Government Eyes Direct-to-Consumer Tests

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FROM THE HOUSE ENERGY & COMMERCE OVERSIGHT AND INVESTIGATIONS SUBCOMMITTEE

WASHINGTON — Direct-to-consumer genetic tests are deceptively marketed and often give misleading results that are of little or no practical use, said the U.S. Government Accountability Office in a report at a hearing of the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations.

Subcommittee chairman Rep. Bart Stupak (D-Mich.) called on the three genetic testing companies in attendance to stop marketing their products to consumers until the Food and Drug Administration or National Institutes of Health can establish standards for how the testing should be conducted and how the results should be shared with consumers.

Results of a GAO investigation show that 'these tests aren't ready for prime time.' Yet, the market for the tests is about $1 billion a year and is growing some 20%-30% a year.

Currently, the tests are being sold without FDA approval. But Dr. Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health, said that the agency has been trying to assess how to regulate the products. A genetic test is subject to FDA oversight if it is a medical device being used in the diagnosis of disease or to cure, mitigate, treat, or prevent disease.

The agency has basically hung back on enforcing the rule of the law on the direct-to-consumer (DTC) tests but now is clamping down, said Dr. Shuren. In May, the FDA told Pathway Genomics Inc. that it had to get approval for its genetic health report, which it was going to sell at Walgreens stores. Pathway is no longer marketing directly to consumers.

Pathway's agreement with Walgreens "lit a fire" at the FDA, said Dr. Shuren. "We thought at this point, it's time to take action," he said.

In June, the FDA sent similar warnings to 4 other companies: Knome Inc., Navigenics Inc., deCODE genetics, and 23andMe, and, on July 19, the agency warned 15 more companies.

The Government Accountability Office (GAO) investigated companies selling DTC tests in 2006 but was asked by the subcommittee to revisit the market in the wake of reports that companies were more "reputable." The agency bought 10 tests each from four companies—23andMe, deCODE genetics, Pathway Genomics, and Navigenics—using five volunteer DNA donors.

Each volunteer used his or her own information when submitting one test, and submitted fictitious information for the second test. Each kit cost between $300 and $1,000.

All five donors received conflicting results. A total of 68% of the time, the donors received a different prediction for the same disease being tested, according to Gregory Kutz, managing director of the GAO's Forensic Audit and Special Investigations Unit. In one case, a donor with a pacemaker implanted for 13 years to treat atrial fibrillation was told he was at a lower risk for developing the condition.

"These results show that these tests aren't ready for prime time," said Mr. Kutz. And yet, the market for the tests is at about $1 billion a year and is growing some 20%-30% a year, he said.

The GAO also made undercover calls to 15 companies, including the 4 from which the agency bought test kits, asking about test reliability, privacy policies, and to inquire about supplements that some of the testing firms were selling. Four of the companies claimed that "a consumer's DNA could be used to create personalized supplements that would cure diseases," said the GAO in its report.

Representatives from 23andMe, Navigenics, and Pathway Genomics all defended their products at the hearing, but added that they agreed that more regulation of the industry was needed. ■