Topic: Consumer Genetic Testing

Direct to consumer genetic testing companies fail in attempt to seek new rules in California

By Jeremy Gruber

A bill sponsored by California State Senator Alex Padilla (D-San Fernando Valley), drafted by the direct to consumer (DTC) genetic testing company 23andMe and publicly supported by Genentech, among other companies, was recently sent back to the Secretary of the Senate after failing to pass due to a mounting public outcry. The bill, SB 482, would have defined a new category of business for companies that provide "post-CLIA bioinformatics services" and exempt such businesses from requirements applicable to traditional clinical laboratory service providers.

Close to 100 DTC companies, including Navigenics, DNA Direct, and Google Inc.-backed 23andMe, are based in California and have jumped into various genetic testing niches by offering genome scans to the general public. The tests cost as little as $399 and the time it takes to provide a saliva sample. These companies have proliferated within an unstable regulatory environment. There is no federal proficiency-testing system for the companies and the U.S. Food and Drug Administration has left it up to the states to decide what's permissible.

The California bill's genesis followed actions in 2008, when the California Department of Public Health sent "cease and desist" letters to 23andMe, Navigenics and 10 other genomics firms requiring them to comply with state and federal regulations. The companies later obtained licenses in compliance with a state law that regulates laboratories in California, but subsequently argued that they should not need to, and that the purpose of their service was merely "education." Critics have argued that with marketing catch phrases such as "take control of your health" (Navigenics) and "get the treatment that's right for you" (23andMe) customers are going to make the reasonable assumption that these genetic tests must have some diagnostic significance. 23andMe may have decided to introduce SB 482 to motivate favorable action by federal regulators that are still contemplating how to regulate the industry.

The legislative findings of the bill indicated an intent to remove regulatory barriers to operation for companies providing personal genome services: "By defining and regulating the distinct role of postproduction data interpretation, the state intends to promote flexibility and innovation in the development of methods to interpret individuals' biological profiles in the context of personalized medicine." The findings state that allowing individuals to access their personal biological data "can also offer research and educational opportunities, since an active, personal stake can promote scientific literacy and a new research model that actively engages with consumers." In order to achieve these goals, the findings continue, "it is necessary for entities providing postproduction interpretation of biological data to be regulated in a different way than are those entities providing traditional laboratory functions."

A number of consumer and privacy groups, including the American Civil Liberties Union and the Council for Responsible Genetics, had raised serious concerns about the bill, fundamentally regarding whether DTC businesses should design their own oversight. Specifically they questioned whether the claims made by such companies regarding the relationship between individual genetic variations and disease risk are subject to adequate review to ensure they are supported by sufficient scientific evidence.

The bill was also heavily criticized for its lack of sufficient privacy protections. In particular, critics had noted that the legislation did not have sufficient protections to ensure that personally identifiable information was not released to third parties, nor did it require entities to destroy biological samples once they had been processed. Furthermore, the bill would have allowed companies to continue to use such information, including the potential sale to third parties, so long as it was not individually identifiable. The definition of individually identifiable information was particularly singled out as insufficient. Many of these companies, they noted, are using the information derived from their tests to compile a vast database of genetic information of data that could be worth millions of dollars to outside researchers. The bill would have required customers to consent to participate in such research as a condition of utilizing the services of a DTC company.

While the legislation is clearly dead for now, the issue is not going away. Senator Padilla has expressed interest in a "forum" on personalized medicine, including DTC genetic testing, and 23andMe is already floating a "simplified" version of their bill to generate renewed interest and support within the legislature and among likely commercial supporters.

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