

**Opening Statement
Rep. Bart Stupak, Chairman
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
“Direct-To-Consumer Genetic Testing and the Consequences to the
Public Health”
July 22, 2010**

“Genetics can affect how well some drugs work for you—or whether they will work at all.”

“Learn if you have a propensity for obesity, cancers, diabetes, and more.”

These are some of the claims featured on the websites of two of the direct-to-consumer genetic testing companies we are examining in today’s hearing.

These companies, and their competitors, make enticing claims about what this promising new field of research can offer the American consumer. I’m sure that many people would want to know if they have a higher risk of being diagnosed with colon cancer or if their body is likely to react poorly to a drug that treats heart disease?

With the decoding of the human genome, medical science opened up the possibility of detecting people's pre-disposition to disease, establishing a better understanding of family ancestry, and developing drugs that are designed to treat genetic conditions.

Some companies are now marketing personalized genetic tests claiming they have the ability to provide extensive information about their health with a simple swab of their cheek. These companies tell consumers that genetic testing can predict whether they are more likely to develop diseases such as breast cancer, diabetes, cystic fibrosis, celiac disease and heart disease. The companies state that genetic tests also inform consumers how they are likely to react to prescription drugs taken to treat HIV medication or high blood pressure.

But how accurate are the companies' analyses of direct-to-consumer genetic tests? By sending the customer the results of genetic tests without counseling or medical advice may cause more harm than good for some consumers? How accurate is the health information? How do companies explain differences in their analyses? Is there sufficient government oversight of the practices of direct-to-consumer genetic testing manufacturers?

Today we will seek answers to these questions as we examine direct-to-consumer genetic testing kits and their potential implications for public health.

A 2008 article in the Journal of the American Medical Association entitled *Risk and Benefits of Direct-To-Consumer Genetic Testing Remains Unclear*, claims these “companies cannot demonstrate causation, and many of the markers being used by the testing companies have not been validated by other groups or by studies that the molecular mechanism by which these genes might lead to disease.”

Yet the Subcommittee has learned that some direct-to-consumer genetic testing companies are advising customers that, based on genetic data, their body is likely to react favorably or unfavorably to certain medications. For example, we discovered internal company documents demonstrating that one company informed customers, based on their genetic markers, that they are likely to have a low risk of serious side effects should they use irinotecan [i-ren-no-tec-an]— a drug commonly used to treat colorectal and other cancers. The document goes on to say that because of the low risk of a bad reaction to the drug, if a person is being treated for cancer, the medical team may want to prescribe irinotecan.

Today's hearing continues previous inquiries within the Subcommittee on Oversight and Investigations on genetic testing issues. In March 2009, Chairman Waxman and I joined Ranking Member Barton and Subcommittee Ranking Member Walden in a request to the Government Accountability Office (GAO) to investigate concerns that "the genetic testing market appears to have expanded rapidly and consumer fraud in this area is on the rise." Our letter requested that GAO direct its Forensic Audit and Special Investigations Unit to "perform proactive testing of the actual products currently marketed by several companies and of the advertising methods used to sell these products to consumers." I thank the Chairman and my colleagues on the other side of the aisle for working together for this important, bipartisan inquiry.

During the course of the investigation, GAO found that some direct-to-consumer genetic testing companies provided misleading results from genetic testing kits. GAO concluded that risk predictions often conflicted with the donors' factual illnesses and family medical histories.

For example, one of the donors in the GAO investigation had a pacemaker implanted 14 years ago to treat an irregular heartbeat

but his genetic test came back stating that he was at decreased risk for developing a heart condition. When GAO consulted with medical and genetics experts, they were told that the direct-to-consumer tests are not diagnostic. As a result, medical predictions based on genetic test results defy actual medical histories. What is less clear is whether the companies are accurate in describing test results to their customers.

Today, Mr. Gregory Kutz, Managing Director, Forensic Audits and Special Investigations, with the Government Accountability Office (GAO) will be informing the Subcommittee of their findings. Mr. Kutz's team conducted the investigation into five direct-to-consumer genetic testing companies.

Joining Mr. Kutz is Dr. Jeff Shuren, Director of Center for Device and Radiological Health with the Food and Drug Administration (FDA). FDA represents the federal agency responsible for the regulation of these direct-to-consumer genetic tests.

We will also be hearing from three direct-to-consumer genetic testing companies. I look forward to hearing from these companies about the quality of the products and services they offer and the steps they take to protect the American consumer.

Joining the manufacturers is Dr. James P. Evans is a Professor and Director of Genetics and Medicine at the University of North Carolina at Chapel Hill. Dr. Evans is an advisor to the U.S. Secretary of Health and Human Services on the subject of “Genetics, Health, and Society”. Dr. Evens currently serves as the Editor-in-Chief of *Genetics in Medicine*, the official journal of the American College of Medical Genetics.

I thank our witnesses for their cooperation and for appearing before us today. I look forward to your testimony and to learning more about the promises and risks of this exciting new field. Thank you.