

ONE HUNDRED ELEVENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

Statement of Rep. Henry A. Waxman
Chairman, Committee on Energy and Commerce
“Direct-To-Consumer Genetic Testing and the Consequences to the Public Health”
Subcommittee on Oversight and Investigations
July 22, 2010

Thank you, Chairman Stupak, for holding this important hearing.

In the past decade, we have witnessed rapid progress in the scientific research of human genetics. These breakthroughs can make profound contributions to medicine and the improvement of public health.

As genetic testing technology has become widespread, people naturally want to understand the mysteries contained in their own genome, and how it applies to their personal health.

Direct-to-consumer genetic testing companies recognize this heightened interest, as evidenced by the marketing messages on their websites.

Here are some of the statements the average consumer will find when they look on the websites of some of the leading direct-to-consumer genetic testing companies:

Navigenics, one of the companies that we will hear from today, promises on its website that its product offers “A new look at a healthier future.”

23andMe, another company testifying today, offers these enticements to the potential consumer of its genetic testing kits. “Take charge of your health.” “Live well at any age.” “Let your DNA help you plan for the important things in life.”

Pathway Genomics, the third company testifying today, advises on its website that “Knowing how your genes may affect your response to certain drugs may improve the quality of your life.”

And DeCODE Me, a fourth company whose genetic testing kit the Government Accountability Office (GAO) reviewed, states on its website that “Your genes are a road map to better health.”

The problem with these marketing practices is that it is not clear today whether the exciting scientific developments in human genetics research actually transfer into ways to improve and individualize medical care.

The science informs us that there is no widely accepted consensus linking genetic markers to specific illnesses.

While understanding human DNA may someday help us cure hundreds of serious illnesses, companies need to be careful that they are not overstating what they have to offer the public. And if a company is making a claim regarding the consumer's use of its products and that person's health, then the company should be subject to compliance with all applicable public health laws and regulations.

Two agencies share jurisdiction over direct-to-consumer genetic tests. Under the Clinical Laboratory Improvement Amendments (CLIA), the Centers for Medicare and Medicaid Services (CMS) regulates the laboratories that conduct testing, but not the health claims made by genetic testing manufacturers.

The U.S. Food and Drug Administration (FDA) has jurisdiction over diagnostic tests, which are intended for use in the collection, preparation, and examination of specimens taken from the human body and are considered medical devices. The three companies testifying today have previously claimed that their products are not medical devices, and thus do not require approval from FDA before they can be sold to consumers.

In May 2010, Walgreens and Pathway Genomics announced a partnership to sell direct-to-consumer genetic testing kits to consumers over-the-counter. In response to this announcement, FDA sent a letter to Pathway Genomics stating that these products fell under the oversight of FDA, and that the genetic testing kits had not been approved by FDA.

Shortly thereafter, FDA sent letters to 23andMe, NaviGenics Health Compass, and deCODE Genetics stating their products were medical devices, but had not been submitted for premarket review. This week, FDA approached 14 other companies on these issues.

FDA is here today to discuss their actions. I applaud FDA's efforts to protect the American consumer. I hope we will hear from the genetic testing companies today that they will cooperate with FDA's enforcement efforts.

The Committee has also conducted its own investigation, reviewing over 450,000 documents. We have uncovered questionable marketing claims, serious quality control and privacy concerns, and questions about the accuracy of information provided to consumers.

Last year, the Committee made a bipartisan request to the Government Accountability Office to evaluate these issues. GAO will report to us today.

Three of the companies that GAO tested have come here to discuss their work and to provide their insights into what the Committee and GAO have found. I thank them for their

cooperation. Additionally, Dr. James Evans, a practicing physician and expert in medical genetics, will give us the clinician's perspective on the medical value of the companies' genetic analyses and the questions they raise.

While genetic research offers great promise to improve human health, we need to ensure that the public is protected against exaggerated claims, abusive marketing, and practices that threaten individual health and safety.

I look forward to today's hearing for an opportunity to explore these crucial issues.