

ONE HUNDRED ELEVENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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WASHINGTON, DC 20515-6115

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MEMORANDUM

July 20, 2010

To: Subcommittee on Oversight and Investigations Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on “Direct-To-Consumer Genetic Testing and the Consequences to the Public Health”

On Thursday, July 22, 2010, at 9:30 a.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing to examine the sale of direct-to-consumer personal genetic tests.

I. BACKGROUND

Personal genetic testing kits are saliva swab kits that are marketed to consumers as a tool to predict whether a person may be genetically predisposed to develop diseases such as breast cancer, diabetes, cystic fibrosis, celiac disease, cancer and other conditions. Some of the companies that offer these genetic testing kits also suggest that the tests can predict how individuals may react to prescription drugs taken to treat conditions such as HIV and heart disease. Genetic testing kits can cost as little as \$20 and are available over the internet. Typically, a consumer receives the kit in the mail, swabs the inside of the cheek to pick up a DNA sample, and mails the sample to the company that sold the genetic testing kit. The genetic testing company either conducts its own analysis of the DNA sample through an in-house laboratory or sends the DNA sample to an outside laboratory. The genetic testing company then sends the consumer an email when the results are ready, and the consumer can access analyses of those results on-line. Several companies offer different levels of genetic analysis that can cost the consumer anywhere from \$229 to \$999.

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. Under CLIA, the Centers for Medicare and Medicaid Services (CMS) also establishes an accreditation program for

clinical laboratories.”¹ CMS regulates laboratories that conduct testing, but has minimal oversight over the companies that sell the test kits and provide analysis of the test results.²

The Food and Drug Administration (FDA) has jurisdiction over *in vitro* diagnostic tests performed in a laboratory. *In vitro* diagnostic tests are intended for use in the collection, preparation, and examination of specimens taken from the human body and are considered medical devices.³ Laboratory developed tests (LDTs) are a subset of tests that are developed by a single clinical laboratory for use only in that laboratory. FDA has stated that laboratories that develop in-house tests are acting as manufacturers of medical devices and therefore subject to FDA jurisdiction, but the agency has “generally exercised enforcement discretion over standard LDTs”⁴. Most genetic tests, including genetic tests sold directly to the consumer, are laboratory developed tests and, until recently, FDA has not asserted their enforcement authority over these tests.

In May 2010, Walgreens and Pathway announced they would partner together to sell their genetic testing kits in retail outlets. Shortly after that announcement was made, FDA sent a letter to Pathway Genomics Corporation indicating their home-use saliva collection kits meet the “definition of a device.”⁵ The letter further indicates that they have not been able to identify any FDA clearance or approval number for their product and to contact the FDA to clarify the matter.⁶ Immediately following FDA’s letter to Pathway, Walgreens decided not to stock the genetic testing kits until it has “further clarity” on the issue.

On June 10, 2010, FDA sent letters to 23andMe, NaviGenics Health Compass, and deCODE Genetics stating that the direct-to-consumer genetic testing kits are medical devices as defined by the Federal Food, Drug, and Cosmetic Act because “it is intended for the use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease, or is intended to affect the structure or function of the body.”⁷ None of the companies

¹ The Food and Drug Administration, *Overview of IVD Regulation* (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm123682.htm>)

² The Centers for Medicaid and Medicare Services, *Clinical Laboratory Improvement Amendments Overview* (online at www.cms.gov/clia/)

³ The Food and Drug Administration, *In Vitro Diagnostics* (online at www.fda.gov)

⁴ The Food and Drug Administration, *Overview of IVD Regulation* (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm123682.htm>)

⁵ Letter from the Food and Drug Administration to James Plante (May 10, 2010).

⁶ Letter from the Food and Drug Administration to James Plante (May 10, 2010).

⁷ Letter from the Food and Drug Administration to 23andMe, NaviGenics Health Compass, and deCODE Genetics (June 10, 2010).

sought premarket approval for their products, and as such, FDA advised the companies to “take prompt action” in response to their letter.⁸

II. THE GAO INVESTIGATION

In March 2009, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations informed the Government Accountability Office that they were concerned that “the genetic testing market appears to have expanded rapidly and consumer fraud in this area is on the rise.”⁹ The letter asked GAO to investigate these issues in the industry and report to the Committee on its findings.

GAO’s Forensic Audit and Special Investigations Unit conducted an investigation into four genetic testing companies: Pathway Genomics Corporation, NaviGenics Health Compass, 23andMe, and deCODE Genetics. At the hearing, GAO will present its findings to the Committee.

III. WITNESSES

The following witnesses have been invited to testify:

- **Mr. Gregory Kutz**
Managing Director
Forensic Audits and Special Investigations
Government Accountability Office

- **Dr. Jeff Shuren**
Director
Center for Devices and Radiological Health
U.S. Food and Drug Administration

- **Dr. James Evans**
Editor-in-Chief; Genetics in Medicine
Bryson Professor of Genetics and Medicine
University of North Carolina at Chapel Hill

- **Ms. Ashley Gould**
General Counsel
23andMe, Inc.

- **Dr. Vance Vanier**

⁸ Letter from the Food and Drug Administration to 23andMe, NaviGenics, Health Compass and deCODE Genetics (June 10, 2010).

⁹ Letter from Rep Joe Barton and Greg Walden to Gene L. Dodaro (March 17, 2009) and letter from Rep Henry Waxman and Bart Stupak to Gene L. Dodaro (August 10, 2009).

President and CEO
Navigenics, Inc.

- **Dr. David Becker**
Chief Scientific Officer
Pathway Genomics Corporation