variants

This class of testing is offered by a range of niche companies that provide information on variants relevant to one or a few specific diseases or traits. For instance, the company HairDX (Irvine, CA) provides information on a handful of genetic variants putatively associated with hair loss. The quality of these tests is likely to vary substantially across companies, and results should be interpreted with caution.

Genome-wide SNP Chips

Currently, most popular health-related consumer genomics products (including those provided by 23andMe [Mountain View, CA], deCODEme [Reykjavik, Iceland], Navigenics [Foster City, CA], Pathway Genomics [San Diego, CA], and Counsyl [Redwood City, CA]) rely instead on SNP chips, typically targeting approximately 1 million sites of known genetic variation and with retail costs between $200 and $2,000. The SNP chips used by DTC companies are based on the same technology used in large-scale genome-wide association studies by academic researchers, and typically generate extremely accurate raw data: One published comparison reported more than 99.7% concordance between 23andMe and Navigenics tests run on the same individual. SNP chips examine directly only a small fraction of the genome (approximately 0.03%), but the variants on the chips are typically carefully selected to provide information about risk for common and/or rare diseases.

WGS

Examination of (nearly) all of the 6 billion letters in the human genome is currently offered by a relatively small number of companies (notably Knome [Cambridge, MA] and Illumina [San Diego, CA]) and at a price beyond the range of most consumers; the cheapest current retail price is close to

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Table 1. DTC Genomic Tests

Company	Web Address	Class of Test	Order	Cost (USD)
HairDX	www.hairdx.com	Targeted genotyping	MD	Variable
23andMe	www.23andme.com	Genome-wide SNP	DTC	Hundreds
deCODEme	www.decodeme.com	Genome-wide SNP	DTC	Thousands
Navigenics	www.navigenics.com	Targeted SNP	MD	Variable
Pathway Genomics	www.pathway.com	Targeted SNP	MD	Hundreds, variable
Counsyl	www.counsyl.com	Targeted SNP	MD	Hundreds, variable
Illumina/Knome	www.illumina.com	Whole exome/genome sequencing	MD	Tens of thousands

Abbreviations: DTC, direct to consumer; USD, U.S. dollars; MD, physician; SNP, single nucleotide polymorphism; unk, unknown.

$20,000. WGS provides an overview of the majority of variation present in an individual genome, with the exception of the approximately 10% to 15% of the genome that is too repetitive to be analyzed using current technologies.[1] However, it should be noted that for most individuals WGS will provide only marginally more health-relevant information than that provided by cutting-edge SNP chips, as a result of our incomplete understanding of the effects of variation in most regions in the genome. In addition, per-variant error rates for WGS are currently higher than those for SNP chips.

Interpretation

DTC companies provide interpretation of many different aspects of genomic data, with genealogy and ancestry being particularly popular. However, we will focus here on interpretation of health-relevant traits.

KEY POINTS

- Modern direct-to-consumer (DTC) genomic products range from tests that genotype a small set of genetic variants up to whole genome sequencing; in general, the more popular tests are based on robust, accurate technology.
- Although the value of consumer genetic tests remains a subject of vibrant debate, early data indicate that purchasers of consumer genetic tests do not act rashly on the basis of what they learn about their own DNA.
- The most commonly cited reasons to purchase a DTC genetic test include curiosity, the desire for knowledge about disease in the family, and desire to learn about genetic make-up without having to go through a physician; whereas the greatest concerns include privacy, test reliability, potential lack of usefulness, and high cost.
- Given the expected increased availability and use of genomic testing within and outside traditional health care settings, oncologists are expected to encounter increased patient requests for genetic tests or requests for advice on how to incorporate test results into their medical care.
- DTC genetic testing remains legal in most of its forms throughout most of the United States, and neither the U.S. Food and Drug Administration or Congress has articulated a clear plan to regulate the industry.

Common Disease Risk

The SNP chips used by most DTC companies target hundreds of thousands of known sites of common variation (present in 5% or more of the population), many of which have been shown to be associated with small increases in risk for common diseases such as type II diabetes or rheumatoid arthritis. By aggregating risk information across multiple variants associated with a disease, it is possible to generate an overall individual risk prediction.

As noted above, the raw accuracy for SNP chips is extremely good, and most mainstream DTC companies perform risk calculations based on scientifically sensible algorithms. However, there are some key caveats with these analyses. First, the genetic variants currently associated with most common diseases explain only a fraction of overall disease risk, meaning that individual risk predictions will change over time as more variants are discovered for that disease.[2,3] Second, these variants have often been studied in only one or a small number of populations (typically Europeans), and care must be taken in extrapolating their findings to individuals with different ancestry, although studies to date suggest that for most risk variants this is not a major problem.[4] Finally, the predictions provided by consumer genetic tests do not currently take environmental risk factors into account, and these environmental factors may increase or decrease the risk of disease development.

Testing for Rare, Severe Disease Mutations

Several companies also offer testing for rare mutations known to cause severe diseases. In some cases the tested variants are known to dramatically increase the risk of severe adult-onset conditions such as breast cancer (23andMe) or Alzheimer's disease (deCODEme). However, most severe disease mutations tested by DTC companies are involved in childhood-onset recessive diseases: individuals carrying a single copy of these mutations (carriers) are unaffected, but a child born to two carriers of mutations in the same gene has a 25% chance of developing the disease. Carrier testing for prospective parents is offered by several consumer genetic companies (e.g., 23andMe, Pathway Genomics, and a more comprehensive service by Counsyl).

It is important to emphasize that, in all cases, the companies detect only a subset of the mutations that could cause these diseases, so a negative result does not exclude the possibility that an individual is carrying an untested mutation in the same gene.

Future of Genetic Testing

The last decade has seen an astonishing increase in the capacity of genomic technology: a modern DNA sequencing

machine produces 12 orders of magnitude more data per run than the most powerful instrument available in 2001.[5] This progress has resulted in a sharp decrease in the cost of complete genome sequencing, which is widely predicted to reach prices below the $1,000 required for broader consumer adoption by 2013.

As the scale of the raw genetic data available to consumers increases, consumer genetics companies will need to develop infrastructure for storing and analyzing these data and simple, user-friendly interfaces for exploring the results. Importantly, the same challenges will be faced by practitioners of genomic medicine, meaning that the consumer genetics industry may provide an important source of innovation for the mainstream medical system.

Emergence of DTC Genetic Testing

In the fall of 2007, two companies—deCODEme and 23andMe—began offering consumers genome scans. For a price of approximately $1,000, one could spit into a tube and mail the tube to a genetic analysis laboratory, which would genotype the sample at somewhere between 500,000 and 1 million SNPs, or approximately 0.03% of the genome. In a few weeks the consumer would receive instructions to log onto a secure website to retrieve the results. Once on the website, the consumer could access company-generated risk estimates and presumptive trait information for a tiny fraction of the genotyped alleles (typically in the dozens). These firms also offered genetic ancestry analyses. In the spring of 2008, another company, Navigenics, entered the fray. Navigenics opted to focus exclusively on health-related genetic risks (i.e., no genetic ancestry or, say, earwax results); for an initial price of $2,500, it would make genetic counseling available to its customers.[6]

Several other companies would soon follow suit, although a number have since backed away from the DTC model and now insist that physicians order their products. With the exception of deCODEme, their prices have fallen precipitously since launch.[7] All have been the subject of vocal criticism from members of the medical community and unwelcome attention from the U.S. Congress and regulators.[8] Both doctors and legislators have suggested that such tests are of little value and may well be dangerous if customers receive bad news in an unmediated fashion.[9,10] Although the value of consumer genetic tests remains a subject of vibrant debate,[11] the early data indicate that purchasers of consumer genetic tests do not act rashly on the basis of what they learn about their own DNA.[12]

Public Genomics: The Personal Genome Project

The Personal Genome Project was and is the brainchild of Harvard geneticist George Church, who, in the early 2000s, foresaw a need to begin to grapple with the social consequences of whole-genome sequencing of potentially identifiable human beings.[6] Church was concerned that because every human genome (other than the genomes shared by monozygotic twins) would constitute a unique identifier, promises of confidentiality to research participants undergoing genome sequencing would be disingenuous at best. He and others also recognized that the anonymization of human biologic data diminishes its value.[13,14] The Personal Genome Project, therefore, would recruit a cohort of individuals willing to assume the risks of full identifiability: their medical and "omic" data would be made public, and their biologic materials would be housed at the Coriell Institute for Medical Research (Camden, NJ), where the research community could access them easily.[15]

Participation in the Personal Genome Project is potentially open to all comers over the age of 18; however, it is not guaranteed. To ensure fully informed consent, would-be participants are asked to review a study guide and take a corresponding online exam. The exam features questions about genetics as well as thorny ethical and social issues that might arise from making one's genomic and health information public. A score of 100% on the exam, which can be repeated, is a prerequisite for enrollment in the study.[15] In late 2010, the Personal Genome Project enrolled its thousandth participant.

Consumer Attitudes and Behaviors

Understanding how patients and consumers view DTC genetic testing has been a primary focus of DTC-related research during the last 10 years. Overall, awareness of DTC advertising (DTCA) for cancer-related drugs and genetic tests is high, with 86% of patients with cancer reporting awareness of DTCA related to cancer drugs and 62% of women in media campaign areas reporting awareness of DTCA for *BRCA* testing.[16,17] Notably, the Myriad Genetics (Salt Lake City, UT) *BRCA*analysis advertising campaign in 2002–2003 resulted in a 244% increase in referrals for genetic services compared with the year before the campaign.[18] Additionally, the advertising campaign led to an increased interest in genetic services by women who were at lower risk for being mutation carriers. Recent studies have shown that awareness of DTC genetic testing is on the rise and that it may be higher in specific sociodemographic groups. Reported awareness of DTC SNP testing in the general population ranges from 20% to 47%, with higher awareness associated with higher levels of education, higher income, female gender, older age, and non-Hispanic ethnicity.[19,20]

When it comes to actually purchasing DTC genetic tests, a number of factors may influence whether people decide to get tested. Among Facebook users who purchased or would purchase DTC genetic testing, reasons to get tested include a general curiosity about one's genetic make-up (81%), the desire to gain knowledge about disease in their family (74%), and the ability to learn about genetic make-up without having to go through a physician (41%).[21] Of people who would not use DTC personal genomic testing, concerns over privacy (39%) and test reliability (21%), the fact that test information may not be that useful (53%), and cost (40%) were reasons not to get tested.[21] Importantly, a study of healthy adults at the Henry Ford Health System in Detroit, MI, demonstrated that there was much lower uptake of genetic testing (even when offered at no cost) for patients who had less than a high-school degree compared with patients with a college degree or more (odds ratio [OR] = 0.51; 95% CI, 0.29 to 0.88).[22]

Despite the fact that early adopters of DTC genetic testing tend to be highly educated, DTC websites are complex enough that even highly educated consumers may still misunderstand test results.[23-25] The mean grade level of readability for DTC genetic testing websites is 15—well above the average U.S. adult reading level, which is estimated to be at a grade level of 8 to 9.7.[26] Additionally, 90%

of websites provide information on the benefits of DTC genetic testing, whereas only 55% give any information on the limitations of testing.[26] Trained coders found that information on the limitations of testing is more difficult to find on websites than information on the benefits of testing. Other authors have argued that the some DTC websites use simplified language in discussing test indications to inappropriately broaden the population for whom testing may be indicated.[27] Given these concerns, it is not surprising to find that 88% of DTC consumers say that company risk information is easy to understand, but between 4% and 7% of consumers misinterpreted risk estimates.[24] Many consumers of DTC genetic testing products endorse tighter regulation of the industry. Between 44% and 51% of study participants support tighter federal regulation, and 73% of consumers felt that it was important for the Federal Trade Commission to monitor companies' claims for scientific accuracy.[21,24] A recent study shows that when information about the limitations of genetic testing are included in a DTC genetic testing website, people have less positive attitudes about DTC genetic testing and may be less likely to get tested.[28]

Finally, a number of large, longitudinal studies are evaluating the effect of DTC genetic testing on consumer behavior.[22-25] Although many of these studies are still ongoing, early reports suggest that consumers have substantially higher intentions to engage in cancer-related screening if they are found to be at higher risk of cancer according to their genetic testing results. Bloss and colleagues report that consumers who had increased genetic risk estimates for colon, prostate, and breast cancer had higher intentions to pursue colonoscopy (OR = 2.17), prostate-specific antigen (PSA) testing (OR = 2.4), or mammography (OR = 2.4), and to perform breast self-exams (OR = 1.9).[25] Aspinwall and colleagues report similar findings that *CDKN2A/p16* genetic test reporting in hereditary melanoma families improves compliance with prevention and early-detection behaviors, particularly in patients who carry mutations but do not have a history of melanoma.[29,30] There are conflicting results in relation to cancer-prevention behaviors such as diet and exercise, with some studies demonstrating that consumers with higher genetic risk are more likely to change their diet and exercise more, whereas other studies show no changes in these behaviors.[24,25] To date, there has been little investigation of the cost-benefit involved in implementing these types of prevention strategies. Importantly, a large study showed no substantial test-related distress among consumers who underwent DTC SNP testing for multiple medical conditions.[25] It will be important in future research to identify mechanisms to reduce or avoid the emotional stress of testing positive by the patient as well as family members and friends. Interestingly, studies differ in how many consumers report sharing their test results with their health care provider. It is estimated that between 27% and 78% of consumers share test results with providers and that 61% of surveyed participants believe that it is a physicians' professional obligation to help individuals interpret DTC genetic testing results.[21,24,25]

Implications for Health Care Providers

Although few genomic applications have proven clinical utility at this time, genetic tests are becoming increasingly advertised (DTCA) and in some cases increasingly available outside the traditional health care setting (DTC testing).[31-33] Health care providers may face particular challenges as DTCA and DTC testing increase. DTCA and availability of genetic tests are particularly complicated by the complexity of genetic information, the social context of genetics, and the questionable clinical utility of many of the currently available DTC genetic tests.[32] Many have criticized DTC genetic testing companies for overstating the value of genetic tests for clinical care, validating patients' worries or health-related fears, and appealing to their desire to assert control over health outcomes.[32,34] As a result, providers may experience inappropriate requests to order genetic tests of questionable clinical utility or tests that are not clinically indicated.[31,32,34] Misperceptions regarding clinical utility and individual health risks among patients could place substantial burden on providers to explain tests, correct inaccuracies, and modify patient expectations, which could negatively affect physician and patient satisfaction with the clinical encounter.[32-35] Although there are currently few data on provider opinions, experience, or use of advertised DTC genomic tests, pharmaceutical DTCA has been associated with physicians' feeling pressured to meet patient requests and lengthened clinical encounters as a result of patient requests for provider assistance in interpreting information presented by advertisers.[35-37] DTCA and use of genetic tests and services may place additional burden on providers to understand the utility and limitations of a variety of genetic tests and the need to interpret test results with limited information.[38] In some cases, the only available information may be commercially sponsored materials, which can be misleading or inaccurate.[32] A study by Hofman and colleagues suggests that physicians who rely on commercially sponsored materials for information on genetics have less knowledge of genetics than physicians who do not report using commercially sponsored materials as a major source of information. Equally important, incorrect interpretation of genetic information by providers or misunderstanding among patients can lead to inappropriate recommendations and compromised care for patients.[34-39]

Despite these potential negative implications of DTCA and use of genetic tests and services, there are potential benefits. As the cost of WGS drops, it is possible that large numbers of patients will seek a global analysis of their genome; it is vital to assure that these data are used appropriately. DTCA and DTC testing have the potential to educate patients and providers, as well as increase awareness of genomic advances and applications among both patients and health care providers. DTC testing also has the potential to increase access to genetic testing, which could be beneficial for many patients.[32,33,36] Additionally, some argue that marketing clinical products, including genetic testing, has the potential to promote more informed patients,[35,38] which could ultimately have a positive effect on patient-provider encounters and relationships. Patient awareness of genomic applications could stimulate patient-physician dialogue, increase communication and trust, and ultimately facilitate the adoption of beneficial clinical recommendations. Although these outcomes are only beginning to be evaluated in the setting of DTCA and DTC testing in genomics, studies have shown that pharmaceutical DTCA does motivate discussions between patients and providers and is associated with increased patient requests for prescriptions and increased prescribing of marketed and re-

quested medications among providers.[35] Thus, despite concerns about the negative effect of DTCA and DTC testing, there are potential benefits for patient care and patient-provider encounters and relationships.

Given the expected increased availability and use of genomic testing within and outside traditional health care settings, oncologists are expected to encounter increased patient requests for genetic tests with limited clinical utility or requests for advice on how to incorporate genetic tests already completed into their medical care.[31,32] Recent studies have found that up to 30% of patients who have completed DTC personal genome scans share their results with their physician.[21,24,25,40] Thus, health care providers will need skills to answer patient questions regarding the risk, benefits, and limitations of available genetic tests and services.[38] Providers may also benefit from regulatory efforts to ensure accurate and understandable information regarding available genetic tests and services.[38] As suggested in the recently updated ASCO policy statement on genetic testing for cancer susceptibility, providers are encouraged to openly discuss the limitations of tests with uncertain clinical utility and provide medical recommendations on the basis of established guidelines and published data.[31] Although this presents potential challenges to the patient-provider encounter and relationship, it may also present opportunities to educate patients and enhance clinical encounters through open communication and respectful dialogue. Additionally, in these scenarios, health care providers may benefit from exploring patient motivations for genetic testing.[34] Some patients may request testing out of curiosity, whereas others may have serious concern for their health. These requests can become "teachable moments" and opportunities to discuss established risk factors for assessing health risk and modifying these risks. In some cases, providers/oncologists may also want to consider collaborating with a genetic specialist. With increased advertising and improved access to genetic tests and services, patients may come to providers requesting testing, or having completed testing with a relatively poor understanding of genetic concepts.[33] Genetic counselors have experience explaining complex genetic concepts and may be better able to provide the additional understanding some patients may seek.[34] Additionally, a genetic specialist may recommend other genetic tests or services with established clinical utility. Even when the patient declines a consult, a genetic specialist may be a valuable resource for oncologists, providing a better understanding of the clinical validity, risks, and benefits of testing, which they can share with their patients.[34]

Although there is a growing body of literature on patient perceptions and use of genomic tests, the effect on providers and the patient-provider relationship remains unknown. There are both potential risks, and potential benefits to DTCA and DTC genetic testing. Thus, there is a need for research evaluating provider opinions of and experience with DTCA and DTC testing of genomic applications and, equally important, the effect on the patient-provider relationship and the delivery of medical care.

Regulation of DTC Genetic Testing

For many, "personal genomics" is synonymous with "DTC genomics." But despite the continued decline in the cost of genomic data, we began 2011 with fewer major providers of DTC genomic services than at the start of 2010. 2010 saw the DTC commercial landscape change as a result of several high-profile events. The key events were the Pathway Genomics/Walgreens (Deerfield, IL) kerfuffle (and FDA response) and the subsequent Congressional hearing, critical Government Accountability Office report, and FDA response.

With the U.S. political climate relatively hostile toward DTC in 2010, some DTC providers (in particular Navigenics and Pathway Genomics) decided, at least for the time being, to shelve the consumer-facing side of their business. Others have continued to push forward, however, with 23andMe remaining the DTC frontrunner, recently raising funds from both venture capitalists and the National Institutes of Health (NIH; Bethesda, MD). A handful of other DTC providers (including deCODE genetics) continue to offer products, and a new generation of do-it-yourself (DIY) genomics companies and researchers strive to put genetic data directly into the hands of increasingly large numbers of individuals.

On the regulatory side, an uncertain and incomplete system of oversight remains the status quo. In 2008, the now-defunct Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) published a comprehensive review of the "U.S. System of Oversight of Genetic Testing."[41] The 276-page report, which remains the most comprehensive analysis of its kind to-date, identified "significant gaps in the U.S. system of oversight of genetic testing that can lead to harms," including incomplete, inconsistent, and overlapping regulations at the state and federal level as they pertain to DTC genetic testing.

Nearly 3 years later, little has changed. For all of the apparent interest in DTC genetic testing from Congress and the FDA, neither has articulated a clear plan to regulate that industry. One likely reason: DTC genetic testing providers and their tests represent a mere fraction of the laboratory-developed tests (LDTs) the FDA has vowed to regulate more aggressively and expansively than ever before. That is not to say that industry will not face increased scrutiny in 2011, or that this would be a bad thing.

There continues to be a clear need for more industry transparency, as well as heightened regulation of the advertising and marketing practices of existing genetic testing companies. The arrival of the NIH's genetic testing registry (GTR), although not without its own critics, remains slated for 2011. The GTR, along with increased enforcement of existing regulations from agencies like the FDA and the Federal Trade Commission, could do much to put a halt to true consumer abuses in the DTC personal genomics market.

There is also a widespread recognition that the DTC industry would benefit from greater standardization. A primary need is for greater definitional clarity. Terms like "DTC genomics" and "DIY genomics" frequently receive user-defined and inconsistent definitions, and no regulation—whether governmental or self-imposed—will be practical until this terminologic confusion is resolved. More substantively, there is a clear need to develop data standards, including both a standard format for returning genomic data and a format for interpreting and reporting those data. Although DTC companies have frequently expressed interest in pursuing the latter, including cooperation with federal agencies, considerable progress in all of these areas still needs to be made.

As things stand today, DTC genetic testing remains legal

in most of its forms throughout most of the United States, even though political pressure has caused some providers to rethink the DTC strategy. Looking ahead, it appears unlikely that regulators or lawmakers will attempt to plug the holes in the existing DTC regulatory framework through direct, comprehensive regulation. DTC regulation, if any, is more likely to take the form of narrower and more targeted regulatory requirements, such as interposing a physician or genetic counselor between the company and consumer at the ordering and/or data delivery stage. Or the FDA or Congress could come up with some other out-of-the-box approach to DTC regulation, likely in conjunction with an overhaul of genetic testing regulation more broadly.

Conclusion

DTC genetic testing is one of the most promising, yet controversial medical advances of the modern era. As technology continues to progress, there will be more pressure to adopt DTC approaches in a free-market economy. This pressure to open up the technology to the general public may serve us well, leading to a more rapid advancement of knowledge than could ever be achieved by working through a purely academic or medical provider system. However, it is equally clear that risks to privacy and other yet-to-be-realized dangers must be carefully considered as we move through these uncharted waters.

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