Transparency First: A Proposal for DTC Genetic Testing Regulation

by Dan Vorhaus

These are hectic days for the field of direct-to-consumer (DTC) genetic testing. Every week, and sometimes every day, seems to bring a new development. Two weeks ago it was pharmacy giants Walgreens and CVS unveiling agreements with Pathway Genomics to offer Pathway's genetic testing kits in drugstores nationwide, to which the FDA responded first by declaring such a strategy illegal and, shortly thereafter, launching an investigation. Last week, on the same day that the University of California, Berkeley announced it would be offering genetic tests to all incoming freshmen, a House of Representatives committee announced it was launching its own investigation into three prominent DTC genetic testing companies.

These developments reflect an uncertainty about the regulatory status of DTC genetic testing that is dramatic, although it is not new. In the summer of 2008, public health officials in New York and California sent warning letters to a number of DTC companies, including 23andMe and Navigenics (both targets of the current Congressional investigation). These state regulatory activities prompted concern that other states might follow suit, potentially subjecting DTC companies to the nightmare scenario of inconsistent state-by-state regulation. Nearly two years later, those particular concerns appear to be unfounded.

An Inevitable Regulatory Response. But as the DTC genetic testing industry expanded, state and federal regulators grew increasingly conspicuous by their silence. The possibility of regulatory activity has been the elephant in the DTC room for some time now (at the Genomics Law Report we have been writing about the possibility of DTC regulation since our inception) and, indeed, many DTC companies have long indicated that they would welcome more definitive federal regulation.

The specific trigger for this recent flurry of activity by the FDA and Congress is something of a puzzle—the distinction between DTC genetic tests offered on Walgreens' shelves as opposed to online at Amazon.com is difficult to parse, and the FDA's initial comments, delivered through the media by a variety of spokesmen, have frequently confused rather than clarified. But the simple fact is that a regulatory response to DTC genetic testing was overdue. That it happened to be Pathway's attempt at creative product placement will prove to be, ultimately, nothing more than a footnote to a larger ongoing discussion about the proper place of DTC genetic testing in this country.

For the remainder of this post, rather than speculate about what manner of regulatory response will be forthcoming from the FDA, Congress and elsewhere, we ask (and answer) the 550,000 SNP question instead: *if a regulatory response to DTC genetic testing is inevitable, what **should** it look like?*

A Transparent Solution. More than anything else, what the DTC genetic testing industry needs right now is enhanced transparency, and not necessarily in the form of traditional direct regulation by the FDA. Rather than driving the regulation of DTC genetic tests through traditional channels, such as the FDA's premarket review and approval regime for medical devices, regulators should focus instead on shining a bright light on DTC genetic testing, improving their own and the public's understanding of what information is available to consumers and how that information is actually used.

As it happens, creating greater DTC transparency can be most efficiently accomplished *without* the application of regulations that would be onerous for early-stage DTC companies and their investors, restrictive for consumers interested in the broadest access to their genetic information and expensive and time-consuming for regulators to enforce.

Over the next 6-9 months, the DTC genetic testing industry and regulators, working together, should take three key steps to enhance transparency industry-wide, ensure that customers, regulators and healthcare professionals are better able to understand and evaluate the products offered, and encourage the DTC industry to grow responsibly without more traditional regulation.

Step 1: Make Participation in the NIH's Genetic Testing Registry Mandatory. The most promising development for improving transparency with respect to specific DTC genetic testing companies and products is the recently announced and NIH-backed Genetic Testing Registry (GTR). The GTR is a direct outgrowth of a 2008 report prepared by the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) on the "U.S. System of Oversight of Genetic Testing" (pdf). The SACGHS report recommended the following:

To enhance the transparency of genetic testing and assist efforts in reviewing the clinical validity of laboratory tests, HHS should appoint and fund a lead agency to develop and maintain a **mandatory**, publicly available, Web-base registry for laboratory tests. (emphasis added)

Although announced two months ago as voluntary initiative, many of the GTR's supporters have long argued that such a registry should be mandatory, and its voluntary character is unquestionably the GTR's most significant departure from the original SACGHS recommendation. At its current early stage of development, however, there is plenty of time for that feature to change.

The upside of the GTR is clear. It would provide a single, comprehensive source of information about DTC genetic tests for regulators, purchasers and other end users (including healthcare professionals), enabling side-by-side comparison of tests and allowing regulators or neutral third parties to evaluate the accuracy of their data and claims. It would also likely standardize (or at least clarify) test offerings, spur healthy competition between providers and enable consumers to make purchasing decisions on the basis of meaningful criteria (e.g., price, information content, insurance coverage, etc.) instead of marketing campaigns.

All of these benefits, however, depend on widespread participation in the GTR by DTC genetic testing companies. At the time of the GTR's announcement, current NIH chief of staff (and long-time GTR proponent) Kathy Hudson conceded that, while she would have preferred a mandatory registry, it was unclear whether the NIH had the authority to enforce such a requirement. While that is likely the case, (arguably) the FDA and (certainly) Congress have the authority to render participation in the GTR mandatory for DTC genetic testing companies.[1] DTC

companies should be eager to embrace a mandatory GTR (as at least one already has) as a relatively painless way to demonstrate to the public and to regulators their willingness to cooperate and their commitment to providing high-quality and transparent genetic testing services.

Step 2: Continue to Improve FDA Regulatory Transparency. An editorial appearing in last week's *New England Journal of Medicine* by two senior FDA officials describes the agency's recent and substantial efforts to improve transparency. The FDA's Transparency Task Force is currently entering its third and final phase, seeking ways to improve transparency to regulated industries.

As part of this initiative, the FDA is seeking comment on 21 proposals (pdf) designed to enhance transparency at the agency. The FDA's recommendations, particularly recommendations 10 and 11, could significantly improve public understanding of how and when the FDA evaluates regulated medical devices. The recommendations are an important step in improving transparency at an agency that has not had enough of it in recent years. Unfortunately, none of the proposed recommendations would improve the transparency of the process by which the FDA determines which products to regulate in the first place, including DTC genetic tests.

Here is where the FDA, specifically the agency's Office of In-Vitro Diagnostic Device Evaluation and Safety (OIVD), headed by Director Alberto Gutierrez, can help appropriately regulate DTC genetic tests without actually increasing its already substantial regulatory burden. Not only should the FDA encourage transparency across the DTC genetic testing industry by supporting the NIH in its development of the GTR, and strongly encouraging or even requiring DTC genetic testing companies to participate, it should also work closely with the NIH, industry and other key stakeholders to clarify exactly what information it would like to see included in the GTR.

One of the difficulties for the DTC genetic testing industry, at least at present, is that the FDA has been less than clear in describing the elements of DTC genetic tests that most concern the agency. Is it the list of conditions or genetic variants tested? The nature of the claims (informational vs. medical) made by the company or the product? The physical locations at which a test is sold? Or is it some other consideration entirely or, more likely, a combination of all of the above?

The FDA is clearly still refining its policy with respect to DTC genetic tests, and there is plenty of time for it to continue to do so. In the meantime, it should involve DTC companies and customers, medical professionals, policymakers and other key stakeholders in determining the relevant information to collect and review with respect to DTC genetic testing. In doing so it can use the already-in-development GTR as a public tool for transparently refining its policy and collecting relevant information. This approach would go a long way toward eliminating the case-by-case review of DTC genetic testing companies and products that appears to have categorized the FDA's approach to date.

Step 3: Involve the Federal Trade Commission. As we wrote last week, there is another regulatory agency that could play an important role in the development of DTC genetic testing: the Federal Trade Commission (FTC).

In 2006, the FTC worked with the FDA and the CDC to publish a guidance document for consumers entitled At-Home Genetic Tests: A Healthy Dose of Skepticism May Be the Best Prescription. Four years in the area of DTC genetic testing is an eternity – the FTC's guidance was issued before any of 23andMe, Navigenics and Pathway Genomics, the three companies currently the focus of the Congressional investigation, existed – but it indicates that the agency has at least some familiarity with the industry. More importantly, the guidance reminds consumers of the FTC's mission, which has not changed: "to work[] for the consumer to prevent fraudulent, deceptive, and unfair business practices in the marketplace and to provide information to help consumers spot, stop, and avoid them."

By making the GTR mandatory (Step 1) and working with the FDA to carefully specify the relevant information to be included in the registry (Step 2), the FTC would be well positioned to monitor the DTC genetic testing industry for companies unwilling to subject their products or claims to the public scrutiny afforded by the GTR (Step 3). While the FDA and Congress have launched investigations into well known DTC genetic testing companies, there are a plethora of other companies (see, for example, this list at DNA Test Index or this list at AccessDNA) that appear, for the moment, to have escaped the attention of regulators. Rather than require the FDA or Congress to investigate each new DTC genetic testing company that sprouts up, why not require those companies to register with the GTR?

This would provide the FTC, along with the rest of us, with a single point of entry to collect and evaluate registered DTC genetic testing companies, while those companies that refuse to participate in the GTR will likely be quickly ferreted out and referred to the FTC by an active community of DTC genetic testing companies and consumers with a vested interest in maintaining order industry-wide.

Reports of DTC's Death Greatly Exaggerated? Using a community- and transparency-driven approach would make it easy to separate the DTC wheat from the chaff, enabling legitimate DTC companies to continue to provide consumers with the genetic information they desire, while minimizing the risk that consumers will be presented with false or misleading genetic testing products or services.

More importantly, focusing on transparency and sustained information gathering is an appropriate, measured response to the developing DTC genetic testing industry. One that will bring companies, consumers and regulators into closer collaboration, without imposing a regulatory regime that would risk stifling the creativity and growth of the industry or depriving consumers of the ability to directly access their genetic information. While it has long been inevitable that regulatory agencies would play a significant role in shaping the future of the genetic testing industry, there is absolutely no reason why, with that day apparently upon us, that development need spell the death of DTC.

[1] As discussed in our earlier article, there is some disagreement over whether the FDA has such authority. What is not debatable, however, is that Congress, should it desire to do so, could take action that would remove all doubt as to the authority of the FDA (or another agency of its choosing, such as CMS) to regulate DTC genetic tests.

Note, also, that a GTR that was mandatory for DTC genetic testing companies would not need to be mandatory for all providers of genetic tests. A majority of genetic tests are *not* provided directly to consumers, and this would be a relatively clear distinguishing characteristic upon which to evaluate whether a test was required to be included in the GTR, or simply permitted to be included at the provider's discretion.