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DIRECT-TO-CONSUMER GENETIC TESTING AND THE CONSEQUENCES TO THE PUBLIC HEALTH

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

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DIRECT-TO-CONSUMER GENETIC TESTING AND THE CONSEQUENCES TO THE PUBLIC HEALTH

THURSDAY, JUNE 22, 2010

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 9:34 a.m., in Room 2123, Rayburn House Office Building, Hon. Bart Stupak [chairman of the subcommittee] presiding.

Present: Representatives Stupak, DeGette, Christensen, Waxman (ex officio), Burgess, Gingrey, Griffith, and Latta.

Staff Present: Phil Barnett, Staff Director; Bruce Wolpe, Senior Advisor; Stephen Cha, Professional Staff Member; Eric Flamm, FDA Detailee; Dave Leviss, Chief Oversight Counsel; Meredith Fuchs, Chief Investigative Counsel; Tiffany Benjamin, Counsel; Erika Smith, Professional Staff Member; Ali Neubauer, Special Assistant; Derrick Franklin, HHS Detailee; Karen Lightfoot, Communications Director, Senior Policy Advisor; Elizabeth Letter, Special Assistant; Alan Slobodin, Minority Counsel; Melissa Bartlet, Minority Counsel; Robert Frisbee, Minority Detailee; and Garrett Golding, Minority Legislative Analyst.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. This meeting will come to order.

Today we have a hearing entitled, "Direct-to-Consumer Genetic Testing and the Consequences to the Public Health."

The chairman, ranking member, and chairman emeritus will be recognized for a 5-minute opening statement. Other members of the subcommittee will be recognized for a 3-minute opening statement. I will begin.

"Genetic testing can effect how well some drugs work for you or whether they work at all." "Learn if you have a propensity for obesity, cancers, diabetes, and more." These are some of the claims featured on the Web sites 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 am sure that many people would want to know if they have a higher risk of being diagnosed with colon cancer or if your 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 predisposition to disease, establishing a better understanding of family ancestry, and the 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 the simple swab of their cheek. These companies tell consumers that greater 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 of how they are likely to react to prescription drugs taken to treat HIV or high blood pressure.

But how accurate are these companies' analysis of direct-to-consumer genetic tests? Sending the consumer 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, "Risks and Benefits of Direct-to-Consumer Genetic Testing Remain Unclear," claims that, and I quote, "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," end of quote.

Yet, this subcommittee has learned that some direct-to-consumer genetic testing companies are advising their 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 consumers based on their genetic markers that they are likely to have a low risk of side effects should they use a certain cancer drug, irinotecan, 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 drug reaction to the drug, if a person is treated for cancer, the medical team may want to prescribe this cancer-fighting drug.

Today's hearing continues previous inquiries within the Subcommittee on Oversight and Investigation of 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 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 the 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 for working together on this important bipartisan inquiry.

During the course of our investigation, GAO found that some direct-to-consumer genetic testing companies provide 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 genetic experts, they were told that the direct-to-consumer tests are not diagnostic. As a result, the 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 Investigation, with the Government Accountability Office, 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 the Center for Device and Radiological Health with the Food and Drug Administration. FDA represents the Federal agency responsible for the regulation of these direct-to-consumer genetic tests.

We will also be hearing from 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 T. Evans, 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. Evans currently serves as the editor-in-chief of Genetics in Medicine, the official journal of the American College of Medical Genetics.

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

[The prepared statement of Mr. Stupak follows:]

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?

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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.

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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.

Mr. STUPAK. I would also ask unanimous consent that Congresswoman Louise Slaughter's statement be made part of my opening statement, without objection.

[The information was unavailable at the time of printing.]

Mr. STUPAK. I would next turn to Mr. Burgess for an opening statement.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. I thank the chairman and I thank Chairman Waxman for convening this hearing. It is an important topic.

The advancements in genomics, as we have heard in other subcommittees in the Committee on Energy and Commerce, have been startling. The Human Genome Project was certainly a long time in coming but worth the wait, and the excitement it has provided has proved that point. The discovery of over 1,800 genes linked to disease is nothing short of remarkable. The promise this research holds to help those suffering or likely to suffer from diseases and medical conditions is very real. We cannot overstate the significance of these advances, and I have no doubt that genomics will revolutionize the daily practice of medicine.

However, we also have to be concerned about a rush to commercialization. It is imperative that the information consumers receive is reliable and accurate. As an obstetrician/gynecologist, I'm disturbed by a recent Washington Post article where the Food and Drug Administration asserts that patients may have had surgery, irreversible surgery, based on questionable results of genetic tests for a certain type of cancer. Consumers should have access to information, but it must be reliable and accurate. No one should be required to make an irreversible health decision, such as a surgical procedure, based on unsettled or evolving science.

Findings from the Government Accountability Office's undercover work with genetic testing companies raises these very concerns. The GAO's secret shoppers or fictitious consumers received disease risk predictions that varied greatly across the different companies. One person was deemed at below-average, average, and above-average risk for prostate cancer and hypertension from four different companies. And in this sort of testing, you don't get to pick the best two out of three.

Overall, the GAO found 68 percent of the time the donor DNA samples resulted in different risk predictions for the same disease. This lack of consistency may indicate the state of the science, but it also begs the question: How can consumers know their true risk?

Furthermore, it is very difficult that companies promise impossible results, tell consumers that they will definitely get cancer, or inappropriately claim celebrity endorsement. One company counseled a patient that the above-average risk prediction for breast cancer meant that she was, quote, "in the high risk of pretty much getting," closed quote, the disease.

The examples by the Food and Drug Administration and the Government Accountability Office show that there is cause for concern about these tests. I'm a proponent of personalized medicine, but I fear that these practices might confuse the potential for these tests to be of benefit in the future. Genetic testing will not realize

its potential if the components are unreliable or, worse, if fraudulent information is pushed.

Apparently, a director of research and development at Pathway Genomics agrees. In a March 17, 2010, e-mail to her colleague regarding weight management genetic testing for contestants of the popular television show "The Biggest Loser," she raises concerns about the ability to distinguish the real science from the hot topics that are generally not validated science or to meet any criteria for strength of genetic association.

On March 18, her colleague responds that she, too, has on many occasions tried to raise the scientific red flag in meetings. If the people doing the research at these companies question the tests' reliability, then there are certainly going to be issues for the consumer.

One might argue that greater Food and Drug Administration regulation of the results is needed, and I believe we must ask, are the kits themselves properly regulated? The Food and Drug Administration recently sent letters to commercial genetic testing companies asserting regulatory authority over their products. Also, the FDA convened a public meeting to look at the broader issues of regulating the developed tests. I do want to hear from the Food and Drug Administration about their plans.

But a more basic question for the FDA is, is the science sound enough to support this market? Can the Food and Drug Administration police genetic tests with a science that is so new and so rapidly changing? If people become uncertain as to the reliability of the results of genetic testing because that reflects the infancy of the science, then medicine may never reap the benefits that this science holds.

Finally, and to the Food and Drug Administration, the science may not be there yet—and I would stress the "yet"—but it will be, so you must be ready. Needed tests and cures should not be denied down the road because our Federal agency, the Food and Drug Administration, has not yet figured out how to adapt to the science.

Ponder this: How will the FDA regulate personalized pharmaceutical and biologic products? How do you do randomized clinical trials on personalized therapies, on therapies that are developed for a single patient? The future may not be here yet, but it is right over the horizon.

Thank you, Mr. Chairman, for holding this hearing. And I will yield back the balance of my time.

[The prepared statement of Mr. Burgess follows:]

Opening Statement of the Honorable Michael C. Burgess
Subcommittee on Oversight and Investigations
Hearing on
"The Outbreak of Salmonella in Eggs"
September 22, 2010

Thank you, Chairman Stupak for convening this important hearing. Once again we find ourselves in the middle of a food-borne illness outbreak, this time involving the safety of a food item that we frequently buy, eat and serve to our families: eggs.

Just this morning I viewed pictures taken by the Food and Drug Administration (FDA) at both company's egg production facilities during their inspections. These photos document some extremely unsanitary and unsightly conditions, including; a pile of chicken manure that has pushed open a doorway and is leaking outside of a laying house, dead flies covering belts that are too numerous to count, dozens of rodent holes, structural damage to buildings, and chicken carcasses. These companies must be able to account for and respond to these photos and I am anxious to ask FDA if the public should take comfort in the fact that these observations are not normal or if the public would be disturbed to find similar observations at other egg production facilities. I wonder if FDA will be able to answer this question considering they have not inspected any other egg production facility besides these two in the last five years.

To date, the Centers for Disease Control (CDC) has reported that over 1,500 illnesses are likely to be associated with this outbreak of Salmonella Enteriditis (SE) in eggs. I want to thank our first panel of witnesses, both victims of this outbreak, for appearing today to share your stories.

This outbreak of salmonella in eggs is unique in that the salmonella contamination was not from the outside or shell of the egg, but from the inside of the egg. Test results indicate the laying hens themselves were infected with salmonella and the hens passed the contamination through to the inside of their eggs.

One very important fact about this investigation, and perhaps an indication that this hearing is being held prematurely, is that the ultimate source of the salmonella contamination is NOT yet certain. Concerns about the feed given to the pullets and the unsanitary conditions at the suspect farms have been raised. I hope that the testimony provided today will move us closer to understanding the original source of contamination and how to prevent it from happening again.

By early August, the epidemiological and trace-back investigations completed by the CDC, the FDA, and the state partners indicated a common source of contamination in shell eggs from a single firm owned by the DeCoster family called Wright County Egg in Galt, Iowa. On August 13, Wright County Egg issued a voluntary recall of approximately 380 million eggs, and on August 19, Hillandale Farms of

Iowa owned by Mr. Orlando Bethel issued a voluntary recall of eggs after being suspected as a potential source of contamination, bringing the total number of recalled eggs to over 500 million.

Responsible corporate actors are crucial in maintaining a safe and reliable food industry. Companies must observe good manufacturing and agricultural practices, identify and rectify weaknesses in their safety systems, and respond quickly in a time of crisis. The documents and subsequent photographs obtained by this committee raise serious questions whether both of these companies were consistently maintaining good manufacturing and agricultural practices and striving to strengthen their food safety systems and plans.

Of particular interest are documents that show test results completed by the Veterinary Diagnostic Laboratory at Iowa State University on behalf of DeCoster Farms from 2008-2010. Tests were run for salmonella, avian influenza, and typhoid, among other things. The occurrence of salmonella positive environmental samples is frequent, illustrated by one battery of tests completed in May, 2010 where 72 environmental sponges were tested for salmonella and only 8 were negative.

Experts who spoke to my staff have indicated that environmental samples that turn up positive for salmonella may be expected on a farm and do not necessarily indicate that the food end-product, in this case the egg, is contaminated. I want to know if these findings warrant cause for

alarm and become troublesome if positive results become a pattern and are not rectified. I want to ask the DeCosters about these tests, ask what the company gleaned from this information and what action was taken in response to prevent salmonella from contaminating the finished product.

I also want to ask Hillandale about what kinds of tests they were conducting for salmonella prior to this outbreak and find out if this type of testing was or is commonplace in the industry.

Other documents obtained by the Committee include numerous Pre-Operative Sanitation Reports completed by the U.S. Department of Agriculture Marketing Services Inspectors show daily non-compliance with HACCP plans, unsatisfactory sanitary conditions, and an array of other observations at Wright County Egg over a four year period. I would like Mr. DeCoster to comment on and explain these records.

Although FDA told my staff that eggs have historically been considered a "high-risk" food product, FDA did not inspect these egg facilities prior to this outbreak. During the inspections discussed in the FDA Form 483, FDA investigators noted that each company failed to fully implement and follow procedures in their salmonella enteritidis prevention plans, and now we have pictures to document these findings.

Tests conducted in late August by FDA investigators at Wright County Egg were positive for the same and other strains of salmonella. These samples were taken from manure pits, walkways, chicken feed, and other surfaces. I want an up-to-date report from the companies and

FDA explaining where the exact matches of SE to the outbreak strain that caused human illness were found and how the companies and the FDA interpret these results.

It is important for the FDA as well as the industry to work cooperatively internally, with other federal agencies, and with state health and agriculture departments to reduce the number of, and help prevent, food-borne illnesses and contamination before tainted products enter the markets. A new Egg Rule became effective this July that addresses several of the concerns associated with the eggs involved in this outbreak and recall. However, it took FDA over ten years to act on this issue, illustrating the continued systematic, problematic, and bureaucratic weaknesses that plague this agency. The future FDA should not be a reactive body dictated by the events of yesterday, but rather an effective and efficient proactive agency preventing the emergencies of tomorrow.

Mr. Chairman I support you in conducting this investigation and holding this hearing, but I have to express my concern that this hearing has not been conducted in the most bi-partisan or useful manner. As my letter to you from September 9th states, I think that the most senior person from FDA, the CEO of FDA, the Commissioner of FDA, Dr. Margaret Hamburg should be here to offer the agency's official testimony. She and the Obama Administration have repeatedly stated publicly that increasing food safety and the resources of the FDA is a top

priority, must be taken seriously and must be quickly addressed. In the 110th Congress, then FDA Commissioner Andrew Von Eschenbach appeared before this sub-committee more than four times, and offered testimony at a July 17, 2007 Food Safety hearing. Yet, not once has the current Commissioner come before this Committee to deliver the Agency's and the Administration's testimony and answer our questions.

Also, the Majority declined to invite a representative from USDA to testify even though the Committee sent a document request to the agency, held a briefing with the agency, and received thousands of pages of relevant information concerning their role in the regulation of these farms and this outbreak. My Committee staff obtained and reviewed relevant and revealing USDA documents, including USDA Shell Egg Plant System Audit Reports, Pre-Operative Sanitation Reports, and USDA inspector notes and observations from Wright County Egg and Hillandale Farms. This hearing would be more productive if a USDA official were here to answer questions related to these documents, discuss their role in food safety, and help identify the gaps and problems with their communication with FDA and other agencies involved in regulating and increasing food safety.

The ultimate goals of this hearing are the same as the ones from the first food safety hearing we held in this subcommittee over four years ago: to examine the facts, determine how to prevent future outbreaks and illnesses, and improve the safety and quality of the

American food supply. I supported the food safety legislation this House passed in 2009 and am eager for the Senate to move on this important issue. Thank you Mr. Chairman and I look forward to today's testimony.

Mr. STUPAK. Thank you, Mr. Burgess.

Mr. Waxman, Chairman Waxman, for an opening statement, please.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Chairman Stupak, for holding this oversight hearing.

This is an important issue for us to examine, the direct-to-consumer genetic testing. The companies that are offering to do this recognize there is a heightened interest in the whole idea of unravelling the mysteries contained in people's own genome and how it might apply to their personal health. And there has been rapid progress in the scientific research on human genetics, which makes all of us very excited.

But we need to look at some of the statements and claims that are being made to the average consumer when they look at the Web site 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 Web site that its product offers, quote, "a new look at a healthier future." And you can see on the screen their claims.

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

Pathway Genomics, the third company testifying today, advises on its Web site that, quote, "Knowing how your genes may affect your response to certain drugs may improve the quality of your life," end quote.

And deCODEme, a fourth company whose genetic testing kit GAO reviewed, states on its Web site that, quote, "Your genes are a roadmap to better health," end quote.

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 widespread accepted consensus linking genetic markers to many 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 of the government share jurisdiction over direct-to-consumer genetic tests. Under the Clinical Laboratory Improvement Act, CLIA, the Centers for Medicare and Medicaid Services, CMS, regulates the laboratories that conduct the 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 of this year, 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, the 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 the 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.

And 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.

Our 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, members of our committee asked the GAO to evaluate these issues, and GAO is going to report to us today. Three of the companies the GAO tested have come here to discuss their work, provide their insights into what the committee and GAO found. I thank them for their cooperation.

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

Thank you, Mr. Chairman. We need to ensure the public is protected against exaggerated claims, abusive marketing, and practices that threaten individual health and safety.

[The prepared statement of Mr. Waxman follows:]

HENRY A. WAXMAN, CALIFORNIA
CHAIRMAN

JOE BARTON, TEXAS
RANKING MEMBER

ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
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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.

Mr. STUPAK. Thank you, Chairman Waxman.

I had asked before Mr. Burgess's opening statement that Congresswoman Slaughter from the 28th district of New York, that her statement be made part of my opening statement. Without objection, that will be the case.

Next we will go to Mr. Griffith for an opening statement, please, 3 minutes.

OPENING STATEMENT OF HON. PARKER GRIFFITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ALABAMA

Mr. GRIFFITH. Thank you, Mr. Chairman and Ranking Member, for this opportunity, this hearing investigating direct-to-consumer genetic testing.

I would also like to thank those witnesses that are here to help us with this investigation.

Today we will closely examine genetic testing and how effective the results have been for consumers. It is evident that, as young as this industry is, there are many things that need to be investigated. Providing a safe, effective product for the public is, of course, the main concern that we will look at today. I'm hoping this discussion today will bring valuable insight into the scientific and ethical issues surrounding the personal genomics industry.

These tests can provide consumers with the information to motivate them to live healthier lives. The development of the tests can help individuals identify if they are at risk for particular medical conditions and seek out specific medical treatments. On the other hand, if the tests are inaccurate, it can lead to confusion, fear, or misdiagnosis, and even unnecessary testing and death.

In addition, for the average consumer, the results of these tests can be too confusing and too complicated for individuals and their families to deal with. It is vital we prepare consumers with the background knowledge and tools they need to interpret their own genetic data in a safe and informed manner.

There have already been evidences of consumer fraud, and we must make sure that this does not continue.

As a physician for 40 years, I understand how important it is to provide accurate health care information to individuals so they can make important medical decisions. We need to ensure that, moving forward from today, that these companies have this same goal. The answer may not be to take these tests away from the public use, as they could be helpful in prevention of disease, but we do need to drive a discussion today on how to better protect the public.

I might say that the diseases that draw the most attention are cancer, Alzheimer's—those we fear the most. If I were to stand up and pull a snake out of my pocket right now and throw it into this audience, very few of you would decide whether it was poisonous or not; everybody would be headed for the door.

No one is more vulnerable to medical fraud than the concerned individual about a family history or a disease. No one is more sensitive to the mysteries of their bodies and genetic testing. And so the marketing of this particular aspect of medicine is fraught—fraught—a minefield of fraud and abuse, pushed by the profit motive, which we admire, but we do know in medicine it can be a problem.

So, with that, I appreciate it very much, Mr. Chairman. Thank you.

Mr. STUPAK. Thank you, Mr. Griffith.

Ms. DeGette for an opening statement, please.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you very much, Mr. Chairman. I want to thank you for holding this hearing on a very important and cutting-edge issue.

Ever since the Human Genome Project was completed in 2003, invigorated scientific interest in genetic analysis and testing has led to complex breakthroughs and now to a process so streamlined it can be marketed directly to the individual consumer. So, today, because of this, we stand at a moral, ethical, and health crossroads, where a significant examination from regulatory agencies is absolutely critical.

Without a doubt, advances in the field have created opportunities for consumers to improve their health through the early detection of certain genetic predispositions. For example, when the technology warns somebody that they are at risk for diabetes in enough time to make significant lifestyle changes in the form of diet and exercise, this helps stave off the onset of the disease. And, in addition, knowledge of an individual's unique genetic composition will allow doctors to give medicine for treatment that they know the bodies of the patients will not reject.

But as we move forward, we have to do so cautiously. Intertwined with the promise of direct-to-consumer genetic testing are the perils of what can happen when this information is used inappropriately.

As a threshold matter, the information provided through direct-to-consumer genetic testing must remain private. When President Bush signed GINA, the Genetic Information Nondiscrimination Act, in 2008—and this committee worked for many years on that legislation—it was an important step towards ensuring a person's genetic composition would not subject them to maltreatment at the hands of insurance agencies and employers. So, today, faced with the reality of genetic testing becoming infinitely more available and more prevalent, it is even more imperative that we make sure that each and every individual's privacy is ensured.

Of equal importance to this is that easily identifiable scientific standards are adopted across the board. Before becoming the director of the NIH, Dr. Francis Collins, in researching his book, "The Language of Life: DNA and the Revolution of Personalized Medicine," was shocked to find out—and some of you here know this. When he sent his own genetic sample to the three leading companies, the results he received in return differed. With the potential volatility of this information, such inconsistencies are impermissible. So we have to have a recognizable set of standards.

You know, Dr. Collins, what he did when he got these three results that differed so much, he just went back in and just tested his own genome because he can do that. The average consumer cannot conduct independent verification tests.

And, in addition, they need some help from their doctors to figure out exactly what these test results mean, what the emotional and physical burden will be. All of these things are important.

I'm excited about the potential for genetic testing, Mr. Chairman, but I also think we need to make sure that we have all the protections available.

Mr. STUPAK. Thanks, Ms. DeGette.

Mr. Latta, opening statement, 3 minutes.

OPENING STATEMENT OF HON. ROBERT E. LATTA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Mr. LATTA. Thank you, Mr. Chairman, Ranking Member Burgess. Thank you very much for holding this subcommittee hearing on direct-to-consumer genetic testing and the consequences to the public health.

Advances in technology led to incredible discoveries in the field of genetics and that an individual can take a simple test in order to find out if he or she is predisposed to certain diseases. Such developments have many potential applications to consumers, and I believe that this is an area that is an important step in the direction of giving individuals more power over their own personal health decisions.

The rapidly growing field of genetic testing symbolizes the entrepreneurial spirit and innovation that makes America great. The possibility of excessive government regulations, which would and could effectively put an end to an increasing technology, should not be our goal. Rather, since the field of genetic testing is still developing, it is important to bring together all the stakeholders to discuss the ethical and health implications and spur the industry to address these concerns.

Furthermore, we must examine the privacy implications for individuals having access to report on their own personal DNA. The potential for fraud and disclosure of personal information necessitates a close examination of the industry.

Mr. Chairman, again, thank you very much for holding this hearing on direct-to-consumer genetic testing. I look forward to hearing the testimony today from our witnesses. And I yield back. Thank you very much.

[The prepared statement of Mr. Latta follows:]

Congressman Robert E. Latta
The Committee on Energy & Commerce
Subcommittee on Oversight and Investigations
Opening Statement – For the Record
September 22, 2010

MR. CHAIRMAN; RANKING MEMBER BURGESS: Thank you for holding this subcommittee hearing on the outbreak of *Salmonella* in eggs, as incidences of contaminated food products are a serious concern for public health. I am very glad that the two witnesses on our first panel who were affected by these eggs are on the road to recovery and are able to be with us today.

This hearing is also of great concern to me because egg production is critical to my state, Ohio, which is the second-largest egg producing state in the nation, with 7.1 billion eggs. Many of you have heard me say that I represent the largest manufacturing district in Ohio, but I also represent the largest agriculture district in Ohio. Furthermore, my district is home to one of the top two egg producing counties in the nation. Ohio's egg industry produces 465.5 million eggs in my district, and has an economic impact of 102.4 million dollars.

Ohio is also one of the ten states with an egg quality assurance program with the aim to minimizing Salmonella in eggs.

First of all, I think it is important that we remember that the purpose of this hearing is to get the facts. While we have the FDA form 483 with general observations about the conditions at the Wright County Egg and Hillendale Farms operations in Iowa that are being investigated, we do not yet have the Establishment Inspection Report which will provide more clear answers. Furthermore, I am disappointed that the FDA Commissioner is not here to testify, nor is a representative from the USDA.

We need to get answers and hear what went wrong from these producers so that the industry learns from this recall. We do not want the public to lose confidence in our egg producers.

Several of the egg producers in my district are fourth generation farmers and have been committed to producing a safe, healthy product for years. If we have over-burdening regulations that are placed out there, many of these farmers may be forced out of business - unfortunately, preventing a fifth-generation from being able to farm.

The safety and security of the nation's food supply is of utmost importance to me. Mr. Chairman, thank you for this opportunity, and I look forward to hearing the testimony from the witnesses on the panel today. I would also like to submit a document for the record from the Ohio Poultry Association on egg facts in Ohio.

Mr. STUPAK. Thank you, Mr. Latta.

Ms. Christensen for an opening statement, please.

OPENING STATEMENT OF HON. DONNA M. CHRISTENSEN, A REPRESENTATIVE IN CONGRESS FROM THE VIRGIN ISLANDS

Ms. CHRISTENSEN. Thank you, Mr. Chairman.

I will admit a bias. As a physician, I was never a fan of direct-to-consumer advertising. And the direct-to-consumer genetic testing raises even greater concern and poses even more serious consequences.

Having information regarding one's health is important. The more, the better. But having the kind of information genetic testing could provide without the guidance, the analysis, and the interpretation of a health professional can and apparently has already led to wrong assumptions and wrong decisions.

So even before seeing the results of the GAO study, I had serious doubts—doubts about the claims of the testing, about the cost, and about the diversity of the genetic pool. Clients may be duped into thinking they could get the genetic analysis by paying the costs of the tests when, in some cases, that is an additional cost, a higher cost, that some can't afford.

The gross underrepresentation of African Americans and other minorities in clinical trials has impacted the kind of information we could receive from the kind of genetic testing generally offered. It is my understanding that, because of this, results may come back with no information on some of the diseases that cause some of the major health disparities. And this is after the client has paid for the information that they don't get.

I had to be, and I'm sure my colleagues had to be, clear certified to do simple tests in our office, where I could sit and counsel the patients myself. Although GAO showed that the information they receive is generally meaningless, to think that such testing could be done and reported in such an unregulated manner is appalling.

I commend the FDA for taking this issue on and the subcommittee for asking for the investigation. And I thank you, Chairman Stupak and Ranking Member Burgess, for holding this hearing.

I yield back my time.

Mr. STUPAK. Thank you, Ms. Christensen.

Mr. Gingrey, opening statement, please.

OPENING STATEMENT OF HON. PHIL GINGREY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. GINGREY. Mr. Chairman, thank you.

I came in just in time to hear three of my colleagues give their opening statements, and they essentially have given two-thirds of my opening statement. I'm not a bit surprised that I would be in agreement with Dr. Christensen in regard to this. I mean, obviously, we all have some real serious concerns about how this information is used and what the patient's understanding of it is.

Genetic tests, indeed, hold great promise for our health care system, but the problem with these tests rests squarely on patients having the necessary information available to use the results effectively. According to the National Cancer Institute's Web site, pa-

tients—this is a quote from their Web site—"should be informed, both verbally and in writing, about the risk of getting tested, as well as what the tests can and cannot tell you." That is a quote. I cannot agree more with these sentiments, as I said, expressed by my colleagues.

Personal genetic testing kits, on the other hand, are generally sold to patients through the Internet, as I understand it. These tests can require that patients send their DNA sample through the mail and check the results of their test online, hopefully in a secure manner.

As a provider myself of 31 years, I am very concerned with the process I just described. I don't see much opportunity to educate patients about the strengths and weaknesses of these tests, what test results can and cannot teach patients, and how these results, most importantly, should be interpreted. You have a lot of hypochondriacs out there in this country, and we are going to make maniacs out of them, I fear.

Tests such as these, they may offer great insights into our health status, but the process by which these tests are conducted and analyzed should include the sound advice of a qualified medical provider, like Dr. Christensen. Without the benefit of such medical insight, I fear patients may jump to wrong conclusions—indeed, they may even jump off a building—and create snap medical decisions simply out of fear or ignorance. Therefore, I believe that patients should have the benefit of medical advice when considering such test results.

With that thought in mind, I look forward to the testimony of all of our witnesses, both panels, in exploring this issue in greater detail.

I've got a few more seconds left. And so quickly—Mr. Chairman, this might not surprise you—before I yield back, I would be remiss if I didn't once more use my opening statement to ask for a congressional hearing on our new CMS administrator, Dr. Berwick.

This committee, Energy and Commerce, Oversight and Investigation, this subcommittee seems like an appropriate place to ask Dr. Berwick about his thoughts on health care rationing and whether it is now the philosophy of our Medicare program, or whether Dr. Berwick still believes that a humane health care system should transfer the wealth and resources from the rich to the poor.

These are valid questions, questions for which I want answers, questions for which my constituents want answers. And I would like to believe that finding these answers is not a partisan endeavor, but one we can accomplish together. It is true that I may not agree with some of my colleagues on what the substance of those answers should be, but I think we should all be able to agree that getting answers to these questions is of utmost importance.

And, Mr. Chairman, with that, I yield back, having used 23 extra seconds. And I appreciate your indulgence.

Mr. STUPAK. That concludes the opening statements by members of the subcommittee who are present. So we have our first panel of witnesses at the table before us.

On our first panel, we have Dr. Jeff Shuren, director of the Center for Devices and Radiological Health at the Food and Drug Administration; and Mr. Gregory Kutz, managing director of forensic

audits and special investigations at the Government Accountability Office.

It is the policy of this subcommittee to take all testimony under oath. Please be advised that you have the right, under the rules of the House, to be advised by counsel during your testimony. Do either of you wish to be represented by counsel?

Both indicated that you do not. Therefore, I'm going to ask you to please rise, raise your right hand, and take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect that the witnesses replied in the affirmative. They are now under oath.

We will begin with opening statements by our witnesses.

And, Dr. Shuren, we will start with you, please, sir.

Doctor, I'm sorry. I guess they want Mr. Kutz to go first.

Greg, do you want to go first then?

Mr. KUTZ. Sure.

Mr. STUPAK. Sorry about that, Doctor.

Dr. SHUREN. Mr. Chairman, I am not going anywhere.

Mr. STUPAK. Go ahead.

TESTIMONY OF GREGORY KUTZ, MANAGING DIRECTOR, FORENSIC AUDITS AND SPECIAL INVESTIGATIONS, GOVERNMENT ACCOUNTABILITY OFFICE; JEFFREY SHUREN, M.D., DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, U.S. FOOD AND DRUG ADMINISTRATION

TESTIMONY OF GREGORY KUTZ

Mr. KUTZ. Mr. Chairman and members of the subcommittee, thank you for the opportunity to discuss genetic testing. Today's testimony highlights the results of our investigation into genetic testing products sold directly to consumers.

My testimony has two parts. First, I will discuss what we did, and, second, I will discuss what we found. Also, at the end of my presentation, I will play audio excerpts from several of our undercover calls of genetic testing companies.

First, we investigated four companies that have been touted as some of the most reputable in the industry. These companies claim that their tests will analyze DNA and provide genetic risk predictions for conditions such as cancer and Alzheimer's disease. They claim that the results of these tests can be used by consumers to help prevent them from getting these diseases.

To test the legitimacy of these claims, we purchased 10 tests from each of these four companies. The cost of these tests range from $300 to $1,000 each. For each of our five volunteer donors, we sent two DNA samples to each company. One of these samples used factual information, while the other used fictitious information, about our age and ethnicity. We used bogus identities for all five of our donors.

We compared the risk predictions that we received for each donor for 15 diseases and made undercover calls to these companies to discuss our results. We consulted with several recognized experts in the field of genetics during all phases of this investigation.

We also conducted interviews with each of the four companies. Separate from these 40 tests, we made undercover calls to 15 com-

panies, including these four, and asked them about their test reliability, privacy policies, and their sales of nutritional supplements.

Now that I have set up what we did, let me go to our second point, our key findings.

First, all five donors received conflicting results. Assuming these tests are credible, one would expect that the same DNA would receive the same predictions. Not so: 68 percent of the time, our donors received different predictions for the same disease.

For example, as shown on the monitor, Donor No. 3 was at the same time at below-average, average, and above-average risk for prostate cancer, high blood pressure, and Type 1 diabetes. By the way, Donor No. 3 is me. So, Mr. Chairman, as a consumer, which of these predictions should I believe? Dr. Burgess advised me to be optimistic and to believe Company No. 2. However, what I really believe, as do our experts, is that these results show that these tests are not ready for prime time.

We also received disease predictions that conflicted with our donors' actual medical history. For example, as mentioned, I have in my hand—and for those who can't see, the monitor shows—the actual pacemaker one of our donors recently had replaced. This pacemaker controlled this donor's atrial fibrillation, or irregular heartbeat, for the last 13 years. However, according to two of these four companies, this donor is at below-average risk for developing atrial fibrillation. So, as we've talked here, is this science or is this art?

We also identified, as mentioned, deceptive and fraudulent marketing practices related to genetic testing. For example, I have in my hand a bag of nutritional supplements that are supposedly customized to my specific DNA. According to the sales representative, these supplements can treat or prevent arthritis. They can also replace prescription medications for high blood pressure and high cholesterol. Sounds great. The problem is that these supplements are illegally being marketed as a drug without the required FDA approval.

One company claimed, as mentioned, that Lance Armstrong and Michael Phelps used or endorsed their supplements. According to representatives for Mr. Phelps and Mr. Armstrong, they have nothing to do with these supplements.

Two companies claim to have a DNA test that will predict which sports children will excel at. And, finally, two companies told our fictitious consumer that she could secretly test her fiance's DNA and surprise him with the results. This secret testing is illegal in 33 States.

In conclusion, our investigation shows that the test results that we received, as all of you have mentioned, are misleading and, in many cases, not of much value to consumers. This is particularly relevant today, as companies are attempting to market these tests in retail stores across the country.

These results should not detract from the great promise of genetic testing and the progress made. However, consumers need to know that, today, genetic testing for certain diseases appears to be more of an art than a science.

As I mentioned, we will now play audio excerpts from some of our undercover calls to genetic testing companies, and you will see the transcription of the conversations on the monitors as you listen.

[Audio clips played.]

Mr. KUTZ. Mr. Chairman, that ends my statement. I look forward to your questions.

[The prepared statement of Mr. Kutz follows:]

United States Government Accountability Office

GAO

Testimony
Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

For Release on Delivery
Expected at 9:30 a.m. EDT
Thursday, July 22, 2010

DIRECT-TO-CONSUMER GENETIC TESTS

Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices

Statement of Gregory Kutz, Managing Director
Forensic Audits and Special Investigations

GAO
Accountability * Integrity * Reliability

GAO-10-847T

July 22, 2010

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Highlights

Highlights of GAO-10-847T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

DIRECT-TO-CONSUMER GENETIC TESTS

Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices

Why GAO Did This Study

In 2006, GAO investigated companies selling direct-to-consumer (DTC) genetic tests and testified that these companies made medically unproven disease predictions. Although new companies have since been touted as being more reputable—*Time* named one company's test 2008's "invention of the year"—experts remain concerned that the test results mislead consumers. GAO was asked to investigate DTC genetic tests currently on the market and the advertising methods used to sell these tests.

GAO purchased 10 tests each from four companies, for $299 to $999 per test. GAO then selected five donors and sent two DNA samples from each donor to each company: one using factual information about the donor and one using fictitious information, such as incorrect age and race or ethnicity. After comparing risk predictions that the donors received for 15 diseases, GAO made undercover calls to the companies seeking health advice. GAO did not conduct a scientific study but instead documented observations that could be made by any consumer. To assess whether the tests provided any medically useful information, GAO consulted with genetics experts. GAO also interviewed representatives from each company. To investigate advertising methods, GAO made undercover contact with 15 DTC companies, including the 4 tested, and asked about supplement sales, test reliability, and privacy policies. GAO again consulted with experts about the veracity of the claims.

View GAO-10-847T or key components. For more information, contact Gregory Kutz at (202) 512-6722 or kutzg@gao.

What GAO Found

GAO's fictitious consumers received test results that are misleading and of little or no practical use. For example, GAO's donors often received disease risk predictions that varied across the four companies, indicating that identical DNA samples yield contradictory results. As shown below, one donor was told that he was at below-average, average, and above-average risk for prostate cancer and hypertension.

Contradictory Risk Predictions for Prostate Cancer and Hypertension

Gender	Age	Condition	Company 1	Company 2	Company 3	Company 4
Male	48	Prostate cancer	Average	Average	Below average	Above average
		Hypertension	Average	Below average	Above average	Not tested

Source: GAO.

GAO's donors also received DNA-based disease predictions that conflicted with their actual medical conditions—one donor who had a pacemaker implanted 13 years ago to treat an irregular heartbeat was told that he was at decreased risk for developing such a condition. Also, none of the companies could provide GAO's fictitious African American and Asian donors with complete test results, but did not explicitly disclose this limitation prior to purchase. Further, follow-up consultations offered by three of the companies failed to provide the expert advice that the companies promised. In post-test interviews with GAO, each of the companies claimed that its results were more accurate than the others'. Although the experts GAO spoke with believe that these tests show promise for the future, they agreed that consumers should not rely on any of the results at this time. As one expert said, "the fact that different companies, using the same samples, predict different directions of risk is telling and is important. It shows that we are nowhere near really being able to interpret [such tests]."

GAO also found 10 egregious examples of deceptive marketing, including claims made by four companies that a consumer's DNA could be used to create personalized supplement to cure diseases. Two of these companies further stated that their supplements could "repair damaged DNA" or cure disease, even though experts confirmed there is no scientific basis for such claims. One company representative even fraudulently used endorsements from high-profile athletes to convince GAO's fictitious consumer to purchase such supplements. Two other companies asserted that they could predict in which sports children would excel based on DNA analysis, claims that an expert characterized as "complete garbage." Further, two companies told GAO's fictitious consumer that she could secretly test her fiancé's DNA to "surprise" him with test results—though this practice is restricted in 33 states. Perhaps most disturbing, one company told a donor that an above average risk prediction for breast cancer meant she was "in the high risk of pretty much getting" the disease, a statement that experts found to be "horrifying" because it implies the test is diagnostic. To hear clips of undercover contacts, see http://www.gao.gov/products/GAO-10-847T. GAO has referred all the companies it investigated to the Food and Drug Administration and Federal Trade Commission for appropriate action.

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to discuss our follow-up investigation of genetic tests sold directly to consumers via the Internet. Using kits at home, consumers simply swab their cheeks or collect saliva and send these DNA samples back to a company for analysis and a report of the results. While the importance of genetics in individual medical care shows promise for the future, the usefulness of the tests these companies offer is much debated.

In 2006, we investigated four companies selling direct-to-consumer (DTC) genetic tests that purported to use DNA to deliver personalized nutrition and lifestyle guidance. We testified before the Senate Special Committee on Aging that these companies misled consumers by providing test results that were both medically unproven and so ambiguous as to be meaningless.[1] For example, one of the results we received vaguely indicated that our DNA donor was at "significant risk of developing the age related conditions associated with elevated levels of DNA damage." Another stated that our donor had "faulty methylation patterns" that may lead to "an above-average risk for developing cardiac aging, brain aging, and cancer." And though some of the companies claimed that they would provide lifestyle advice based on a consumer's DNA, we found that they simply provided generally accepted health guidance linked to background information submitted by our donors on test questionnaires. Further, two of the companies we tested recommended costly dietary supplements that were in reality nothing more than inexpensive multivitamins available at any drug store.

As a result of these findings, in 2006 the Centers for Disease Control and Prevention (CDC) in conjunction with the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) issued alerts warning consumers to be wary of claims made by these types of DTC genetic testing companies. In October 2008, FTC again warned consumers that "no standards govern the reliability or quality of at-home genetic tests. The FDA and Centers for Disease Control and Prevention recommend that genetic tests be done in a specialized laboratory and that a doctor or counselor with specialized training interpret the results."

[1]GAO, *Nutrigenetic Testing: Tests Purchased from Four Web Sites Mislead Consumers*, GAO-06-977T (Washington D.C.: July 27, 2006).

Despite these warnings, several new DTC genetic test companies have been touted as being more reputable and medically accurate than those we tested previously; in 2008, *Time* magazine named one new company's test the "invention of the year." More recently, another company's plan to sell tests at retail pharmacies has drawn significant attention from the media and scientists. However, given the scientific evidence currently available, many experts remain concerned that the medical predictions contained in the results mislead consumers. In this context, you requested that we proactively test DTC genetic products currently on the market and the advertising methods used to sell these products to consumers.

To investigate DTC genetic products currently on the market, we purchased tests, for $299 to $999, from a nonrepresentative selection of four of the dozens of genetic testing companies selling kits to consumers on the Internet.[2] Using online search terms likely to be used by actual consumers, we identified and selected these companies because they were frequently cited as being credible by the media and in scientific publications and because they all provided consumers with risk predictions, accessible through secure Web sites, for a range of diseases and conditions.[3] Although their tests are not identical, all four companies' Web sites contain a variation of the statement that their tests help consumers and their physicians detect disease risks early so that they can take preventive steps to reduce these risks. They also note that their tests are not intended to provide medical advice or to treat or diagnose disease. We purchased 10 tests from each company (40 tests in total) to compare risk predictions for a variety of serious illnesses and determine whether the companies were consistent in their predictions. We selected for comparison 15 common diseases and conditions that were tested by at least three of the four companies: Alzheimer's disease, atrial fibrillation (a type of irregular heart beat), breast cancer, celiac disease (a chronic digestive problem caused by an inability to process gluten), colon cancer, heart attack, hypertension, leukemia, multiple sclerosis, obesity, prostate

[2]The companies are not the same as the companies tested in our 2006 investigation.

[3]The companies also provided consumers with ancestry reports; drug response tests; and predictions for various traits and characteristics, such as eye color. We focused our investigation on testing the companies' disease risk predictions.

cancer, restless leg syndrome, rheumatoid arthritis, type 1 diabetes, and type 2 diabetes.[4]

As shown in table 1, we then selected five DNA donors and created two profiles for each donor, one using factual information about the donor and one using fictitious information, including age, race or ethnicity, and medical history.

Table 1: Donor and Profile Information

Donor	Profile	Gender	Age	Race or Ethnicity	Selected Medical History Information
1	Factual	Female	37	Caucasian	Colon cancer
	Fictitious	Female	68	African American	Hypertension and diabetes
2	Factual	Female	41	Caucasian	Breast cancer, diabetes, and heart disease
	Fictitious	Female	19	Asian	Heart arrhythmias
3	Factual	Male	48	Caucasian	Asthma, non-melanoma skin cancer, and heart disease
	Fictitious	Male	69	African American	Auto-immune disorders
4	Factual	Male	61	Caucasian	Colon cancer, heart disease, and atrial fibrilation
	Fictitious	Male	53	Caucasian	Prostate cancer and hypertension
5	Factual	Male	63	Caucasian	Type 2 diabetes, Alzheimer's disease, and obesity
	Fictitious	Male	29	Hispanic	Asthma and thyroid and colon cancer

Source: GAO

Note: We did not alter the gender on the donors' fictitious profiles because we believed that this difference would have been easily identified by these companies.

For each donor, we sent two DNA samples (saliva or a cheek swab) to each company—one sample using the factual profile and one using the fictitious—to determine whether altering the donors' backgrounds had any effect on the companies' DNA analysis. Three of the four companies asked for age and race or ethnicity prior to purchase; only one asked for medical history information. We also made undercover telephone calls to the companies seeking additional medical advice for both our factual and fictitious donors. We then documented our observations on the test results and advice we received. It is important to emphasize that we did not

[4]Type 1 diabetes is usually first diagnosed in children, teenagers, or young adults. With this form of diabetes, the cells of the pancreas no longer make insulin because the body's immune system has attacked and destroyed them. Type 2 diabetes is the most common form of diabetes. People can develop type 2 diabetes at any age—even during childhood. This form of diabetes usually begins with insulin resistance, a condition in which fat, muscle, and liver cells do not use insulin properly.

conduct a rigorous scientific study; our observations are those that could be made by any consumer. To assess whether we received any scientifically based or medically useful information, we consulted with external experts in the field of genetics and incorporated their comments as appropriate. Our primary consultant was Dr. James Evans, the Director of Adult Genetics Services at the University of North Carolina and the Editor-in-Chief of *Genetics in Medicine*, the official journal of the American College of Medical Genetics. After we completed our proactive testing, we visited each company and interviewed representatives who were willing to speak with us. We did not notify the companies prior to these visits and did not specifically disclose the results of our undercover testing or reveal the identities of our donors or the other companies that we tested.

To investigate the advertising methods used to sell DTC genetic products, we reviewed the Web sites of a nonrepresentative selection of 15 genetic testing companies, including the 4 from which we purchased tests. We identified the companies by again using online search terms likely to be used by actual consumers. Posing as fictitious consumers, we made contact with these companies, both by phone and in person, seeking additional information about genetic testing. During these contacts, we asked a series of questions about the reliability and usefulness of test results, privacy policies regarding consumers' genetic information, and the sale of supplements or other products. To assess the accuracy and reasonableness of the marketing claims, we again consulted with external experts in the field of genetics. We also purchased supplements sold by one of the companies.

Our findings are limited to the individual DTC genetic test companies we investigated and cannot be projected to any other companies. We performed our work from June 2009 to June 2010 in accordance with standards prescribed by the Council of Inspectors General for Integrity and Efficiency.

Test Results Are Misleading and of Little Use to Consumers

The test results we received are misleading and of little or no practical use to consumers. Comparing results for 15 diseases, we made the following observations: (1) each donor's factual profile received disease risk predictions that varied across all four companies, indicating that identical DNA can yield contradictory results depending solely on the company it was sent to for analysis; (2) these risk predictions often conflicted with the donors' factual illnesses and family medical histories; (3) none of the companies could provide the donors who submitted fictitious African

American and Asian profiles with complete test results for their ethnicity but did not explicitly disclose this limitation prior to purchase; (4) one company provided donors with reports that showed conflicting predictions for the same DNA and profile, but did not explain how to interpret these different results; and (5) follow-up consultations offered by three of the companies provided only general information and not the expert advice the companies promised to provide. The experts we spoke with agreed that the companies' claims and test results are both ambiguous and misleading. Further, they felt that consumers who are concerned about their health should consult directly with their physicians instead of purchasing these kinds of DTC genetic tests. See appendix I for comprehensive information on the test results we received for each donor.

Different companies often provide different results for identical DNA: Each donor received risk predictions for the 15 diseases that varied from company to company, demonstrating that identical DNA samples produced contradictory results. Specifically, in reviewing the test results across all four companies for the donors' factual profiles, we found that Donor 1 had contradictory results for 11 diseases, Donor 2 for 9 diseases, Donor 3 for 12 diseases, Donor 4 for 10 diseases, and Donor 5 for 9 diseases. Specific examples of these contradictory predictions are listed below; note that some of the diseases we compared were only tested by three of the four companies. To facilitate comparison among companies, we chose to use the terms "below average," "average," and "above average" to describe the risk predictions we received; the exact language used by each of the companies is reprinted in appendix I.

- For Donor 1, Company 1 predicted an above-average risk of developing leukemia, while Company 2 predicted a below-average risk, and Company 3 reported that she had an average risk for developing the disease. In addition, Companies 2 and 4 told the donor that her risk for contracting breast cancer was above average, but Companies 1 and 3 found her only to be at average risk. See figure 1.

Figure 1: Selected Contradictory Risk Predictions for Donor 1

Gender	Age	Condition	Company 1	Company 2	Company 3	Company 4
Female	37	Leukemia	Above average	Below average	Average	Not tested
		Breast cancer	Average	Above average	Average	Above average

Source: GAO.

- Companies 1 and 2 claimed that Donor 2 had an above-average risk of developing type 1 diabetes, while Company 3 reported that she was at below-average risk for the disease. Further, Company 2 predicted she was at above-average risk for restless leg syndrome, Company 1 claimed she was at below-average risk for the condition, and Company 4 found that she was at average risk. See figure 2.

Figure 2: Selected Contradictory Risk Predictions for Donor 2

Gender	Age	Condition	Company 1	Company 2	Company 3	Company 4
Female	41	Type 1 diabetes	Above average	Above average	Below average	Not tested
		Restless leg syndrome	Below average	Above average	Not tested	Average

Source: GAO.

- Company 4 claimed that Donor 3's risk of developing prostate cancer was above-average, Company 3 found that he was at below-average risk, and Companies 1 and 2 found that he was at average risk. For hypertension, Company 3 found that he had an above-average risk of developing the condition, Company 2 found that he was at below-average risk, and Company 1 found he was at average risk. See figure 3.

Figure 3: Selected Contradictory Risk Predictions for Donor 3

Gender	Age	Condition	Company 1	Company 2	Company 3	Company 4
Male	48	Prostate cancer	Average	Average	Below average	Above average
		Hypertension	Average	Below average	Above average	Not tested

Source: GAO.

- Donor 4 was told by Companies 1 and 4 that he was at above-average risk for celiac disease, but Company 2 reported that he was only at average risk. In addition, Companies 1 and 4 found that he was at below-average risk for multiple sclerosis, while Companies 2 and 3 found that he was at average risk. See figure 4.

Figure 4: Selected Contradictory Risk Predictions for Donor 4

Gender	Age	Condition	Company 1	Company 2	Company 3	Company 4
Male	61	Celiac disease	Above average	Average	Not tested	Above average
		Multiple sclerosis	Below average	Average	Average	Below average

Source: GAO.

- For Donor 5, Companies 2 and 3 reported an above-average risk for heart attacks, and Companies 1 and 4 identified only an average risk. Company 2 found him to be at below-average risk[5] for atrial fibrillation, while Companies 1, 3, and 4 predicted an average risk. See figure 5.

Figure 5: Selected Contradictory Risk Predictions for Donor 5

Gender	Age	Condition	Company 1	Company 2	Company 3	Company 4
Male	63	Heart attack	Average	Above average	Above average	Average
		Atrial fibrillation	Average	Below average	Average	Average

Source: GAO.

These contradictions can be attributed in part to the fact that the companies analyzed different genetic "markers" in assessing the donors' risk for disease. As described in a recent article published in the science journal *Nature*, researchers determine which markers occur more frequently in patients with a specific disease by conducting "genome-wide association studies, which survey hundreds of thousands or millions of markers across control and disease populations."[6] DTC companies use these publicly available studies to decide which markers to include in their analyses, but none of the companies we investigated used the exact same markers in its tests. For example, Company 1 looked at 5 risk markers for prostate cancer, while Company 4 looked at 18 risk markers.

In our post-test interviews, representatives from all four companies acknowledged that, in general, DTC genetic test companies test for different risk markers and that this could result in companies having different results for identical DNA. When we asked the representatives whether they thought that any DTC genetic test companies currently on the market were more accurate than others, all claimed that their own companies' tests were better than those offered by their competitors. For example, Company 1 said that it offers consumers more information than other companies because its results are based on both preliminary research reports as well as clinical data. Company 2 claimed that other companies do not test for as many markers as it does and that while none

[5]In a "research" report contained in the test results, Company 1 also found this donor to be at below-average risk for atrial fibrillation. These conflicting reports will be discussed later in the testimony.

[6]Pauline C. Ng, Sarah S. Murray, Samuel Levy, and Craig J. Venture, *An Agenda for Personalized Medicine*, Nature, vol. 461, October 8, 2009.

of the companies are "wrong," using more markers is "probably more accurate." Company 2 also stated that disparate test results from different companies are "caused, in part, due to a lack of guidance from the federal government, CDC in particular." Company 3 similarly claimed to test for more markers than other companies and stated that its test is "the best." Company 3 also said that there is a movement within the DTC genetic test industry to standardize test results, but that such standardization is a work in progress. Finally, Company 4 claimed that it uses stricter criteria to select risk markers than other companies. Company 4 also told us that it has been involved in a collaborative effort with other DTC genetic test companies to develop standard sets of markers, but stated that there are many unresolved differences in philosophy and approach.

When we asked genetics experts if any of the companies' markers and disease predictions were actually more accurate than the others, they told us that there are too many uncertainties and ambiguities in this type of testing to rely on any of the results. Unlike well-established genetic testing for diseases like cystic fibrosis, the experts feel that these tests are "promising for research, but the application is premature." In other words, "each company's results could be internally consistent, but not tell the full story....[because] the science of risk prediction based on genetic markers is not fully worked out, and that the limitations inherent in this sort of risk prediction have not been adequately disclosed." As one expert further noted, "the fact that different companies, using the same samples, predict different...directions of risk is telling and is important. It shows that we are nowhere near really being able to interpret [such tests]." We also asked our experts if any of our donors should be concerned if the companies all agreed on a risk prediction; for example, all four companies told Donor 1 she was at increased risk for Alzheimer's disease. The experts told us this consensus means very little because there are so many demographic, environmental, and lifestyle factors that contribute to the occurrence of the types of diseases tested by the four companies.

Risk predictions sometimes conflict with diagnosed medical conditions or family history: Four of our five donors received test results that conflicted with their factual medical conditions and family histories.[7] When we asked the experts about these discrepancies, they told us that the results from these DTC tests are not conclusive because the

[7]Company 3 is the only company that asked consumers to provide medical history information as part of the DNA submission process.

tests are not diagnostic, as is noted on all of the companies Web sites. Because risks are probabilistic by definition, it is very likely that consumers will receive results from these companies that do not comport with their knowledge of their own medical histories. However, one expert noted that the discrepancies between actual health and the predications made by these companies also serve to illustrate the lack of robustness of such predictive tests. Moreover, experts fear that consumers may misinterpret the test results because they do not understand such distinctions. For example, a consumer with a strong family history of heart disease may be falsely reassured by below-average risk predictions related to heart attacks and consequently make poor health choices. In fact, one expert told us that "family history is still by far the most consistent risk factor for common chronic conditions. The presence of family history increases the risk of disease regardless of genetic variants and the current genetic variants do not explain the familial clustering of diseases." Another expert stated that "the most accurate way for these companies to predict disease risks would be for them to charge consumers $500 for DNA and family medical history information, throw out the DNA, and then make predictions based solely on the family history information." Examples we identified include the following:

- Donor 2 has a family history of heart disease yet all four companies predicted that she was at average risk for having a heart attack. Donor 2 also has a family history of type 1 diabetes, but Company 3 reported that she was at below-average risk for the disease.

- Donor 3 has a family history of heart disease, but Companies 1, 2, and 3 reported that he was at average risk for having a heart attack and Company 4 reported he was at below-average risk.

- Donor 4 had a pacemaker implanted 13 years ago to treat atrial fibrillation. However, Company 1 and 2 found that he was at below-average risk for developing atrial fibrillation,[8] and Companies 3 and 4 claimed that he was at average risk. Donor 4 is also a colon cancer survivor, but Company 2 reported that he was at average risk of developing the disease.

[8]In another report contained in the test results, Company 1 also found this donor to be at average risk for atrial fibrillation. These conflicting reports will be discussed later in the testimony.

- Donor 5 has Type 2 diabetes, but Companies 1, 2, and 3 indicated that he had an average risk of developing the disease. Donor 5 is also overweight, but all four companies found him to be at average risk for obesity.

In our post-test interviews, representatives from all four companies reiterated that their tests are not diagnostic, but they all believe that their tests provide consumers and their doctors with useful information. Specifically, Company 1 stressed that its tests empower consumers to recognize their risk of developing a health-related condition and then take the information to a doctor for further discussion. Company 2 emphasized that its tests provide consumers with the "incentive" to be "aggressive" about their health, while Company 3 said its goal is to "empower individuals with information to help them make necessary lifestyle changes." Similarly, Company 4 stated that its risk predictions are a useful first step in that they offer "something for the consumer and their physician to consider in deciding whether or when to proceed with more invasive or costly tests." However, experts we spoke with cautioned that most doctors are not adequately prepared to use DTC genetic test information to treat patients. In addition, experts noted that there is currently no data or other evidence to suggest that consumers have taken steps to improve their health as a result of taking DTC genetic tests. As one expert noted, "even if such information is found to be an especially effective motivator of behavioral change, we're in trouble...because for everyone you find who is at increased disease risk, you'll find another who is at decreased risk. So if this information is actually powerful in motivating behavior then it will also motivate undesirable behaviors in those found to be at low risk."

Fictitious profiles did not receive complete test results: Many of these studies the companies use to make risk predictions apply only to those of European ancestry. Consequently, our fictitious Asian and African American donors did not always receive risk predictions that were applicable to their race or ethnicity, although the companies either did not disclose these limitations prior to purchase or placed them in lengthy consent forms. The experts we spoke to agreed that these limitations should be "clearly disclosed upfront" and suggested that our fictitious donors try to get their money back. Companies 2 and 3 did give us a refund, but Company 1 refused and company 4 never responded to our request. In our post-test interviews, company representatives acknowledged that race and ethnicity do affect disease risk predictions, but that most genetic research has only been done on persons of European ancestry and therefore such individuals receive more accurate results.

Representatives from Company 1 also said that the company can provide only current information and that one of its primary goals is to expand upon this research by collecting DNA from as many persons as possible. Further, Companies 2 and 4 stated that they believe they communicate this limitation to consumers on their Web sites or in their test result reports, though our observations do not support this claim. Examples of the discrepancies we identified include the following:

- Company 1 provided Donor 1's fictitious African American profile with test results based on her race for just 1 of the 15 diseases we compared: type 2 diabetes. For the remaining diseases, Company 1 provided a risk prediction but included a disclaimer, such as "this result applies to people of European ancestry. We cannot yet compute more precise odds" for those of African American descent. However, Company 1 did not explicitly disclose the fact that African Americans would receive incomplete results prior to purchase, even though it did ask consumers to specify their ethnicity as part of the purchase process. The company only vaguely refers to any testing limitations on the first page of its consent form, which states that "gene/disease associations are typically based on ethnicity and the associations may not have been studied in many world populations and may not apply in the same or similar ways across populations."

- Company 2 claimed on its Web site that it had "better coverage [of genes] associated with the most important diseases for all ethnicities" than its competitors. However, the company provided Donor 2's fictitious Asian profile with test results for just 6 of the 15 diseases we compared. The company did not explain these discrepancies and did not disclose the testing limitations prior to purchase, even though it requested that consumers specify their race or ethnicity as part of the purchase process. The only references to these limitations are made in the "frequently asked questions" section and on page six of an eight-page service agreement, where the company notes that "the genetic result reported may in some cases only be applicable to a certain group of people, e.g. based on gender, ethnicity, lifestyle, family history etc. that you may or may not belong to."

- Company 3 sent Donor 3's fictitious African American profile results for just 3 of the 15 conditions we compared. The company did not disclose this limitation prior to purchase even though it requested that consumers specify their race or ethnicity during the purchase process.

- For 10 of the 15 conditions we compared, Company 4 sent all of our donors results that applied only to individuals of European ancestry.

However, for restless leg syndrome, the predictions were accompanied by the following statement: "most conditions have only been studied in people of European ancestry. But this condition is a little different." For atrial fibrillation, colon cancer, type 2 diabetes, and heart attack, the predictions were accompanied by the following statement "most conditions have only been studied in people of European ancestry, but this one also has been studied in other groups." The company provided no additional explanation as to how these differences applied to our donors. The only other reference to testing limitations is made on page five of a nine- page consent form, where the company notes that "most of the published studies in this area of genetic research have focused on people of Western European descent. We do not know if, or to what extent, these results apply to people of other backgrounds."

Company 1 provided conflicting predictions for the same DNA within the same test result report: Company 1 provided our donors with conflicting risk predictions for atrial fibrillation, celiac disease, and obesity. In reviewing the test results for just the factual profiles, we observed the following:

- Donor 1 received a "clinical report" predicting that she had an average risk for developing atrial fibrillation and a "research report" stating that she was at below-average risk for the disease.
- Donor 2 received a "clinical report" stating that she was at below-average risk of developing celiac disease and a "research report" claiming that she was at above-average risk.
- Donor 4 received one "research report" claiming that was at above-average risk for obesity and another "research report" stated that he was at average risk.

According to information in the test results, the company distinguishes between clinical and research reports by noting that predictions based on the clinical reports are for "conditions and traits for which there are genetic associations supported by multiple, large, peer-reviewed studies." In contrast, the research reports provide information "that has not yet gained enough scientific consensus to be included in our clinical reports." However, there is no additional information explaining how consumers should interpret the results. Because the company does not offer any follow-up consultations on test results, our fictitious donors could not request clarification. When we interviewed representatives from Company 1 about this issue after our testing, they simply reiterated the information contained in the results, describing research reports as being peer

reviewed and "almost clinical" but noting that clinical reports are "four star" in that they are widely accepted according to scientific standards.

Follow-up consultations provide only general information: As part of the test results, all four companies provide generally accepted health information related to the diseases that were tested, including a description of symptoms, treatments, and methods of prevention. This information is not targeted to specific consumers; all of our donors' results contained the same descriptions of treatments and methods of prevention, regardless of the risk predictions they received. For example, all the companies note that stopping smoking and increasing exercise are ways to reduce the risk for heart attacks. Representatives for Company 4 also encouraged consumers to make dietary changes such as adopting a Mediterranean diet or eating curry to prevent Alzheimer's disease, claims that cannot be proven, according to our experts. To supplement this information, Companies 2, 3, and 4 offer follow-up consultations.[9] Only Company 4 has U.S. board-certified genetic counselors on staff for this purpose, but all three companies claimed on their Web sites that their representatives would help consumers understand the implications of their disease risk predictions. However, for the most part, these representatives provided our donors with little guidance beyond the information contained in the test reports; at times, it seemed as though they were simply reading information directly from these reports. When our donors asked for more information on alarming results that indicated that they were at increased risk for serious diseases like colon cancer and Alzheimer's disease, representatives for Companies 2 and 3 pointed out symptoms to be aware of, but acknowledged that there is very little the donors could do to mitigate these risks. Representatives for Companies 2 and 4 also conceded that the donors' own doctors would probably not know what to do with the test results, a fact that our experts repeatedly noted. Examples include the following:

- Company 2 offers follow up consultations with "experts" to help consumers "interpret their results." In our post-test interviews, the company further noted that it provides the option of speaking with genetic counselors or a medical geneticist, but that consumers rarely exercise this option. Because the company is located outside the country, we were unable to determine whether all of its counselors are

[9]In our post-test interviews, Company 1 told us that it is in the process of entering into an agreement with a genetic counseling provider service to which the company will refer interested customers.

board certified in the United States; however, one counselor told us that he was not certified. During one of our undercover follow-up calls, Donor 4 asked what to do about his test results in general and what lifestyle changes he should make as a result. The representative told Donor 4 that he could not tell him what to do because he was not a physician and that the donor should take his results to a physician if he wanted advice on making any changes. When Donor 4 expressed concern that his doctor may not know what to do with the test results, the expert told him "True, not all physicians are familiar with these tests, so if you were to take it into a physician's office, they may not be familiar with it." Furthermore, when discussing Donor 3's increased risk for colon cancer, one of Company 2's experts told our donor that while he should become familiar with the symptoms such as blood in the stool, there was not much else he could do because "colon cancer is quite silent."

- Company 3 states that "because of the complexity and inherent uncertainties in genetic information, we recommend that you discuss the results of your genetic test with a genetic professional....Our on-staff Genetic Counselors are available any time to review your...results with you." In our post-test interviews, the company further claimed that its genetic counselors are certified by the American Board of Genetic Counseling and that the counselors review family history and provide consumers with additional information that is not in the test results. However, our donors spoke to the same person, who admitted that she was not a board-certified genetic counselor. She told us that she had completed her master's in genetic counseling and just had to take her test to become licensed. Donor 5 called Company 3 because he was extremely concerned about the company's prediction that he had genetic markers that are highly correlated with Alzheimer's disease. Instead of providing addition information, the counselor simply acknowledged that "there is no cure or prevention strategy with Alzheimer's."

- Company 4 notes that its "genetic counselors are healthcare professionals who are trained to help you understand what genetic information means for you and for your family." In our post-test interview, the company stressed that its counselors explain the results, discuss beneficial next steps, and ensure that consumers and their physicians understand the meaning and limitations of the tests. However, when Donor 2 asked what she could do about her test results, the counselor told her that she could take the results to a physician. When Donor 2 pressed the counselor about whether a

doctor would know what to do, the counselor responded "With this stuff? Probably not, no, I think they're learning just like everyone else."

"Personalized" Supplements, Bogus Endorsements, and Scientifically Invalid Claims among Deceptive Marketing Practices

Posing as consumers seeking information about genetic testing on the Internet and through phone calls and face-to-face meetings, we found that 10 of the 15 companies we investigated engaged in some form of fraudulent, deceptive, or otherwise questionable marketing practices. For example, at least four companies claimed that a consumer's DNA could be used to create personalized supplements to cure diseases. One company's representative fraudulently used endorsements from high-profile athletes to try to convince our undercover investigators to purchase its supplements. He also told our fictitious consumers that they could earn commission checks and receive free supplements if they could convince their friends to purchase the products. More detailed information on our experiences with this company follows table 2. Another flagrant example of deceptive marketing involved several companies' claims that they could predict which sports children would excel in based on DNA analysis. We also found examples of highly misleading representations about the reliability of the tests and the ability of health care practitioners to use the results to help treat patients. In addition, two companies are placing consumers' privacy at risk by condoning the potentially illegal practice of testing DNA without prior consent. Selected audio clips from our undercover calls and meetings are available at http://www.gao.gov/products/GAO-10-847T. Table 2 contains a selection of representations made by these companies. Note that companies 1 through 4 are the same companies we proactively tested, as discussed earlier in this testimony.

Table 2: Examples of Deceptive Marketing, Misinformation, and Questionable Practices

Source	Representation	Comments
Company 5	Representative claimed Michael Phelps used the companies' supplements. Representative also claimed that he would be meeting with Lance Armstrong because his doctors thought that test was "the most amazing thing they've ever seen."	Representatives for Michael Phelps and Lance Armstrong told us that they had never heard of this product and had no endorsements or dealings with the company.
Company 5	Company representative claimed that use of the company's supplements cured the arthritis in his knee and prevented him from getting high blood pressure and high cholesterol. He also suggested that our fictitious consumer could stop taking his cholesterol medication once he started taking the company's supplements.	"Absolute lies," said one expert about these claims. Experts also stated that the claims have no scientific basis and consumers could suffer serious health consequences if they follow this advice. Moreover, FDA and the National Institutes of Health have noted that no dietary supplement can treat, prevent, or cure any disease.

Source	Representation	Comments
Company 6	Genetic counselor claimed that tests and related products could help "repair damaged DNA."	Experts told us there is no scientific basis for this claim.
Companies 7 and 8	Companies claim to use a consumer's DNA and or genotype to create a "custom blend of nutrients" and "diet and exercise guidelines."	During a conversation with one of our fictitious consumers, a company representative admitted that supplements are just "high-quality vitamins and minerals" and that diet and exercise guidelines are merely based on a consumer's responses to a questionnaire. Experts told us that there is no scientific basis for suggesting that supplements, diet, or exercise can be customized to DNA.
Companies 9 and 10	Web sites claim to be able to predict athletic performance by analyzing DNA and also to be able to determine which sports children will excel in.	"In unqualified terms, [these claims] are complete garbage," according to one expert.
Companies 1, 2, 3, and 4	Web sites and company representatives told us that consumers should bring test results to their physicians to be used as a "tool" for treatment.	According to the Department of Health and Human Services' Secretary's Advisory Committee on Genetics, Health, and Society, "[practitioners] cannot keep up with the pace of genetic tests and are not adequately prepared to use test information to treat patients appropriately." Therefore, direct to consumer genetic tests may not provide any substantial utility to the consumer.
Companies 4 and 9	Although their Web sites state that tests are not intended to diagnose diseases, a representative for Company 4 claimed that its tests were "diagnostic" and a representative for Company 9 claimed that its tests were "prognostic" when asked about their reliability.	Experts described these statements as "horrifying" and "disconcerting," because they could mislead consumers into thinking that they have a disease or provide a false sense of assurance that they don't. In addition, experts told us that for the types of conditions being tested by these companies, multiple studies have confirmed that DNA testing adds little to an analysis of a person's weight, age, gender, and family history.
Company 4	"You'd be in the high risk of pretty much getting it," is how a representative responded when our fictitious consumer asked if results indicating she was at above average risk for breast cancer meant she's definitely getting the disease.	Experts also called this statement "disconcerting" and "horrifying" because it erroneously implies that the test can diagnose breast cancer and could needlessly alarm consumers.
Company 6	In response to general inquiries about genes and genetic testing, a representative stated that "genes are a symptom not a source of our biology."	An expert characterized this statement as "nonsensical."
Companies 3 and 4	Although company Web sites require consumers to explicitly consent to genetic testing before submitting a DNA sample, representatives from these companies told our fictitious consumer that she could secretly send in her fiancé's DNA and "surprise" him with the results.	One expert characterized the companies' willingness to conduct tests without prior consent as "dangerous" and "irresponsible." According to the Johns Hopkins Genetic and Public Policy Center, this "surreptitious" testing could lead to people "learning of health risks or family relationships that he or she would prefer remain unknown." Currently 33 states place some type of restrictions on surreptitious testing.[3]

Source: GAO.

[4]For purposes of our testimony, surreptitious testing refers to the collection, analysis, or disclosure of the results of DNA samples without the consent of the person tested. State laws restricting surreptitious testing vary. For example, some states prohibit surreptitious testing for health-related purposes while other states restrict such testing for other purposes, including the determination of parentage. In a few states, the laws restricting surreptitious testing only apply to insurance companies.

Company 5: On its Web site, Company 5 claimed that it would use a consumer's DNA to "create a personalized formula for nutritional supplements and skin repair serum with 100% active ingredients individually selected to enhance or diminish the biological processes causing you to age." To investigate these claims, we posed as a fictitious consumer interested in purchasing the product and met in person with a company representative.

During our initial meeting, the representative not only fraudulently suggested that Michael Phelps and representatives for Lance Armstrong endorsed the product, he also implied that the company's supplements could cure high cholesterol and arthritis, claims that one of our experts characterized as "absolute lies." Moreover, the FDA and the National Institutes of Health have clearly stated that no dietary supplement can treat, prevent, or cure any disease. As part of the company's promotional materials we found that the company's DNA assessment cost $225 and that the customized supplements cost about $145 per month. However, if our fictitious consumer immediately purchased a 3-month supply of supplements, she would be able to get the DNA test for free. The representative also told her that she could become a company affiliate and earn commission checks and free products by recruiting new affiliates. She, along with another fictitious consumer, subsequently registered as company affiliates, and ultimately received commission checks totaling more than $250. In addition to sending us the test kits, the company sent us packages of starter supplements in a bag that was not labeled with an ingredient list.

In an attempt to compare the test results from Company 5 with the results we received from Companies 1 through 4, we again used the same five donors and replicated the same methodology: submitting DNA samples using one factual profile and one fictitious profile. However, when we received the results, we found that Company 5 did not provide a set of risk predictions for specific diseases, making it impossible for us to compare the results against those we received from the other four companies. Instead, the company sent our donors a list of gene variants tested, a description of bodily functions affected by those variants, and a determination of whether the donors needed additional "nutritional support" to maintain health. In comparing the results, we found that each

donor appeared to have a unique assessment and that using the fictitious profile did not seem to affect the results. However, the results were so ambiguous and confusing that they did not provide meaningful information. For example:

- Donor 1 was told that she needed "maximum support" to maintain the "VDR gene" which accounts for "75% of the entire genetic influence on bone density" among healthy people. Maximum support means that the "protein molecule expressing a specific enzyme, hormone, cytokine or structural protein is functioning minimally" and maximum nutritional support is needed to keep the body functioning optimally.

- Donor 5 was told that he needed "added support" to maintain the "EPHX" gene, which "detoxifies" epoxides or "highly reactive foreign chemicals present in cigarette smoke, car exhaust, charcoal-grilled meat, smoke from wood burning, pesticides, and alcohol." "Added support" means that the gene is functioning less than optimally and therefore needs added nutritional support.

According to one of the experts we spoke with, these claims are simply "nonsensical" and "while it is true that one can find alleles[10] of many of these genes that don't have the same activity as 'normal,' we have no idea of (a) whether that reduced activity has any real health implications and (b) what one would reasonably do about it if so."

Along with the test results, the company sent supplements that it claimed were "blended" based on our donors' DNA assessments. The supplements arrived in the same type of unlabeled bag as the starter supplements. This time, the ingredients were printed inside the test result booklet sent to each donor and included substances such as raspberry juice powder, green tea extract, and garlic powder. The recommended daily dose is 10 supplements per day. Based on a review of all the ingredient lists, our five donors appeared to get supplements with different combinations of substances. However, we did not test the supplements to verify their contents. Moreover, an expert we spoke with told us that there is no scientific basis for claiming that supplements can be customized to DNA.

In post-test interviews, Company 5 told us that this company differs from others in that it does not attempt to diagnose or calculate a predisposition

[10]An allele is one member of a pair or series of genes that occupy a specific position on a specific chromosome.

to any disease. Instead, the company said that it focuses on the overall health and well-being of their clients by creating personalized nutritional supplements based on their client's specific DNA. When we asked about the ingredients in the supplements, the company told us that all supplements have a base formula of ingredients that their scientists have determined to be "beneficial for everyone." Additional nutrients are then added to the base formula based on deficiencies identified by the company's DNA test. When we asked about the endorsements, we were told that several celebrities and professional athletes use the company's products, but that many of these high-profile clients do not want to disclose this affiliation.

Corrective Action Briefings

We briefed FDA, the National Institutes of Health, and FTC on our findings on May 25, 2010; June 7, 2010; and June 17, 2010, respectively. In addition, we have referred all the companies we investigated to FDA and FTC for appropriate action.

Mr. Chairman, this concludes my statement. I would be pleased to answer any questions that you or other members of the committee may have at this time.

Contacts and Acknowledgments

For additional information about this testimony, please contact Gregory D. Kutz at (202) 512-6722 or kutzg@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. The following individuals made key contributions to this testimony: Jennifer Costello and Andrew O'Connell, Assistant Directors; Eric Eskew; Grant Fleming; Christine Hodakievic; Barbara Lewis; Vicki McClure; Ramon Rodriguez; Anthony Salvemini; Barry Shillito; Tim Walker; John Wilbur; and Emily Wold.

Appendix 1: Test Results by Donor

This appendix provides (1) a description of both the factual and fictitious profiles used by each donor and (2) tables documenting the risk predictions we received from all four companies for the 15 diseases we compared.

To the extent possible, we have used in the risk prediction language directly from the test results. However, Company 2 did not use terms like "average" or "below average" to describe risk. Instead the company used charts showing each consumer's risk level as compared to others with the consumer's gender and ethnicity or as compared to those of European ancestry. The results were color coded, with green to light green appearing to correspond to a below-average risk level, yellow corresponding to an average risk level, and orange and red corresponding to an above-average risk level. To facilitate comparison, we chose to use these corresponding terms to describe the results, as shown in the table. In addition, Company 1 used two different types of reports in its test results: clinical and research. According to the company, the clinical reports contain "information about conditions and traits for which there are genetic associations supported by multiple, large, peer-reviewed studies." Research reports contain "information from research that has not yet gained enough scientific consensus to be included in our clinical reports." Where applicable, we noted when a risk prediction was derived from a research report; all the other predictions were derived from the clinical reports.

Donor 1: Donor 1 is a 37-year old Caucasian female, who eats a balanced diet and exercises regularly. She has elevated cholesterol and arthritis in her back. In addition, she has a strong family history of colon cancer and a grandparent who was diagnosed with dementia. In Donor 1's fictitious profile, she is a 68-year old, African American female, who is overweight and rarely exercises. She has type 2 diabetes, hypertension, and asthma, but has no family history of colon cancer or dementia.

Table 3: Comparison of Test Results for Donor 1

		Risk predictions			
Disease or condition	**Profile**	**Company 1**	**Company 2**	**Company 3**	**Company 4**
Alzheimer's disease	Factual	Not tested	Above average	Increased susceptibility	Above average
	Fictitious	Not tested	Not tested	Increased susceptibility	Above average
Atrial fibrillation	Factual	Typical and decreased (research)	Average	Average predisposition	About average

Disease or condition	Profile	Risk predictions			
		Company 1	Company 2	Company 3	Company 4
	Fictitious	Typical and decreased (research)	Not tested	Not tested	About average
Breast cancer	Factual	Typical	Above average	Average predisposition	Greater than most women's
	Fictitious	Typical	Not tested	Average predisposition	Greater than most women's
Celiac disease	Factual	Decreased and typical (research)	Average	Not tested	Below average
	Fictitious	Decreased and typical (research)	Not tested	Not tested	Below average
Colon cancer	Factual	Elevated	Above average	Increased susceptibility	Above average
	Fictitious	Elevated	Not tested	Not tested	Above average
Heart attack	Factual	Decreased	Average	Average predisposition	Average
	Fictitious	Decreased	Not tested	Not tested	Average
Hypertension	Factual	Elevated (research)	Average	Average predisposition	Not tested
	Fictitious	Elevated (research)	Not tested	Not tested	Not tested
Leukemia	Factual	Elevated (research)	Below average	Average predisposition	Not tested
	Fictitious	Elevated (research)	Not tested	Not tested	Not tested
Multiple sclerosis	Factual	Decreased	Average	Average predisposition	Below average
	Fictitious	Decreased	Not tested	Not tested	Below average
Obesity	Factual	Typical and typical (research)	Below average	Average predisposition;	Below average
	Fictitious	Typical and typical (research)	Not tested	Not tested	Below average
Prostate cancer	Factual	Not applicable	Not applicable	Not applicable	Not applicable
	Fictitious	Not applicable	Not applicable	Not applicable	Not applicable
Restless leg syndrome	Factual	Decreased	Below average	Not tested	Below average
	Fictitious	Decreased	Not tested	Not tested	Below average
Rheumatoid arthritis	Factual	Decreased	Below average	Average predisposition	Below average
	Fictitious	Decreased	Not tested	Not tested	Below average
Type 1 diabetes	Factual	Elevated	Above average	Do not show strong susceptibility	Not tested
	Fictitious	Elevated	Not tested	Not tested	Not tested
Type 2 diabetes	Factual	Typical	Average	Average predisposition	Below average
	Fictitious	Typical	Below average	Average predisposition	Below average

Source: GAO analysis of results from four companies.

Donor 2: Donor 2 is a 41-year-old Caucasian female. She is in good health; however she has a family history of breast cancer, type 1 diabetes, and heart disease. In Donor 2's fictitious profile, she is a 19-year-old Asian female who smokes, drinks and uses recreational drugs. She suffers from heart arrhythmias and an elevated resting heart rate, but has no family history of breast cancer or diabetes.

Table 4: Comparison of Test Results for Donor 2

		Risk predictions			
Disease or condition	**Profile**	**Company 1**	**Company 2**	**Company 3**	**Company 4**
Alzheimer's disease	Factual	Not tested	Below average	Do not show strong susceptibility	Below average
	Fictitious	Not tested	Not tested	Do not show strong susceptibility	Below average
Atrial fibrillation	Factual	Elevated and typical (research)	Average	Increased susceptibility	Above average
	Fictitious	Elevated and typical (research)	Below average	Average predisposition	Above average
Breast cancer	Factual	Typical	Above average	Average predisposition	Average
	Fictitious	Typical	Average	Average predisposition	Average
Celiac disease	Factual	Elevated and decreased (research)	Below average	Not tested	Below average
	Fictitious	Decreased and elevated (research)	Not tested	Not tested	Below average
Colon cancer	Factual	Typical	Below average	Average predisposition	Below average
	Fictitious	Typical	Average	Increased susceptibility	Below average
Heart attack	Factual	Typical	Average	Average predisposition	Average
	Fictitious	Typical	Below average	Average predisposition	Average
Hypertension	Factual	Typical (research)	Average	Increased susceptibility	Not tested
	Fictitious	Typical (research)	Not tested	Increased susceptibility	Not tested
Leukemia	Factual	Elevated (research)	Average	Increased susceptibility	Not tested
	Fictitious	Elevated (research)	Not tested	Not tested	Not tested
Multiple sclerosis	Factual	Decreased	Average	Average predisposition	Below average
	Fictitious	Decreased	Not tested	Not tested	Below average
Obesity	Factual	Typical and typical (research)	Average	Average predisposition	About average
	Fictitious	Typical and typical (research)	Not tested	Increased susceptibility	About average
Prostate cancer	Factual	Not applicable	Not applicable	Not applicable	Not applicable
	Fictitious	Not applicable	Not applicable	Not applicable	Not applicable
Restless leg syndrome	Factual	Decreased	Above average	Not tested	About average
	Fictitious	Decreased	Not tested	Not tested	Abut average

Disease or condition	Profile	Risk predictions			
		Company 1	Company 2	Company 3	Company 4
Rheumatoid arthritis	Factual	Decreased	Below average	Do not show strong susceptibility	Below average
	Fictitious	Typical	Average	Average predisposition	Below average
Type 1 diabetes	Factual	Elevated	Above average	Do not show strong susceptibility	Not tested
	Fictitious	Elevated	Not tested	Increased susceptibility	Not tested
Type 2 diabetes	Factual	Typical	Average	Average predisposition	About average
	Fictitious	Typical	Above average	Average predisposition	About average

Source: GAO analysis of results from four companies.

Donor 3: Donor 3 is a 48-year-old Caucasian male who has never smoked and rarely drinks. The donor has asthma as well as a family history of heart disease. In Donor 3's fictitious profile, he is a 69-year-old African American male who is overweight, smokes, and is in somewhat poor health. He has a family history of bone and lung cancer, but no history of asthma or heart disease.

Table 5: Comparison of Test Results for Donor 3

		Risk predictions			
Disease or condition	**Profile**	**Company 1**	**Company 2**	**Company 3**	**Company 4**
Alzheimer's disease	Factual	Not tested	Average	Increased susceptibility	Above average risk
	Fictitious	Not tested	Not tested	Increased susceptibility	Above average
Atrial fibrillation	Factual	Typical and decreased (research)	Average	Average predisposition	About average
	Fictitious	Typical and decreased (research)	Not tested	Not tested	About average
Breast cancer	Factual	Not applicable	Not applicable	Not applicable	Not applicable
	Fictitious	Not applicable	Not applicable	Not applicable	Not applicable
Celiac disease	Factual	Decreased and typical (research)	Below average	Not tested	Below average
	Fictitious	Decreased and typical (research)	Not tested	Not tested	Below average
Colon cancer	Factual	Typical	Above average	Increased susceptibility	Above average
	Fictitious	Typical	Not tested	Not tested	Above average
Heart attack	Factual	Typical	Average	Average predisposition	Below average
	Fictitious	Typical	Not tested	Not tested	Below average
Hypertension	Factual	Typical (research)	Below average	Increased susceptibility	Not tested
	Fictitious	Typical (research)	Not tested	Not tested	Not tested
Leukemia	Factual	Elevated (research)	Average	Average predisposition	Not tested
	Fictitious	Elevated (research)	Not tested	Not tested	Not tested
Multiple sclerosis	Factual	Decreased	Average	Average predisposition	Below average
	Fictitious	Decreased	Not tested	Not tested	Below average
Obesity	Factual	Typical and typical (research)	Average	Average predisposition	About average
	Fictitious	Typical and typical (research)	Not tested	Not tested	About average
Prostate cancer	Factual	Typical	Average	Do not show strong susceptibility	Greater than most men's
	Fictitious	Typical	Below average	Average predisposition	Greater than most men's

		Risk predictions			
Disease or condition	**Profile**	**Company 1**	**Company 2**	**Company 3**	**Company 4**
Restless leg syndrome	Factual	Elevated	Average risk	Not tested	Higher than most people
	Fictitious	Elevated	Not tested	Not tested	Higher than most people
Rheumatoid arthritis	Factual	Elevated	Above average	Average predisposition	Above average
	Fictitious	Elevated	Not tested	Not tested	Above average
Type 1 diabetes	Factual	Elevated	Average	Do not show strong susceptibility	Not tested
	Fictitious	Elevated	Not tested	Not tested	Not tested
Type 2 diabetes	Factual	Typical	Average	Average predisposition	About average
	Fictitious	Typical	Below average	Average predisposition	About average

Source: GAO analysis of results from four companies.

Donor 4: Donor 4 is a 61-year-old Caucasian male who smokes. The donor has elevated cholesterol, has an elevated resting heart rate, and has had colon cancer. Thirteen years ago, the donor had a pacemaker implanted to treat atrial fibrillation. In Donor 4's fictitious profile, he is a 53-year-old Caucasian male who has never smoked. He has hypertension and prostate cancer but has no family history of colon cancer or atrial fibrillation.

Table 6: Comparison of Test Results for Donor 4

		Risk predictions			
Disease or condition	**Profile**	**Company 1**	**Company 2**	**Company 3**	**Company 4**
Alzheimer's disease	Factual	Not tested	Below average	Not tested	Below average
	Fictitious	Not tested	Below average	Average predisposition	Below average
Atrial fibrilation	Factual	Typical and decreased (research)	Below average	Average predisposition	About average
	Fictitious	Typical and decreased (research)	Below average	Average predisposition	About average
Breast cancer	Factual	Not applicable	Not applicable	Not applicable	Not applicable
	Fictitious	Not applicable	Not applicable	Not applicable	Not applicable
Celiac disease	Factual	Elevated and typical (research)	Average	Not tested	Higher risk than most people
	Fictitious	Elevated and typical (research)	Average	Not tested	Higher risk than most people
Colon cancer	Factual	Elevated	Average	Increased susceptibility	Above average
	Fictitious	Elevated	Average	Increased susceptibility	Above average
Heart attack	Factual	Typical	Average	Increased susceptibility	Average
	Fictitious	Typical	Average	Increased susceptibility	Average
Hypertension	Factual	Elevated (research)	Average	Average predisposition	Not tested
	Fictitious	Elevated (research)	Average	Average predisposition	Not tested
Leukemia	Factual	Elevated (research)	Average	Average predisposition	Not tested
	Fictitious	Elevated (research)	Average	Average predisposition	Not tested
Multiple sclerosis	Factual	Decreased	Average	Average predisposition	Below average
	Fictitious	Decreased	Average	Average predisposition	Below average
Obesity	Factual	Typical and elevated (research)	Average	Average predisposition	About average
	Fictitious	Elevated and typical (research)	Average	Average predisposition	About average
Prostate cancer	Factual	Typical	Above average	Average predisposition	Greater than most men's
	Fictitious	Typical	Above average	Average predisposition	Greater than most men's
Restless leg syndrome	Factual	Decreased	Below average	Not tested	Below average

Disease or condition	Profile	Risk predictions			
		Company 1	Company 2	Company 3	Company 4
	Fictitious	Decreased	Below average	Not tested	Below average
Rheumatoid arthritis	Factual	Decreased	Below average	Do not show strong susceptibility	Below average
	Fictitious	Decreased	Below average	Do not show strong susceptibility	Below average
Type 1 diabetes	Factual	Decreased	Average	Do not show strong susceptibility	Not tested
	Fictitious	Decreased	Average	Do not show strong susceptibility	Not tested
Type 2 diabetes	Factual	Typical	Average	Average predisposition	About average
	Fictitious	Typical	Average	Average predisposition	About average

Source: GAO analysis of results from four companies.

Donor 5: Donor 5 is a 63-year-old Caucasian male who eats a balanced diet and exercises. He has elevated cholesterol and blood sugar. The donor suffers from type 2diabetes and is obese. He also has a family history of Alzheimer's disease. In Donor 5's fictitious profile, he is a 29-year-old Hispanic male who chews tobacco and suffers from asthma. However, he has no family history of diabetes or Alzheimer's disease.

Table 7: Comparison of Test Results for Donor 5

		Risk predictions			
Disease or condition	**Profile**	**Company 1**	**Company 2**	**Company 3**	**Company 4**
Alzheimer's disease	Factual	Not tested	Above average	Genetic markers are highly correlated with this disease	Above average
	Fictitious	Not tested	Above average	Genetic markers are highly correlated with this disease	Above average
Atrial fibrillation	Factual	Typical and decreased (research)	Below average	Average predisposition	About average
	Fictitious	Typical and decreased (research)	Average	Average predisposition	About average
Breast cancer	Factual	Not applicable	Not applicable	Not applicable	Not applicable
	Fictitious	Not applicable	Not applicable	Not applicable	Not applicable
Celiac disease	Factual	Elevated and decreased (research)	Above average	Not tested	Higher risk than most people
	Fictitious	Elevated and decreased (research)	Above average	Noted tested	Higher risk than most people
Colon cancer	Factual	Decreased	Average	Average predisposition	Average
	Fictitious	Decreased	Average	Average predisposition	Average
Heart attack	Factual	Typical	Above average	Increased susceptibility	Average
	Fictitious	Typical	Above average	Increased susceptibility	Average
Hypertension	Factual	Elevated (research)	Average	Average predisposition	Not tested
	Fictitious	Elevated (research)	Average	Average predisposition	Not tested
Leukemia	Factual	Elevated (research)	Average	Average predisposition	Not tested
	Fictitious	Elevated (research)	Average	Average predisposition	Not tested
Multiple sclerosis	Factual	Decreased	Average	Average predisposition	Below average
	Fictitious	Decreased	Average	Average predisposition	Below average
Obesity	Factual	Typical and typical (research)	Average	Average predisposition	About average
	Fictitious	Typical and typical (research)	Average	Average predisposition	About average

Disease or condition	Profile	Risk predictions			
		Company 1	Company 2	Company 3	Company 4
Prostate cancer	Factual	Typical	Average	Average predisposition	Average
	Fictitious	Typical	Average	Average predisposition	Average
Restless leg syndrome	Factual	Decreased	Above average	Not tested	Higher than most people
	Fictitious	Decreased	Above average	Not tested	Higher than most people
Rheumatoid arthritis	Factual	Decreased	Below average	Do not show strong susceptibility	Below average
	Fictitious	Typical	Below average	Do not show strong susceptibility	Below average
Type 1 diabetes	Factual	Elevated	Average	Average predisposition	Not tested
	Fictitious	Elevated	Average	Average predisposition	Not tested
Type 2 diabetes	Factual	Typical	Average	Average predisposition	Above average
	Fictitious	Elevated	Average	Average predisposition	Above average

Source: GAO analysis of results from four companies.

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Mr. STUPAK. Thanks, Mr. Kutz.

Dr. Shuren, your testimony, please.

TESTIMONY OF JEFFREY SHUREN, M.D.

Dr. SHUREN. Good morning. And I'm pleased to explain FDA's recent activities related to direct-to-consumer genetic tests, also called DTC or direct access genetic tests.

Scientific advances resulting from the Human Genome Project have created opportunities to better identify people at risk for particular medical conditions and to target medical treatments based on the chances that the patient will respond to a treatment or experience an adverse event based on their genetic profile. FDA supports the promise and development of innovative genetic tests.

However, the field of personalized medicine will not make good on that promise if the in-vitro diagnostic tests doctors and patients rely on are inaccurate, with only a tenuous link between what the test measures and its clinical significance. Failure to validate the accuracy, reliability, and clinical implications of the test can result in patient harm from misdiagnosis, failure to treat, delay or inappropriate treatment, or avoidable adverse events. Those risks can be increased when the test is marketed directly to consumers without medical advice or genetic counseling.

A genetic test is subject to FDA oversight only if it is a medical device—that is, if it is intended in the use of diagnosis, cure, treatment, mitigation, or prevention of disease. A test to determine a person's risk of developing heart disease is a device, but a test to determine ancestry or curly hair is not a device.

At the time of the 2006 GAO investigation, most of these diagnostics were nutritional genetic tests that assess what kinds of foods consumers should eat and dietary supplements they should take. FDA followed up with those companies, and FDA, CDC, and FTC published a cautionary statement on DTC genetic tests.

In 2007, FDA began meeting with some of the companies that are the subject of the GAO's new investigation. FDA's Center for Devices did not inform these companies that they could lawfully market their tests without FDA oversight. Instead, the Center met with them to gain a better understanding of what they were doing or planning to do. At that time, these tests were being marketed for such purposes as antiquity determinations.

Since then, though, we have seen changes in the number and types of claims being made. One company provided test reports for 17 conditions in 2008 but provides over 100 types of results now. Some companies now are making claims about high-risk medical indications like cancer, about the likelihood of responding to a specific drug. In many cases, the link between the genetic results and the risk of developing a disease or drug response has not been well-established. Even the experts don't know what the results mean.

Marketing DTC can increase the risk of the test because a patient may make a decision without a medical professional that adversely affects their health based on a false result, such as stopping or changing the dose of a medication.

More aggressive DTC marketing efforts became evident recently when Pathway Genomics was poised to offer their home-use saliva-collection kit directly to consumers through more than 6,000

Walgreen stores. 23andMe is marketing to consumers on Amazon.com.

The escalation and risk in aggressive marketing caused FDA to notify Pathway Genomics on May 10 of this year that their offering appeared to meet the definition of a medical device. On June 10, FDA sent similar letters to four other diagnostic test firms offering their tests directly to consumers. FDA considers all of these products to be a medical device on the basis of the manufacturers' claims about the test results.

In addition, a letter was sent to Illumina, Incorporated, for supplying an unapproved genetic test to several of these DTC companies.

All six companies have been invited to discuss further the regulatory status of their products with FDA. FDA is meeting with these companies now and may take additional actions, depending on the outcome of those meetings. Earlier this week, we sent similar letters to 14 other firms marketing DTC genetic tests.

FDA supports consumers having information about their genetic profile. We just believe consumers should have results that are accurate, supported by sound science, and understandable. We are not being paternalistic; we are being patient advocates.

I commend the subcommittee's efforts to further the dialogue about the safety and effectiveness of genetic tests being marketed today.

Mr. Chairman, that concludes my formal remarks.

[The prepared statement of Dr. Shuren follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

STATEMENT OF

JEFFREY SHUREN, M.D.

DIRECTOR

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

July 22, 2010

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, I am Dr. Jeff Shuren, Director of the Center for Devices and Radiological Health (CDRH or the Center) at the Food and Drug Administration (FDA or the Agency). I am pleased to be here this morning to explain FDA's recent activities related to direct-to-consumer (DTC) genetic tests and our future plans for the regulation of laboratory-developed tests.

Scientific advances resulting from the Human Genome Project completed in 2003 have expanded our understanding of the genetic contribution to health and disease. These advances have also resulted in the development of new tests that can better identify individuals at risk for particular medical conditions and target medical treatments based on the likelihood that a patient will respond or experience an adverse event based on their individual genetic profile. FDA supports the promise and development of innovative genetic tests.

As Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, and Francis S. Collins, M.D., Ph.D., Director of the National Institutes of Health, note in their jointly authored article entitled "The Path to Personalized Medicine," published in the June 15, 2010, *New England Journal of Medicine*, "Major investments in basic science have created an opportunity for significant progress in clinical medicine. Researchers have discovered hundreds of genes that harbor variations contributing to human illness, identified genetic variability in patients' responses to dozens of treatments, and begun to target the molecular causes of some diseases. In addition, scientists are developing and using diagnostic tests based on genetics or other

molecular mechanisms to better predict patients' responses to targeted therapy.... Together, we have been focusing on the best ways to develop new therapies and optimize prescribing by steering patients to the right drug at the right dose at the right time."

However, Dr. Hamburg and Dr. Collins also note that the field of personalized medicine will not make good on that promise if the *in vitro* diagnostic tests on which practitioners and patients rely to inform treatment decisions are inaccurate or the link between what the test measures and its clinical significance is tenuous. Failure to validate the accuracy, reliability, and clinical implications of a test can result in patient harm from misdiagnosis, failure to treat, delay in treatment, inappropriate treatment, or avoidable adverse events.

OVERVIEW OF FEDERAL REGULATION

Congress gave FDA explicit authority to regulate medical devices, including *in vitro* diagnostic tests, in the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act). *In vitro* diagnostic devices (IVDs) are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or conditions arising from a disease. Genetic tests are a type of IVD.

Under the Act, FDA assigns medical devices to one of three "classes" based upon their attendant risks. The level of regulation applied to IVD devices is based primarily upon risk to the patient of an undetected incorrect test result.

- Class I, subject only to general controls applicable to all devices, is the lowest risk category for a device. Class I IVDs include certain reagents and instruments, as well as a number of highly adjunctive IVD tests, where one test is dependent on the results of another; consequently an incorrect result would generally be detected easily. Most Class I devices are exempt from premarket review. An example of a Class I test is a luteinizing hormone test that, if it gives a false result, may lead to delayed conception but is unlikely to directly harm the patient.
- Class II, generally subject to general controls and special controls, is the moderate-risk category for a device, and includes many standard laboratory tests, such as chemistry and immunology tests. Most Class II tests are subject to FDA review through premarket notification under section 510(k) of the Act. For example, a false sodium result (a Class II test) may be life-threatening if the error is unrecognized and treatment decisions to correct the sodium level are made based on the false result.
- Class III, subject to premarket approval requirements, is the highest risk category for a device and includes devices and tests that present a potentially unreasonable risk of illness or injury. For example, a false negative result for a hepatitis C virus test (a Class III test) may result in failure to provide appropriate treatment, leading to risk of liver failure due to delayed treatment. In addition, without the knowledge that he or she is infected, the patient may put others at risk by spreading the disease.

Many IVD tests are Class II or Class III devices, and some also may be biological products subject to section 351 of the Public Health Service Act. In addition to premarket controls, the FD&C Act provides FDA with authority to perform post-market review, and monitor adverse events or even mandate a recall if, based on adverse event reports or other data, there is a

reasonable probability that a test could cause serious adverse health consequences or death in clinical use.

Federal oversight of IVDs includes oversight of laboratories that perform these tests by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and the Federal Trade Commission (FTC) under the Federal Trade Commission Act (FTCA). Under CLIA, CMS regulates laboratory testing activities performed on humans in the United States for health purposes, covering more than 200,000 laboratory entities. FDA's role under CLIA is to categorize commercially marketed IVDs in terms of their complexity. This complexity categorization determines the stringency of requirements to which the laboratories performing the tests are subject and the attendant personnel education, training, and skill level required.

CLIA and FDA regulations complement one another. CLIA regulations focus on the quality of the clinical testing process, such as laboratory quality control; i.e., daily check that the test is working, external accuracy checks, credentials of laboratory personnel, and documentation of laboratory procedures. FDA regulations address the safety and effectiveness of the diagnostic tests themselves and the quality of the design and manufacture of the diagnostic tests.

Section 5 of the FTCA prohibits unfair or deceptive acts or practices in or affecting commerce. Section 12 of the FTCA specifically prohibits the dissemination of false advertisements for foods, drugs, devices, services, or cosmetics. The FTC analyzes the role of advertising in bringing health-related information to consumers and can bring law enforcement actions against false or deceptive advertising.

OVERVIEW OF FDA REGULATION OF GENETIC TESTS

The purpose of genetic tests includes predicting risk of disease, screening newborns, directing clinical management, identifying carriers, and establishing prenatal or clinical diagnoses or prognoses in individuals, families, or populations. To date, 353 U.S. laboratories have listed themselves on a voluntary website that provides information about laboratories offering genetic tests, but estimates are that there may be as many as 700 laboratories offering such tests.

A genetic test is only subject to FDA oversight if it is a medical device; that is, if it is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. For example, a test to determine a person's risk of developing heart disease is a device, whereas a test to determine ancestry is not a device. The type of genetic testing has changed over the past two decades. Whereas early tests tended to identify a single genetic mutation and a patient's risk for developing a disease, some newer tests evaluate thousands of genes or the entire genome and report out risk for a disease based on the combination of dozens of genetic variations.

There currently are two paths to market for a genetic test used in clinical management of patients, as is the case for other IVDs. One is through development of a commercial test kit by an IVD device manufacturer for distribution to multiple laboratories. The Agency has exercised its regulatory authority over these products and has approved several tests for specific genetic factors.

The second pathway is through the development of a test by a laboratory for use only by that laboratory; these are commonly called laboratory-developed tests (LDTs). Conservative estimates are that there are between 2,500 – 5,000 LDTs, including genetic tests that are developed and offered by hundreds of different laboratories.

FDA has the authority to regulate LDTs as it does all IVDs. The extent of FDA oversight of an IVD, such as a genetic test that meets the definition of a device, is based on the risk of an inaccurate result from the test, not who makes the tests or their business models. However, although FDA has the authority to regulate LDTs, FDA has generally exercised enforcement discretion since the device law was passed in 1976. At that time tests made by laboratories were generally low-risk diagnostic tools or relatively simple, well-understood tests that diagnosed rare diseases and conditions, and which were more dependent on expert interpretation. Therefore, the accuracy of the results was more dependent on the expertise of the pathologist/laboratorian than on the design of the test. Furthermore, these LDTs were used by pathologists/laboratorians and the results reported to physicians within a single institution where both professionals were actively involved in the care of the patient being tested. Most genetic tests being offered today are LDTs.

The nature of laboratory-developed tests has changed over the last 30 years, but most dramatically in the last few years. Today, LDTs are increasingly used to assess high-risk but relatively common diseases and conditions, often are used to provide critical information for patient treatment decisions, rely on novel (sometimes preliminary) scientific findings to support their usefulness, often require complex software and may incorporate automated interpretation in

lieu of expert interpretation, often are used when there are alternative tests available that have been cleared or approved by FDA, and are performed in commercial laboratory settings that are geographically separate from the patient's primary health care professional and health care setting. In addition, some entities marketed their tests without prior FDA review, claiming that they are LDTs, when they are not. Furthermore, the ability of laboratories to market tests without any regulatory oversight creates a disincentive for traditional manufacturers to develop new tests, thereby stifling innovation.

FDA has observed the following problems with some LDTs in recent years:

- Faulty data analysis
- Exaggerated clinical claims
- Fraudulent data
- Lack of traceability/change control
- Poor clinical study design
- Unacceptable clinical performance

FDA believes that a test used for patient care should have the same assurances of safety and effectiveness whether it is manufactured for distribution to multiple laboratories or created for use in only one laboratory. Premarket review of moderate and high risk LDTs would ensure that the tests are evaluated for analytical validity and clinical validity, based on their claimed intended use, and would provide an independent and unbiased assessment of the data used to support analytical and clinical claims for those LDTs. This is important because when tests are not well validated, the possibility of incorrect results, which can lead to misdiagnosis or

inappropriate treatment decisions, increases. Premarket review would also ensure that labeling includes the test claims, the data that support those claims, how the test may be interpreted, and the limitations of the test. FDA's post-market surveillance and enforcement tools ensure that tests remain safe and effective once on the market.

In 2001, the Secretary's Advisory Committee on Genetic Testing recommended that "the Food and Drug Administration should be involved in the review of all new genetic tests regardless of how they are formulated and provided." In 2008, the Secretary's Advisory Committee on Genetics, Health, and Society recommended that FDA address all genetic testing using a risk-based approach.

Historically, FDA's oversight of genetic testing has been focused intensively on commercial test kits. The Agency is now engaging in a public dialogue on how it should develop a consistent, reasonable, and fair approach to all genetic tests, whether packaged as kits or provided as LDTs, to ensure safety and promote innovation.

GENETIC TESTS BEING SOLD DIRECTLY TO CONSUMERS

An emerging market segment for the laboratory testing industry is direct-to-consumer testing. A few companies have sought to popularize genetic testing through advertisements and social media. FDA has been aware of these companies marketing to consumers for several years. At the time of the 2006 Government Accountability Office (GAO) investigation of DTC testing, most of these diagnostics were "nutritional genetic" tests—tests to assess what kinds of foods individual consumers should eat and dietary supplements they should take. FDA followed up

with the companies and FDA, CDC, and FTC published a cautionary statement on DTC genetic tests.

New DTC genetic tests subsequently came on the market. FDA met with some of these companies starting in 2007. FDA's Center for Devices and Radiological Health, which is responsible for the oversight of these tests, never informed these companies that they could lawfully market their tests without FDA oversight. Instead, the Center met with these companies to have a better understanding of what the companies were in fact doing or planning to do. Initially their business models were not clear and the tests were being marketed for such purposes as "antiquity determinations." However, since then we have seen changes in the number and types of claims being made. For example, one company provided test reports for 17 diseases, conditions, or traits in 2008 but provided over 100 types of results by 2010. In particular, some companies are making claims about high-risk medical indications, such as determining the risk for cancer or the likelihood of responding to a specific drug. Moreover, in many cases the link between the genetic results and the risk of developing a disease or responding/not responding to a drug has not been well-established.

Marketing genetic tests directly to consumers can increase the risk of a test because a patient may make a decision that adversely affects their health, such as stopping or changing the dose of a medication or continuing an unhealthy lifestyle, without the intervention of a learned intermediary. The risk points up the importance of ensuring that consumers are also provided accurate, complete, and understandable information about the limitations of test results they are obtaining.

- Physical and near-real-time analysis of the member's identity through private, public and government data sources, in concert with the eligibility card. Similar process to current credit/debit card authentication and verification.
- Requiring eligibility transactions to be performed for each member visit in combination with the member identification verification. (H.R. 3590 will cover the electronic eligibility transaction and receipt requirements.) Validation of these steps could be required as part of the claim submission process.

Complexity in the United States healthcare system fosters a breeding ground for criminal activity and an environment where the member is neither well informed, nor engaged in verification and validation of services rendered. The following enhancements would aid in the member's transformation into a true healthcare consumer, empowering them to take control and responsibility of their healthcare:

- Post visit, provide the patient/member with a "bill of services". This 'receipt' would detail in easily understandable terms the services rendered, the estimated provider billed charges, likely Medicare reimbursement and potential member liability.
- Post visit, but before claim adjudication, require the member to authorize and approve that the claim submission is factually consistent with the services rendered and the billed amount(s) are directionally equivalent to the "bill of services".
- Offer online data to the member in the form of a Personal Health Record that reflects services rendered, associated charges and discounts, and organized in a meaningful way that enables better understanding of the purpose and results from healthcare services.
- Provide for the creation of a Medicare call center, staffed with nurse and billing advocates, to assist members with any questions regarding the claim authorization and approval requirements. Enact a penalty and loss of benefits for members knowingly authorizing and approving invalid claims.

The two main areas of detection described above, in addition to the measures described within H.R. 5546, need to be interconnected and provide for regular feedback loops to create an optimal Prevention System solution whereby the member/patient/consumer is actively engaged. A combination of initiatives is the best way to provide complete detection assurance or reduce the approximately $60Bn of Medicare fraud, waste and abuse. Engaging the consumer in the process has the added value of eventually bending the cost curve as well.

Sincerely,

John Reynolds
President, FIS Government, Education & Healthcare

claimed to describe the genetic basis of specific disease traits or conditions on which consumers may base medical decisions; provide personalized information on which medications are more likely to work given a person's genetic makeup; and provide genetic predispositions for important health conditions and medication sensitivities. In addition, a letter was issued to Illumina, Inc. for supplying unapproved reagents and instrumentation (marked "for research use only" and thus not approved or cleared by FDA) to several DTC manufacturers who use the reagents as critical components in their products being offered directly to consumers for clinical, not research, use. These manufacturers generally havenot submitted information on the analytical or clinical validity of their tests to FDA for clearance or approval. All six companies have been invited to discuss the regulatory status of their products further with the Agency. Meetings with the companies are taking place now or have been or are being scheduled. FDA may take additional actions, depending on the outcome of those meetings.

On July 19, 2010, FDA sent similar letters to 15 other firms marketing DTC genetic tests.

PUBLIC MEETING ON LABORATORY-DEVELOPED TESTS

On July 19 and 20, FDA held a public meeting for the purpose of obtaining input from stakeholders on how the Agency should apply its authority to implement a reasonable, risk-based, and effective regulatory framework for LDTs, including genetic tests, in particular, taking into account circumstances unique to LDTs and to avoid any duplication with CLIA. We provided an overview of the history and current regulatory status of LDTs. The meeting discussions focused on:

Statement of Dino Martis, President, On-e Healthcare

Chairman Pallone and Ranking Member Shimkus, I am pleased to provide my thoughts on combating fraud, waste and abuse in the Medicare and Medicaid programs and throughout our health system. Too many resources are wasted to criminals who game our inadequate program integrity systems. Equally important, and a point that is missed too often in the fraud and abuse debate, is that we spend a great deal of resources on law enforcement and chasing crooks rather than leveraging technology to prevent fraud before it bears fruit. This point cannot be overstated: our fraud and abuse laws do not reflect the advances in technology that will protect taxpayer assets and consumer resources.

Despite the recent, well intentioned and useful changes in Federal laws to provide more tools and to create disincentives to defraud Federal health programs, including modernizations included in the Patient Protection and Affordable Care Act, Congress needs to deploy all tools at its disposal to protect program integrity. One step would be to prevent fraud through use of technologies that identify patient and provider, label durable medical equipment for tracking purposes and make use of electronic health records to track services and claims by provider and patient.

Fraud and Abuse is Pervasive

As a society, we are experts when it comes to keeping our possessions safe. We have home security systems, car alarms, surveillance cameras in our businesses, PIN numbers, passwords, and dozens of other methods. Why is it then that our large investment in healthcare does not receive the same level of security?

The U.S. spends more than $2.5 trillion on healthcare annually. According to the National Health Care Anti-Fraud Association, at least 3 percent of that spending — or $68 billion — is lost to fraud each year. The FBI estimates at least 10 percent – or $226 billion --- is annually lost to health care fraud. These numbers are staggering. Think of the benefit to people that might be provided if those dollars were captured.

Medicare and Medicaid made an estimated $23.0 billion in provider overpayments in 2009. While not necessarily fraudulent, they highlight program vulnerabilities that need to be addressed. One example of this problem is the Medicare program paid 16,548 to 18,240 deceased physicians 478,500 claims totaling more than $92 million from 2000 to 2007 according to the U.S. Senate Permanent Committee on Investigations.

Unfortunately, the US trails behind most of the world in leveraging technology to keep up with the latest health crime schemes. To combat healthcare fraud, countries across the world invest in IT to save money. According to the Council on Foreign Relations, the U.S. government invests $0.43 annually per capita on IT whereas the Canadian government, by contrast, spends $31 per capita. Other industries, particularly in financial services, have adopted predictive modeling and sophisticated data analytics and program rules to detect new fraud schemes,

Mr. STUPAK. Thank you, Doctor.

We will start with questions. I will begin.

Mr. Kutz, cotton swabs—so how do I go about—if I go online, what do I do? Do I have to get a kit? And what does that cost me? How do I go about doing it?

Mr. KUTZ. Well, the first step is you need a credit card to pay for it.

Mr. STUPAK. OK. Well, that is always number one.

Mr. KUTZ. That is usually the first step. And then when you get the actual kit——

Mr. STUPAK. And what does that cost, that actual kit?

Mr. KUTZ. The four we bought were anywhere from about $300 to a $1,000 each.

Mr. STUPAK. And that was for the kit.

Mr. KUTZ. For the kit. And there were no other products. These four companies were not marketing supplements with theirs. So that was something very different than what we have seen before.

Mr. STUPAK. OK.

Mr. KUTZ. So once you get that, you fill out a certain profile information, mostly age and ethnicity. And three of the four actually had you spit saliva into a little container and then seal that container and put it in the mail. The other one used, like, what was a Q-tip to do cheek swabs to get the DNA samples, and then you put that into a plastic container and send that in.

Mr. STUPAK. OK. And that is costing me anywhere between $300 and $1,200 for this test.

Mr. KUTZ. There is others that are more expensive and less expensive. There is a lot more on the market. But with these, it was $300 to a $1,000.

Mr. STUPAK. OK. What do you estimate Americans spend each year on this genetic testing? How large is this industry, would you say?

Mr. KUTZ. We don't know. The only source we have seen, I think, is the National Academy of Sciences' report. It was approaching a billion dollars and growing at 20 or 30 percent a year. But I don't think anybody would ever know with the Internet being one of the primary ways that this is marketed.

Mr. STUPAK. And so, if it is estimated at a billion dollars a year and it is growing at 20 to 30 percent per year—but yet, on your reports that you showed, one of the first charts you showed, 68 percent of these findings were wrong, correct?

Mr. KUTZ. Well, they differed. For example, you know, when I mentioned in my opening statement, for prostate cancer, I had different companies tell me I was at below-average, average, and above-average risk. So, 68 percent of our 40 tests, we got different results for the same disease.

Mr. STUPAK. OK. And how did you get the bag of supplements there, that black bag there?

Mr. KUTZ. That was a fifth company we tested. And, actually, they were very, very different. They would be more of what we would describe as the bottom feeders in this industry, the ones who are really more of a consumer scam. They are telling you, based on your DNA, that they have customized these supplements to me.

And I've got my fake person's name, and I am not going to tell you what it is because we will use it again someday probably. But, yes, they are saying if I take these supplements, that it is going to reduce the probability I am going to get these diseases they say my genetic tests show I'm predisposed to have.

Mr. STUPAK. So if it says you are predisposed to high blood pressure, they would send you these supplements. And what do the supplements cost, that little black bag of supplements?

Mr. KUTZ. $140 a month.

Mr. STUPAK. All right. And how long are you supposed to take those supplements, then?

Mr. KUTZ. Forever, I assume. I don't think it said you stop at any point. So when you give them your credit card, it is $140 a month and they send you a new bag. I think you take 20 of these a day, is what we were told.

Mr. STUPAK. Do you know what they are, what the pills in that bag——

Mr. KUTZ. There's not ingredients. It says it's got a number of different plant and herbal and a bunch of things in it. But I don't know—I think we've got maybe the detailed components. We could provide them for the record, if you're interested in that.

Mr. STUPAK. OK. So you really don't know what you are taking.

Mr. KUTZ. No, we don't really know what we are taking.

Mr. STUPAK. And it is $140 a month.

Mr. KUTZ. Correct.

Mr. STUPAK. OK.

Dr. Shuren, in 2009, you testified that the FDA sent letters to a variety of companies regarding the direct-to-consumer genetic testing and medical devices. And then again this year, you did the same thing, you sent additional letters to companies, informing them they had to go through the medical device premarket approval process.

So the FDA regards these direct-to-consumer genetic tests, then, as medical devices?

Dr. SHUREN. Yes, we view these tests by these companies as medical devices.

Mr. STUPAK. Would the company then selling me back this black bag of supplements every month for $140, would they have to get FDA permission to do that?

Dr. SHUREN. If they are making a claim that——

Mr. STUPAK. That it would lower my high blood pressure.

Dr. SHUREN [continuing]. If it is going to lower cholesterol, then they are making a drug claim, and the answer is, yes, they are selling an unapproved drug.

Mr. STUPAK. So if I do my genetic test and it shows that I'm predisposed to high blood pressure, let's say, and I sign up for this supplement, bag of supplements, as Mr. Kutz has there, then they would have to be registered with the FDA to send me that, because they are sending me medication, if you will, to lower my blood pressure. Is that correct?

Dr. SHUREN. If they are sending medication to treat high blood pressure, they're going to need to get that product approved by the FDA.

Mr. STUPAK. OK. So the product has to be approved. They would have to have a license, would they not? Would the DEA, the Drug Enforcement Administration, yourself, be licensed to do this?

Dr. SHUREN. They would have to—if they are now making a drug and selling it, then they are going to have to register with us. And there is a whole bunch of other requirements. They have to meet good manufacturing practices, reporting requirements. And it sounds like this company hasn't done any of that.

Mr. STUPAK. Mr. Kutz or Dr. Shuren, has any State certified these genetic testing kits to be sold in their States? Do you need a State certification to sell these?

Mr. KUTZ. I think some States, as we understand it—I don't have the details—but do regulate or limit the ability to sell these directly to consumers. I don't know which ones, but we did see some of that in our research.

Mr. STUPAK. But all you do is go on the Internet, right?

Mr. KUTZ. Yes. And no one is going to know.

Mr. STUPAK. OK.

Dr. SHUREN. And the State of New York, for example, prohibits direct-to-consumer marketing. They also, in order to use a test on a sample from New York, they will have to approve that test before you can use it in that State.

Mr. STUPAK. OK.

My time has expired. Maybe we will go another round of questions. Very interesting. Thank you both.

Mr. Burgess for questions?

Mr. BURGESS. Thank you, Chairman.

Dr. Shuren, FDA sent a letter to Pathway Genomics, June 11, 2009, stating that its health kit, a home DNA test, was a device that did not have FDA approval or clearance. And it appears that FDA has been corresponding with them for over a year. But has any action occurred as a consequence of this?

Dr. SHUREN. No action has occurred until recently, when we did send the other letter to say, "We think it is a device. Come in and talk. Otherwise, we are serious about taking action."

If there is any issue here with the FDA, quite frankly—and I will say this—it is, why didn't we act sooner?

Mr. BURGESS. That was going to be my next question.

Dr. SHUREN. And we should have acted sooner.

Mr. BURGESS. So do you have any idea how many of these tests have been sold in the year's time, now 13 months' time it has taken to get to this point?

Dr. SHUREN. So we should have acted before this time, now. And I think the recent actions just, if you will, lit a stronger fire under the agency, when we saw Pathway Genomics now entering into an agreement with Walgreens to sell their collection kit through those pharmacy stores.

Mr. BURGESS. So Walgreens was the catalyst?

Dr. SHUREN. A combination of things. We started to see these companies market for higher-risk claims, marketing more claims. And we thought, at this point, it is time to take action.

We also were trying to sift through if these companies were making tests that might fall under our enforcement discretion policy for

laboratory-developed tests. And we do not believe that these companies are making laboratory-developed tests.

Mr. BURGESS. How many of these companies with whom have you been communicating? We have the letters from Pathway. Are all the ones on Mr. Kutz's list ones with which you have communicated in the past year?

Dr. SHUREN. No. Seven of the companies we have been communicating with either in the past year, or just recently we sent letters to. Three we have not. We will follow up on the information that was given us to GAO. We have also shared this information with the Federal Trade Commission as well.

Mr. BURGESS. You know, look over the horizon for just a minute. What do you see as the next steps as far as the regulatory process? What is going to happen as a consequence of the chairman calling this hearing today?

Dr. SHUREN. Sir, what we will be doing with these companies, we are giving them an opportunity to come in and tell us what is it you want to do? If these companies are going to go out and market tests that are not for device claims, they are not making medical claims, that is one thing. If they are going to go out and make medical claims, then we are going to talk about what you need to do in order to sell that test lawfully on the market.

Mr. BURGESS. I would just ask the question again: Do you have any idea how many of these kits were sold in the year between the letter that was sent to Pathway in June of 2009 and the present time?

Dr. SHUREN. No, we do not.

Mr. BURGESS. And presumably it is not just Pathway, of course; it is the other companies as well. So whatever it is, probably you can conservatively multiply it by three or four to get to the total number.

Dr. SHUREN. That is correct. I believe 23andMe, and they may able to answer this, put some information out they had about 50,000 customers for their tests. I believe that is the number we heard.

Mr. BURGESS. But that is total. That is not just in the last year.

Dr. SHUREN. That is correct.

Mr. BURGESS. Mr. Kutz, do you have any idea over the year that we have kind of been aware that there might of sort of be a problem here, and now getting really serious about it, do we have any idea of how many kits have been sold and how many dollars have been spent on this?

Mr. KUTZ. No. This was primarily an undercover investigation, so we didn't do a lot of market research, and I don't know how anyone could tell for sure, but the companies can represent that hopefully in the next panel.

Mr. BURGESS. Maybe we will go there with the next panel.

Dr. Shuren, have any of the companies ever been denied marketing devices requiring approval?

Dr. SHUREN. They haven't come to us to have their devices approved.

Mr. BURGESS. So it has not even been on the radar screen?

Dr. SHUREN. They haven't. In years past when the tests were first being developed, with some of the companies we actually sug-

gested that they come to us if they want greater clarification. Back then they were making much simpler claims. They never came to us with any data or information.

Mr. BURGESS. Now, Mr. Kutz, do you feel it would be important to associate—you have four companies that were blinded up on the slide. Do you think it would be important for this committee to know—to unblind those so we know which companies provided which results?

Mr. KUTZ. Of the four?

Mr. BURGESS. Yes.

Mr. KUTZ. If you like, yes.

Mr. BURGESS. Maybe that information could be made available to the committee.

I am advised if you know, you may state it.

Mr. KUTZ. All right, of the four companies described as Number one, two, three and four in our report, number one is 23andMe, two is Decode Genetics, three is Pathway Genomics, and four is Navigenics.

Mr. BURGESS. And, again, you can look at the glass as half full. So I would definitely take the best results you got of the four.

Mr. KUTZ. I slept better last night, thank you.

Mr. BURGESS. I knew you would. I did that for your benefit. And your testimony notes that company two claimed that testing for more markers is probably more accurate. If the company tests for more markers, that increases their accuracy. Can you comment on that?

Mr. KUTZ. Yes. Well, we did visit with the companies. They don't know exactly what we did at this time, but they did each claim that they weren't surprised that we got different results, and the differences were attributable to the number and type of markers that they looked at. So several of them claimed they were more reliable than the other ones. But they all were not surprised, from what I understand from the interviews.

Mr. BURGESS. Are we are going to get to go a second round? I will yield back.

Mr. STUPAK. Chairman Waxman, please.

Mr. WAXMAN. Thank you, Mr. Chairman.

Dr. Shuren, you believe that these are medical devises that should be regulated by the FDA. Is the basis of that the claims made by the Web sites and the producers of these tests?

Dr. SHUREN. Yes, that is correct, so claims for risk of cancer or sensitivity to drugs.

Mr. WAXMAN. OK. Now, what do they have to do to stay in business if they are considered medical devices?

Dr. SHUREN. Well, we hear from them the particular claims they in fact they want to make, and for some of these they are going to have to come to us and submit pre-market data.

What we have done with companies in the past who may be marketing a test already who need to get FDA clearance and approval, we may allow them, if they are ready to come in the door with a submission and they have got the data and there isn't a risk to patient safety, we may allow them to continue to market for a short period of time to allow us to look at data and make a determination. But if they are not prepared to do that or there are concerns

about patient safety, then we would have them no longer market that test.

Mr. WAXMAN. I assume that the science is not advanced to the point where they can say you are going to get this disease or you are not going to get this disease. They are looking at the trend, the likelihood.

Now, if they have a scientific ability to say that it is more likely than not, isn't that helpful to the consumer and how would they be able to get approval for that kind of a claim from the FDA when they can't show the absolute scientific backing for a claim like that?

Dr. SHUREN. Well, what is critical here is, first of all that information has to be accurate, and there is a lot of questions now about the accuracy of that information, as you saw from what GAO showed, and it has been in some published reports already that in fact the companies disagree.

One of the companies even in letters to us admitted that different genetic testing companies can report inconsistent results even when based on tests with proven analytical validity, and they go through all the different reasons. Because they are looking at the data, they are making their own determinations on where to make cutoffs on the science.

Another company on their Web site has said many of the genetic discoveries that we report have not been clinically validated and the technology we use, which is the same technology used by the research community, to date has not been widely used for clinical testing.

So, in terms of what we are going to want to see, is not only is it accurate, but if we are going to give information to patients, is that information truthful, not misleading, are they going to understand it, what is going to be the emotional impact with that patient? Is it information they are going to be able to handle by themselves, or is it really information they need a physician or genetic counselor to provide back to them? We are going to look for data to answer those questions.

Mr. WAXMAN. That is an interesting point, because you are saying not only does the information have to be accurate, but FDA is going to evaluate how the information is going to be received.

Now, let's say there is a maternity test, someone wants to markets a maternity test. I assume that requires FDA approval, premarketing approval. Did FDA in reviewing those tests look at how the information would be received?

Dr. SHUREN. When we do look at tests that are over-the-counter, so here the test is simple enough that the patient can use it and test themselves and they can understand and use the results. So the answer is for these tests where there are concerns about how the patient will——

Mr. WAXMAN. But I asked you about a specific one.

Dr. SHUREN. Well, for maternity, maternity may not be actually a device claim.

Mr. WAXMAN. As I understand a paternity test, a paternity test is not something to that would be approved by the FDA. Why is that?

Dr. SHUREN. That is correct. Because if it is using, for example, as evidence in a court case for determining if you are the father of the child, that is not a medical claim. However, there may be things about paternity. If you are saying that, well, we are looking at paternity for making a decision of your risk for heart disease, then you are making a medical claim.

Mr. WAXMAN. Now the consequence of some of these lines, for exactly where you draw it, for a company to get a medical device approval would mean what, they would have to do lots of tests, it will cost them lots of money, and I suppose that some of these companies won't be able to stay in business. Is that a fair statement?

Dr. SHUREN. Well, it depends upon what they are going to actually test for and to show that it is actually accurate, you are measuring what you are supposed to. For example, this is the genetic profile we are looking for. Much of that is bench testing.

Mr. WAXMAN. Let me ask you this question, because I have just a few seconds left. If the requirement for the test, and this is yet to be determined by FDA in talking with these companies, if the cost of doing the test to get pre-market approval by the FDA would turn out to be so expensive that the companies could not stay in business and there were no companies in business, is that a good result? Does the FDA think is it is a good idea not to have any of these companies doing this kind of this work?

Dr. SHUREN. We think that it is good to have companies doing the work if the tests are accurate, they are supported by sound science and they are understandable. We don't think it is good to be giving misinformation to patients.

Mr. WAXMAN. Thank you. Thank you, Mr. Chairman.

Mr. STUPAK. Mr. Kutz, if I may, you identified the four companies that you dealt with in your investigation. The company you bought the supplements from? That was not one of the four?

Mr. KUTZ. Right. That was, again was GeneWise Life Sciences.

Mr. STUPAK. OK. Mr. Griffith for questions, please.

Mr. GRIFFITH. Just a couple of comments. I think that Chairman Waxman is making a very good point. I don't think that the companies that are in question here would, if they disappeared tomorrow, would impact the scientific community and our desire to do research into genetics. I don't think that that is—I don't think that is really a discussion here. I think the discussion is that whether you are a Ph.D. or a physicist or you are a farmer with a limited education, your medical IQ levels out when someone says "cancer" or "Alzheimer's" in front of you, and you do not have the ability to interpret these results, much less have a follow-up as to what is necessary. As far as prostate cancer is concerned, we know that if a man lives long enough, he will develop prostate cancer.

This is all bogus. This is nothing more than the snake oil salesman revisited again in a high-tech community and in a high-tech way. I think that the proof is in many of the discussions that you have had with these companies, and it is very difficult to protect the public from itself and its desire to be healthy.

So I think this committee is doing something that I think is very, very important, that we do impose significant strenuous regulations on these laboratories and what they are doing and what they say they are doing.

It reminds me of a story that they used to tell about the snake oil salesman. He had two medicines, one was High Popalorum and one was Low Popahirum. High Popalorum was taken from the bark of the tree from the limb down, and Low Popahirum was taken from the bark of the tree from the root up. They were both good, but they were different. And I think what we are seeing here is the High Popalorum-Low Popahirum story with a large check attached to it on a credit card or what have you.

The other thing is this is nothing more than a lead-in to a marketing effort. Anyone that takes the time to find out whether they have got Alzheimer's is already concerned about it. They go on the marketing list for medications, vitamins, et cetera, and they begin to get bombarded with mail. They probably say, well, how did anyone know I was interested in Alzheimer's? The lists are being sold. Breast cancer is the same way. Most malignancies are the same way.

So I think we are on to something here as far as what we need to do for the public. I yield back the balance of my time.

Mr. BURGESS. Would the gentleman yield? I thank the gentleman for yielding.

I do just want to point out that this science has evolved so rapidly in just a few short years that I have been here on this committee, and I can remember Dr. Zerhouni talking to us sitting at this very witness table, his last public appearance in front of this committee, talking to us about the single nucleotide polymorphisms that are being used as these tags to ascertain the risk factors.

He put a slide up on the board that showed the number that were available in 2003 and then went through the years. And by the time we got to 2008, which was the year then, the entire slide was filled up with these. So there has been a dramatic expansion of the information that is available.

A field trip that I took to the National Institutes of Health in 2003, I went to a room where they were doing the testing for the genetic tag for Type 1 or Type 2 diabetes, now I don't remember which it was. It was an enormous room full of people at the bench testing. They were linked in on the Internet to at least two other labs located in other places in the world that I was told were equally as large where people were working away around the clock at doing this sequencing.

Last spring, I went to the NIH and I saw a machine that was the size of two file cabinets and it was doing the same work of three large labs from just a few years ago and doing it much faster, and I suspect with at least as great or if not greater accuracy.

So, Dr. Shuren, this knowledge is going to evolve at a very rapid pace. And I would just restate the question that I stated in my opening statement, are you ready, is the FDA ready for what is going to be delivered to it by the NIH and private companies and researchers across the country?

Mr. WAXMAN. Would the gentleman yield to me in the few seconds he has remaining?

Mr. BURGESS. I had asked a question to the witness and I was hoping to get a response.

Mr. STUPAK. Let's get a response, and then we will let the chairman follow up.

Dr. SHUREN. It is a great question, and the answer.

Mr. BURGESS. That is why I wanted a response. It was a great question.

Mr. WAXMAN. He wanted a phrase.

Dr. SHUREN. And I am sure your question will be just as great.

So we held a public meeting on June 30th to get at this question. We are thinking, and I will tell you our initial thinking is really an out-of-the-box approach on genetic testing.

We have two issues. Does the technology being used, is it accurate? And as you mentioned, you could be looking at hundreds of thousands of these single nucleotide SMPs, and you are not going to have a validation that looks at every single one of them. So we are looking at maybe there would be a subset. And if you could show, you could demonstrate you are accurate with that subset, that is good enough and we would trust you on all the rest of the things you are looking at.

The second piece goes to then when I test for that profile, do I really know that it is detecting or predicting the disease it is supposed to detect and predict. And that is where the science really is evolving.

What we are thinking about is FDA along with NIH pulling in from the health care community, pulling in from patient groups, actually sit there going through the science, and when we set the standards of what is good enough and when it is ready, allow those claims. The companies then would not have to come back in the door with a new application. We would say you are already a validated test. You can now make this claim.

That would actually be a way to allow for a lot of tests to be out there, and we would be able to sort of go through that science with a lot of experts to then allow for those claims. And that would actually be a much less expensive way of doing it for these companies as well.

Mr. BURGESS. And that could tie into the disease registries that we are building as a result of work in this committee.

Thank you, Mr. Chairman. I yield back.

Mr. STUPAK. The gentleman has a question?

Mr. WAXMAN. The gentleman's times has expired. Others are waiting to ask their questions.

Mr. STUPAK. Mr. Griffith?

Mr. GRIFFITH. One quick comment. In addition to the disease, one of the things that is going on is most of our good legitimate genetic labs are wide open information. They share it. It is a real scientific endeavor. We know that we can expose 100 of our troops to a traumatic event in Afghanistan and Iraq and only 10 percent will develop post-traumatic stress syndrome. We believe there is a genetic tendency for that.

So a lot of the research that we are doing is unrelated to the snake oil concept, but it is ongoing and it is certainly not part of this discussion.

So I yield back.

Mr. STUPAK. Remember, in the last 48 hours this committee went from Gulf Oil to snake oil. So we are on top of our game.

Ms. DeGette for questions, please.

Ms. DEGETTE. Thank you, Mr. Chairman. I would like to follow up on the points that Mr. Burgess was just making, because I am interested to know, Dr. Shuren, if in fact—in your written testimony you say the FDA has cleared a number of genetic tests since 2003, and I am wondering if in your opinion we have the technology to be able to determine that these mail order type of tests can be accurate and can be approved?

Dr. SHUREN. So there are two parts of accuracy. The technologies used today are getting better and better and some of them are pretty good. But in terms of what the results mean, for many of the claims being made by these companies, the science has not yet sufficiently evolved.

Ms. DEGETTE. So you do the technology, you can do the tests, but it is the interpretation of the tests?

Dr. SHUREN. That is right. The technology is moving faster than the science behind the interpretation of the tests.

Ms. DEGETTE. So given that, do you think that it is likely under the process you have described the FDA will be able to approve some of these mail order testing?

Dr. SHUREN. It is possible. We are going to have to wait and see what data they have, what claims they make. I think some of those claims they may not be able to make today. Some of them maybe they would be able to make. But it is going to be based on sound science.

Ms. DEGETTE. And do you think that primary care physicians are adequately trained to interpret and assess and make recommendations based on these tests at this point?

Dr. SHUREN. I am not an expert in that, but I will tell the Secretary's Advisory Committee on Genetics, Health and Society concluded that physicians generally are not well prepared to provide that kind of counseling.

Ms. DEGETTE. Is that going to be part of the FDA's consideration as well?

Dr. SHUREN. Yes.

Ms. DEGETTE. I wanted to ask you, Mr. Kutz, because obviously your testimony was compelling, but the audio clips were even more compelling of what people were being told by these companies. One thing that struck me was how little regard was shown in that audio clip for patient privacy. The woman says I want to have, I guess as a wedding gift or something, I want to have my fiance tested, and the company said, well, that is a super good idea and we have done that with others.

I know that both of the companies that did that have specific policies prohibiting the sharing of genetic information with a third party. Were you aware of that?

Mr. KUTZ. Yes, we knew that they had policies contrary to that. That is why we were testing to see if they would actually say no, we don't encourage that or we are not going to do that if we know about it.

Ms. DEGETTE. And do you think it was a problem with the employee on the phone not knowing what the company policy was and that training within that company could have helped that?

Mr. KUTZ. We didn't talk specifically to anyone about that, so I don't know. But I believe the two companies will probably be on the next panel.

Ms. DEGETTE. And what were those companies?

Mr. KUTZ. Let me get it for you. I believe it is Pathway is one and Navigenics is the second.

Ms. DEGETTE. Thank you. Here is my other question. I am wondering if you know if these companies went out of business or any of these companies went out of business that held this genetic data. Is there some kind of a system right now for what would happen to that data if the companies went out of business?

Mr. KUTZ. I don't know that.

Ms. DEGETTE. Dr. Shuren, is that part of what the FDA is considering when it decides whether to approve these tests?

Dr. SHUREN. It is not an area that we have jurisdiction over, for the most part. If we are dealing with labs, then CLIA does have certain protections in place. Covered entities under HIPAA. But you may be dealing with companies that fall outside of that scope, and that could be a problem.

Ms. DEGETTE. I am going to yield my remaining minute to the Chairman, who has another question.

Mr. WAXMAN. You are very kind. Thank you.

I guess the question that I just want to raise, and we will have the witnesses on the second panel that can be helpful in answering this question, but do these companies have researchers that are adding to the information that will help us have these breakthroughs for learning more about propensity to disease and how to make medicine more personal? Do they have researchers? Are they adding to the scientific knowledge? Or are they, as the gentleman from Alabama seems to suggest, charlatans, and if they are all closed down, then so be it, they don't really serve a useful purpose.

I don't think the public ought to be misled. I don't want people to be abused. So I think there ought to be some scientific standards. But I think we have to look at what the consequences will be if they have to go through a process at FDA that may be so expensive that they can't survive it and what the loss will be.

I just want to raise that question, more for the second panel, unless either of you have an idea, an answer to it. But otherwise it would go to the second panel.

Mr. KUTZ. I can answer it a certain way. I don't believe these four companies are involved with fraud. I don't believe this is fraud necessarily, because I think they believe what they are doing. I don't think they believe they are intentionally deceiving anybody.

Whereas I believe this is fraud (indicating). So I just want to make that distinction. I didn't necessarily answer your question directly, but there is a difference between companies that believe they are doing something good and right versus ones that know they are deceiving consumers.

Mr. WAXMAN. That product if sold without a claim can be sold without any FDA review.

Mr. KUTZ. Yes, and it is being. There are lots of companies.

Mr. WAXMAN. The question is, there is a claim by one of these direct-to-consumer advisories make that something for which FDA would review, be required to review it. And I have a serious ques-

tion about that, again, these lines that we are drawing. So the product that you are worried about that could be fraudulent could be sold freely, but the people that make the claim, if they just couched it another way, may avoid any regulation.

Mr. KUTZ. Right.

Mr. WAXMAN. Thank you.

Dr. SHUREN. I would add in terms of—from the information we know they are not doing their own research on the genetic profiles but they are interpreting the studies that have been performed by others.

I would raise, regarding companies going out of business, there is another side to this. The failure of FDA to regulate for many of these tests has created a disincentive for traditional manufacturers to get more involved in this area, and I think that stifles innovation as well. We need to consider it. Smart regulation can enable innovation.

Mr. WAXMAN. Thank you.

Mr. STUPAK. Ms. Christensen, any questions, please?

Mrs. CHRISTENSEN. Thank you, Mr. Chairman.

Mr. Kutz, you said in your testimony that many of the studies on which the genetic testing companies based their risk predictions include only data for people of European ancestry. I understand that GAO sent DNA samples with altered ethnicity information to four genetic testing companies.

Can you explain how exactly that worked, what altered ethnicities were submitted in your investigation, and did the genetic analyses you received differ based on what you told the companies about ethnicity?

Mr. KUTZ. Yes. That is another interesting angle to this, and I will just use myself since I was one of the donors. In one of my cases, case number one for me, I was a 48-year-old Caucasian, et cetera. In the other case, I was a 69-year-old African American man. So with respect to that, the results I got back in two of the cases were identical, but there was like a footnote saying but these results really don't mean anything because you are comparing your African American to people of Eastern European descent, et cetera. The other two, the results were different.

So they were apparently comparing me as an African American against other African American men, or perhaps just African Americans, I am not sure. And those were different, and there were a lot less of them. In other words, certain diseases they weren't able to compare.

So it was a combination of I think misleading—they all disclosed something about it, but at the end of the day we got different results for two and the same results for two.

We asked for refunds, and two of the four gave us refunds because we felt we had been ripped off on that as a minority.

Mrs. CHRISTENSEN. OK. That kind of responded to my other question. Which companies gave the refund and which ones didn't?

Mr. KUTZ. The refunds were Decode and 23andMe. And Pathway and Navigenics did not give us refunds.

Mrs. CHRISTENSEN. Do you feel that—did the companies say up front, do they let the customer know up front—you do have to put your ethnicity on it.

Mr. KUTZ. All of them I believe ask for age and ethnicities. Some asked for additional medical information on your history.

Mrs. CHRISTENSEN. And do the companies say up front, well, we don't have a lot of data for minorities because our data pool really comes from people of European ancestry? Is that information provided up front?

Mr. KUTZ. It is disclosed, I believe, but not necessarily in a prominent way.

Mrs. CHRISTENSEN. And in the case of minority customers, do you feel that the marketing is misleading and deceptive?

Mr. KUTZ. Yes. I believe that there should be much more prominent disclosure. If someone says they are African American or Asian, which were our two scenarios, they should be told very clearly before they take their credit card information that you are not going to get the same results as if you are Caucasian.

Mrs. CHRISTENSEN. I think it is appalling that the companies would ask about their customer's ethnicity at the outset, and despite knowing immediately they can't provide the customer with the full results, still run the tests and charge the same price.

Let me ask Dr. Shuren a question, also. The reason that FDA can—and it sort of follows up on the chairman's question. The reason that you have any jurisdiction over these tests is because they qualify as a medical device because of some of the claims that they make, is that right?

Dr. SHUREN. That is correct.

Mrs. CHRISTENSEN. So the company can just change their claim and fall below the threshold, can't they not, and then what recourse do we have to have any oversight whatsoever?

Dr. SHUREN. So if they make claims, they are not making medical claims at all, but they are engaging in fraudulent practices, then we would be engaging with FTC. And that is one of the reasons too, the information that GAO provided, we have shared that with them at all. While we may not have authority over everything, our other sister agencies have additional authorities and we work with them in such situations.

Mrs. CHRISTENSEN. And I know that in answer I think it was to Ms. DeGette's question, I don't remember who asked it, but do primary care physicians, of which I am one, have enough expertise to be able to interpret the results? Despite your answer, we are talking about direct-to-consumer sales of these tests. Would the FDA or GAO's position based on your investigation be that these tests should be only done if ordered by a health care professional?

Mr. KUTZ. Well, the genetic experts we spoke to said that most doctors would not be able to interpret—I think it is consistent what Dr. Shuren said, that the HHS studies showed. Our experts in genetics told us the same thing.

Mrs. CHRISTENSEN. So who would interpret it? I mean, what is the use of the test?

Mr. KUTZ. I mean, I can speak for myself, because I am one of the donors actually, and I showed you only the chart for three very serious conditions or diseases, I got three different answers. So I am still confused about that.

Dr. SHUREN. And for some of the tests you will get a result and who knows what to actually do with it. In other cases, people may

be making a decision even it is on lifestyle. If you tell them they have low risk for diabetes, they may not have low risk and that person may be obese. A physician would say, you are obese. You have unhealthy habits. You are actually at high risk for diabetes, regardless of what your genetic test says. Yet that person may decide I can have my cake and eat it, too.

Mrs. CHRISTENSEN. So if they had a provider, a health professional, nurse, nurse-practitioner, physician assistant or physician involved in the process, they would be better off?

Dr. SHUREN. Yes.

Mrs. CHRISTENSEN. Thank you.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you.

Let me just follow up a little bit, if I may. These companies, Dr. Shuren, the FDA contacted them with letters, some in 2009, some in 2010. The FDA invited them to come in to say if you are going to do this type of testing, come on in, lets's talk about it, is that correct?

Dr. SHUREN. That is correct.

Mr. STUPAK. And no one took you up on that offer?

Dr. SHUREN. The offer we made now, the companies are now scheduling to come in. We have met with one company once and they are coming in again. We have met with a second company and they are going to come back and talk to us.

Mr. STUPAK. But these companies, they know darn well that FDA has oversight of what they are doing and they are trying to avoid FDA regulation, are they not?

Dr. SHUREN. Well, they should know that we have oversight over them. It would be a good question for the next panel.

Mr. STUPAK. Well, there is a binder right there in front of you, that binder. Go to Exhibit No. 8, if you would, in there. In there, in one of the letters, all these companies before us, 23andMe, Navigenics, Pathway Genomics Corporation, and Decode Genetics, they have all received letters from the FDA, have they not?

Dr. SHUREN. Yes.

Mr. STUPAK. OK. So if you go to Tab 8 there, this is a document dated—it is an e-mail actually—July 1, 2009, it is from a Pathway employee who is discussing the advantages and disadvantages of using a swab for DNA collection. You can see in there they have the pros and cons. One of them they list is under the pros, the employee says for using swabs is to "avoid issues of the FDA regs regarding device manufacture and licensure of collection container."

So they are trying to avoid FDA regulation. They think if they use a swab, they avoid the FDA. Do they avoid FDA regulation using a swab?

Dr. SHUREN. No, not necessarily. And I think this was for Pathway Genomics, did you say?

Mr. STUPAK. Correct.

Dr. SHUREN. So Pathway Genomics isn't even—if they are trying to argue on a laboratory developed test, and when I get a collection sample I have to use something that is approved and cleared by the agency for that use, they are not a lab developed test. Their genetic test they use, they buy from another company. That is our under-

standing. If that is not the case, they can demonstrate to us otherwise.

Mr. STUPAK. OK. So they have the lab. But also when they send the results, like to Mr. Kutz, they are making a medical decision or diagnosis, are they not?

Dr. SHUREN. Yes.

Mr. STUPAK. And you need a license for that, do you not?

Dr. SHUREN. That is something that goes, I hate to do it this way, but for State law, it is sort of who can actually practice medicine. If they are engaging in the practice of medicine. But regardless, they are acting as a manufacturer under FDA law.

Mr. STUPAK. Then if they send you a bag of supplements there for $140, now they are actually practicing medicine, because they say bag of supplements might lower my blood pressure, correct?

Dr. SHUREN. They would certainly be acting as a drug manufacturer.

Mr. STUPAK. OK. Go to document, Exhibit No. 2, and this is a document from 23andMe that outlines a conversation between two employees about CLIA. We have heard by CLIA, which is the Clinical Laboratory Improvement Amendments, which is a law administered by the Centers for Medicare and Medicaid, that regulates diagnostic lab testing on humans in order to ensure reliability of the tests.

If you look at Exhibit No. 2, it says in there, Alex says, "CLIA is so useless for a lot of things it sees. It ensures that all," and they have some colorful language in there, "are well documented and validated, but doesn't actually prevent them."

So, Dr. Shuren, I understand that the CLIA tests whether the lab test is reliable, but does the CLIA process have any role in protecting consumers from being confused or misled about diagnostic value in these genetic testings?

Dr. SHUREN. No, CLIA does not address that.

Mr. STUPAK. OK. Does the CLIA process make sure that the direct-to-consumer genetic test does what it purports to do?

Dr. SHUREN. No, it doesn't.

Mr. STUPAK. What kind of regulatory scheme then would address both the reliability of the test and ensure the safety and the efficacy of these tests?

Dr. SHUREN. What you need is both FDA oversight and CMS oversight under the Food and Drug Cosmetic Act and under CLIA.

Mr. STUPAK. As the investigation has shown, there are some with the direct-to-consumer genetic testing market that will go to great lengths to avoid government regulation. So we really hope that this hearing provides more balance and demonstrates why stronger and more diligent regulation is necessary.

You also mentioned CFTC, or I am sorry, FTC, the Trade Commission, would also have a role in this?

Dr. SHUREN. They may. When we got the results the other day, we shared it with them. We are going to have follow-up dialogue.

Mr. STUPAK. Mr. Kutz, you have something you wanted to add on this?

Mr. KUTZ. Well, we referred these to FTC, too, for potentially deceptive marketing practices.

Mr. STUPAK. OK. Mr. Burgess, questions?

Mr. BURGESS. Dr. Shuren, in a regulatory environment for these tests, would they be Class 1 or Class 2 devices?

Dr. SHUREN. It depends on the claim. Many of these claims that are medical claims look to be more. Some of them look like Class 3, some would be Class 2. We would need to get the specifics on them.

Mr. BURGESS. So Class 3 or Class 2 would be eligible for the tax under the health care bill that we passed and signed into law a few months ago, correct? Have you relayed this information to the Congressional Budget Office, because they are always looking for scores and savings on that patient care bill that we passed.

Let me just ask you a question, Dr. Shuren, regarding the regulatory pathways. Is the Food and Drug Administration at the present time looking at the development of new regulatory pathways for things that are just on the horizon and perhaps a few steps over the horizon?

Dr. SHUREN. The answer is yes. I think the approach I laid out on genetic testing is an entirely different way of approaching technology. FDA has done this over the years. As we deal with new sciences, we have a lot of flexibility under our existing authority and we adapt it to new technologies. I think this is one area where you are going to see us do that.

Mr. BURGESS. You know, one of the disappointing things about this here has been that we have done absolutely nothing on a Federal budget at the congressional level. We have had no hearings, we have not had the ability to have anyone in and talk to them about their views and estimates for their agencies for the fiscal year that is just around the corner now.

What can you tell us about the budget that you have to provide this new regulatory environment that is clearly going to be required? We are dealing with one small aspect of it today, but there are a lot of things that are just over the horizon in regenerative medicine, in the types of cancer therapy that may be available, where again your target population is a single patient and it is tough to do a randomized clinical trial on that, a population of one.

So what is the budgetary outlook for your department as far as this any regulatory environment?

Dr. SHUREN. Well, that is one where we are working through the usual budgetary procession to handle. I will say as we gear up, as we see more diagnostics coming down the pike, we do a re-look at our existing list of diagnostics, and for some that are moderate risk we better understand, we sometimes move to down-classify them into Class 1, which means we don't do a pre-market review.

We are doing such a review right now, and when we do that and it is appropriate to down-classify, we free up resources that we can then apply to new technologies coming in the door.

Mr. BURGESS. Now, bear in mind, when you down-classify, that is going to take something off the tax rolls for the PPCRA, or whatever the dang thing is. So there will be a Congressional Budget Office score to that. And I am being a little bit lighthearted, but obviously we have an obligation, we will be looking at reauthorization of the Food and Drug Administration in just really a very short period of time. I can't believe it has already come back around again so quickly.

But I think it is an important time for us to look at how you all are doing with establishing the FDA, that will be required to meet the challenges. Again, we are looking at one tiny little part of it this morning, and it is terribly interesting and terribly important, but there are a lot of things on the horizon out there that the 20th century FDA was ill-equipped to handle, and the FDA has to be able to handle the things that are going to occur in the 21st century with the speed of research and development.

I have been concerned for some time that we put $10 billion into the NIH in the stimulus bill, but we didn't do anything for the FDA. Now, assuming that those dollars we have invested in research at NIH are going to lead to deliverables and products, are you all able to keep up with getting those things out to the patient population that may need them, or was the money spent on research really never intended to get to a deliverable anyway, we were just spending money to spend money.

Now I don't know the answer to that question and I have never been able to get a satisfactory answer from anybody at the FDA. Again, we never had any budgetary hearings.

So what is your sense on this? Do you have the tools that you need? Are you going to be able to talk to us at some point about what is over the horizon and what is required to have a good functioning 21st century FDA?

Dr. SHUREN. I think it is a discussion we would be happy to have, to talk about our thoughts on what is coming down the horizon, our thinking about what it may take to be well prepared.

Mr. BURGESS. I can only pray that our chairman will invite you in to discuss that some day, because it has been lacking this past year and it has been an omission that is significant, as we are seeing here this morning.

Thank you. I yield back the balance of my time.

Mr. WAXMAN [presiding]. The gentleman's time has expired.

Ms. DeGette.

Ms. DEGETTE. I don't have any further questions.

Mr. BURGESS. Can I just ask one last question on the issue of genetic counseling? Under whose regime does that fall? Clearly the phone calls that Mr. Kutz was playing for us, these were telemarketers giving genetic counseling. That is so inherently dangerous that regardless of anything else we decide this morning, that has got to stop. So who is the cop on the beat for that? Who pulls the plug on that activity or makes these companies understand that this has to cease and desist and you need to hire genetic counselors to give genetic information?

Dr. SHUREN. Well, in some respects we have a certain responsibility, so we may decide these are tests that actually can't be provided directly to consumers, it is actually test results that have to go through a health care professional. If it is something where we decide that it could be provided through a genetic counselor, and we have done that in the past, then the appropriateness of those counselors and their credentialing I believe is handled at the State level.

Mr. BURGESS. Thank you.

Mr. WAXMAN. Thank you very much. We appreciate your testimony. We look forward to talking to you further about this issue.

Mr. KUTZ. Chairman Waxman, can I correct something real briefly before the second panel?

Mr. WAXMAN. Yes.

Mr. KUTZ. I had said before I think that I think the refunds for our minorities were Decode and 23andMe. They were really Decode and Pathway gave us the refunds. Just so if you are asking questions of the second panel, that that is the correct answer. I apologize for that.

Mr. WAXMAN. Thank you.

I would like to now call forward our second panel of witnesses.

We have Dr. James Evans, Editor-in-Chief, Genetics in Medicine and Bryson Professor of Genetics and Medicine at the University of North Carolina at Chapel Hill; Ms. Ashley Gould, General Counsel, 23andMe; Dr. Vance Vanier, President and CEO of Navigenics; and Dr. David Becker, Chief Scientific Officer with Pathway Genomics Corporation.

I want to welcome you to our hearing today. We appreciate your being here. It is the practice of the Oversight Subcommittee to have all testimony given to us done under oath, and so, if you would, now that you have sat down, please rise.

You are advised that you are entitled to be represented by counsel during your testimony. Do any of you wish to have counsel assist you during your testimony?

Ms. GOULD. Yes.

Mr. MADIGAN. Michael Madigan of the Orrick law firm, Your Honor. Pleased to be here.

Mr. WAXMAN. I haven't been addressed as "your honor" in quite a while. Thank you.

[Witnesses sworn.]

Mr. WAXMAN. Let the record indicate that each of the witnesses answered in the affirmative.

Dr. Evans, why don't we start with you. There is a button on the bottom of the mike. We will have a clock running for 5 minutes. We would like to ask you to keep to that time.

TESTIMONY OF DR. JAMES EVANS, EDITOR-IN-CHIEF, GENETICS IN MEDICINE, BRYSON PROFESSOR OF GENETICS AND MEDICINE, UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL; ASHLEY GOULD, GENERAL COUNSEL, 23ANDME; DR. VANCE VANIER, PRESIDENT AND CEO, NAVIGENICS, INC.; AND DR. DAVID BECKER, CHIEF SCIENTIFIC OFFICER, PATHWAY GENOMICS CORPORATION

TESTIMONY OF DR. JAMES EVANS

Dr. EVANS. Mr. Chairman and members of the committee, thank you for inviting me to testify.

Mr. Chairman, I ask that my prepared remarks be submitted for the record.

I am a physician and scientist who specializes in genetics. I conduct research on the genetics of cancer, and I am Editor-in-Chief of Genetics in Medicine, the journal of the American College of Genetics. But first and foremost, I am a physician. I am a board certified internist with a general medical practice and a board cer-

tified general geneticist who sees patients with genetic disorders. I regularly utilize genetic testing in my practice.

Advances in technology hold great promise for a future of personalized medicine. We should encourage individuals to be the primary directors of their own health care. Truly participatory medicine is a worthy goal and people should have access to the information contained in their own genome.

But it is critical that such information be of high quality, that individuals receive accurate advice about the meaning of that information, that their privacy be protected, and that claims concerning those tests comport with reality.

Unfortunately, this is not always the case at present. One egregious problem is the gap between claims by the providers of such services and the value of the information actually imparted.

Most purveyors of DTC genetic testing appeal explicitly to its alleged medical value. We hear that genomic analysis allows one to "take control of your health future." Yet on each page of every report is some variant of the following disclaimer. "Information provided is not intended as nor does it provide medical advice, treatment, diagnosis, or treatment guidelines."

The explicit health claims and the small print disclaimers cannot both be true. Indeed, they are not. The disclaimer is correct. Such information by and large lacks medical significance. This would be true even if we understood how to interpret such results which, as clearly demonstrated by the literature and by the recent GAO investigation, we do not. The gap between claims and reality should be closed, and this could be accomplished in part by simply enforcing existing standards promulgated by the FTC.

But while the vast majority of DTC tests are of merely entertainment value, some have serious, indeed potentially life changing, medical consequences. Thus, having signed up for innocuous information about her ear wax consistency or possible food preferences, a woman may also discover via a company Web site that she should consider bilateral mastectomy and removal of her ovaries. Startlingly, the recipient of such information from at least one major purveyor has no recourse to even talk with a qualified professional about her result. It is dangerous to allow the conflation of entertainment with medicine.

With regard to quality, if genomic information has true medical value, then it is only logical that its quality be insured like that of any other medical test. I applaud the recent move of the FDA to take a risk calibrated approach to regulation, a timely endeavor in light of the recent mix-up of 87 samples by one major DTC company.

Protecting privacy is also critical. A minute sample of your DNA can differentiate you from every human who has ever lived. What do we do when a company goes bankrupt and ownership of your uniquely identifying genomic information might suddenly become the property of a venture capital firm? We need clear and enforceable guidelines for how such information is handled by its inevitably unpredictable owner.

Regulation does not mean proscription. We can embrace an exciting future in which the public has access to its genome in a way that includes reasonable risk calibrated regulation. Indeed, the in-

terests of companies and public health are fully aligned, since both long-term business interests and the public's health will thrive only when tests and the claims about those tests can be trusted.

No one is more excited about the future of genomics than me. You can probably tell that by my questionable choice of tie for this hearing. I welcome the entry of responsible entrepreneurs into this field. Medicine has plenty to learn from innovative companies.

I agree that people deserve access to the information contained in their genomes. But as a physician who deals with these issues daily, I do not feel it is paternalistic to simply maintain that they also deserve an honest accounting of what such information means and the assurance that it is derived in a manner that ensures quality, reliability and privacy.

Thank you.

[The prepared statement of Dr. Evans follows:]

Testimony of James P. Evans MD, Ph.D
Hearing of the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations, July 20, 2010

Thank you very much for inviting me to testify. I am a physician and scientist who specializes in medical genetics. My research involves the use of emerging technologies to analyze the human genome for genes involved in cancer predisposition and the ways in which people use genetic information. I am the Editor-in-Chief of *Genetics in Medicine*, the official journal of the American College of Medical Genetics. But first and foremost I am a physician. I am a board certified internist who has a general medical practice. I am also board certified in Clinical Medical Genetics and in Molecular Genetic Diagnostics in which capacity I see and test patients who have, or are at risk of having, genetic disorders such as predisposition to cancer.

The breathtaking pace of discovery in the field of genetics is providing new opportunities for rapidly and inexpensively analyzing the human genome. We are now able to routinely query an individual's genome at over 1 million sites and the "$1,000 genome", in which access to one's entire genetic code will be feasible for many individuals, will soon be a reality.

Such advances in technology have great promise to revolutionize medicine and usher in a new era of genomic medicine. These advances will lead to great progress in our basic understanding of disease, improved diagnostic abilities, new therapies and personalized prescription of drugs.

But the rapid pace of technological progress has left us understandably impatient for immediate application to patient care. Like scientists and doctors, the public is curious and hopeful about genetics and has demonstrated an interest in analyzing and understanding their own genome. Indeed, we may be approaching an era in which much, if not most, genetic testing could be done outside the confines of the traditional doctor's office or medical setting.

In part to meet this burgeoning interest, a wide range of direct to consumer (DTC) genetic testing entities has arisen, a potentially positive development for both patients and the public. We should encourage individuals to be involved in, and be the primary directors of, their own healthcare. Truly participatory, individualized medicine is a worthy goal and one we should strive for. People should have access to the information contained in their own genome.

But it is also critical that they be assured that the information they receive is of high quality, that they have recourse to disinterested advice about the meaning of that information, that their privacy be protected and that claims made by the purveyors of such testing comport with reality.

Unfortunately this is not always the case at present. The most egregious problem – and the most remediable – is the distinct gap between claims made by the providers of such services and the value of the information actually imparted. Most of the purveyors of

DTC genetic testing appeal both implicitly and explicitly to the purported medical value of the genetic tests in question. We hear claims that scanning your genome for genetic variants provides a "road map to better health", allows one to "take control of your health future" or that "knowledge is power" with regard to disease. Indeed, these are the central advertising logos of the three most prominent players in the genomic DTC arena. Yet on each page of every report provided to patients by these companies, some variant of the following disclaimer is made: "Information provided is not intended as, nor does it provide, medical advice, treatment, diagnosis, or treatment guidelines." The explicit health claims and the accompanying disclaimer (in tiny font) cannot both be true. And indeed they are not. The disclaimer is correct. Such information, by and large, utterly lacks medical significance. This would be true even if we understood how to interpret such tests, which, as clearly demonstrated by scrutiny of the literature and the recent GAO investigation, we do not.

It is often submitted by boosters of such technology that mere knowledge of one's risks will be of benefit to an individual. Yet, little evidence suggests that this is the case. Statistics about risk are tricky. I know, to a first approximation, what you, the reader of this document, will likely die of…cardiovascular disease or cancer. These maladies are not called "common diseases" for nothing. They are exceedingly common and one is at considerable risk for them regardless of whether one happens to be at a *relatively* increased or decreased risk when compared with the average individual in the population. Thus, even for those at decreased relative risk, the chances are that they too will die of one of these common diseases. Thus, finding out that you're at double or half the "average" risk of a common disease is simply not medically meaningful.

Likewise, for rare diseases, what does defining your risk really mean? The risk of a US citizen developing Crohns disease, a disease of the GI tract, is about 1/1000. In what way is it useful to know that I'm instead at a 1/500 risk or a 1/2000 risk?

It is instructive to examine how we use risk information in pursuit of better health. Your doctor doesn't measure your cholesterol and blood pressure because simple knowledge of that risk information is beneficial to your health. Rather, she measures it because we have ways of altering your blood pressure or cholesterol. As a physician, I simply don't know what to do with the knowledge that I or my patient is at, say, a 40% increased risk for prostate cancer. We have no interventions that make that information useful.

Some claim that knowledge of an increased risk will motivate people to live more healthy life styles. Yet there is no good data thus far that genetic information has any special qualities that will motivate individuals any more effectively than do our current admonitions.

But what if I'm wrong? What if there really is something inherently special about genetic information that will induce behavioral change? I sincerely doubt that this will be the case but let's grant that dubious proposition for a minute. If so, we have an even bigger problem. Because for everyone I find to be at increased risk of, say, heart disease, I am mathematically guaranteed to find another at decreased risk. If genetic information has

magical abilities to affect behavior then we run the inevitable risk that such information will induce adverse behavior in the other half of the population, to their ultimate detriment. The bottom line is that whether you are at increased risk or decreased risk of disease, a healthy lifestyle will benefit you and there is little to be gained from finely parsing that risk. The gap between claims and reality should be closed. And it doesn't even require new regulations, just enforcement of existing standards that are, at least in part, promulgated and promoted by the FTC.

Another important issue before us is what sources of information the public has about the meaning of their results. I would argue that the vast majority of test results provided by most DTC genetic companies are simply of entertainment, not medical value. As such I see little potential for harm and see no problem with the public having full access to such information - as long as it is not oversold in the way I've just been describing.

But mixed in with trivial and fun tests (that, for example, assay your likelihood of having thick earwax or liking Brussels sprouts) are a few tests offered by such companies that have very serious medical consequences. For example, one major purveyor's panel of DTC tests include, along with trivial matters, a test for specific mutations which result in an exceedingly high risk of breast and ovarian cancer. Thus, having signed up for innocuous information about one's ancestry and possible food preferences, women may also find out via the company's website that they should perhaps consider bilateral mastectomies and removal of their ovaries. Startlingly, the recipients of such information have no recourse to even talk with a qualified professional about their result and its implications. I think that people should be free to get medical tests on their own terms. But if one takes on the responsibility of informing someone that they have tested positive for a mutation that could well lead to very serious – indeed life changing - consequences, then one should ensure that the individual can at least pick up a phone and talk with someone knowledgeable about its implications for them and for their loved ones. I don't leave my patients in the lurch when I discover devastating information about their health and doing so should not become a new standard of the internet age.

Ensuring quality testing is also of paramount importance as we try to realize the potential of genomic information. Simply put, if such information has true medical value, then its quality should be ensured like any other medical test. This is not too much to ask. I applaud the recent move of the FDA to take a risk-calibrated approach to the regulation of such testing. Their action is especially timely given the recent mix up of 87 samples which occurred from a major purveyor of DTC genomics. In formulating appropriate regulations it is important to keep in mind that risk calibration is possible. There is no reason that each test must be regulated to the same degree. Rather, the seriousness of the implications of a given test can guide the degree to which it must be regulated.

Protecting the public's privacy is critical. A tiny sample of your DNA can serve to differentiate you from every other human who has ever lived. Thus, it seems reasonable that the public should be assured that their samples and their genomic information are protected. What do we do when a company goes bankrupt and ownership of your uniquely identifying genetic information suddenly may become the property of a venture

capital firm? We need clear and enforceable guidelines for how such information is handled by its (likely numerous) owners.

As we seek to employ genomic information in healthcare it's critical and sometimes difficult to remember that medicine and science are very different pursuits. Unfortunately good ideas are insufficient to guide the practice of medicine. We've learned that we must demand evidence of efficacy and safety before we translate what seem like good ideas into medical care. If we do not it is our patients who will inevitably pay the price.

No one is more excited about the future of genomics than I am, nor feels more strongly that it has the potential to usher in a new era of medicine that will benefit us all. I welcome the entry of quality-minded and responsible entrepreneurs into the field. Medicine is often validly criticized for being too slow to change and I think we have plenty to learn from innovative cutting edge companies, some of the representatives of which are also testifying today.

But as a physician who deals these issues daily I do not feel that it is paternalistic to ask that the public not be deceived by exaggerated claims, that their privacy be protected, that tests be of high quality and that they have recourse to unbiased information about the meaning of their results. Regulation does not mean proscription. We can embrace an exciting future in which the public has access to its genomic information but we should do so in a responsible manner and risk-calibrated regulation is part of the answer. Indeed, it seems obvious to me that the interests of companies and the public are actually fully aligned since both their long-term business interests and public's health will thrive only when tests and the claims made for those tests are trusted.

I believe that the public deserves access to the information contained in their own genomes. But they also deserve an honest accounting of what such information means and the assurance that it is derived in a manner that ensures quality, reliability and confidentiality.

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Mr. STUPAK. Thank you, Dr. Evans.

Ms. Gould, your testimony, please. You are General Counsel for 23andMe.

Ms. GOULD. That is correct. Thank you.

Mr. STUPAK. If you want to pull that mike forward, and the green light should go on when you press the button.

TESTIMONY OF ASHLEY GOULD

Ms. GOULD. Chairman Stupak, Ranking Member Burgess, and members of the subcommittee, good morning and thank you for inviting 23andMe to testify today.

My name is Ashley Gould, and I am the General Counsel of 23andMe, as you just heard. I ask that my full written testimony be submitted for the record. Thank you.

It was really helpful to hear and we embrace the prior panel. We were disturbed by the percentage of discordants in these reports, and we have proposed standards to NIH and FDA. I will be talking more about that today.

In the last 10 years, the Human Genome Project has revolutionized genetics. Direct-to-consumer genetics leverages these advances by allowing individuals to access their own genetic information. Consumers empowered with this information have made lifestyle changes aimed at reducing their risks of developing disease and have provided information to their physicians to aid in diagnosis and treatment.

23andMe believes the subcommittee's hearing today presents an opportunity for all of us to understand the state of the science, how best to protect consumers, and to design a sensible regulatory framework for the future. We look forward to working with Congress as well as the FDA and NIH on these issues.

We strongly agree with the subcommittee that DTC genetic testing must be scientifically valid, accurate, and well-explained to consumers. We are entirely confident in our own reports, which we develop in conjunction with our physician and scientific advisers.

We support the subcommittee and FDA in the effort to create an improved regulatory framework for genetic testing. We are already working with FDA, NIH and other organizations to strengthen regulations for all laboratory testing, including genetic testing. Indeed, we first met with FDA in 2007 before we ever offered our service to consumers. Thereafter, in 2008, we met with FDA Commissioner von Eschenbach and his staff and they encouraged us to proceed. We have had ongoing discussions with FDA since that time.

Tomorrow, we will present our regulatory proposal to the FDA. Our plan takes into account rapid technological innovation and ensures the analytical and clinical validity of all laboratory tests. In addition, we think new regulations should provide transparency across the industry so consumers know what they are getting from the services they choose.

At the heart of any new regulation should be the requirement that DTC genetic companies operate at the highest levels of science and ethics. 23andMe grounds its service in several core elements: Informed consent and strong privacy protection; educating customers about personal considerations they should take into account when using our service; educating customers in providing full

transparency about the science behind our service; and recommending that if customers have questions about their results, they should coordinate with their physicians or a genetic counselor.

Indeed, we are proud that in 2008 our company's DNA testing was selected by Time Magazine as the number one invention of the year.

One of 23andMe's core missions is the development of innovative solutions for accelerating genetic research. Our database is one of the largest collections of genetic and health information in existence and has already led to published discoveries. We are currently working with the Parkinson's Institute on research aimed at discovering the genetic factors underlying Parkinson's disease. We are proud to have with us today the head of the Parkinson's Institute, Dr. William Langston, one of the leading Parkinson's researchers in America.

We appreciate the concern that people who receive DTC genetic information could make harmful decisions without consulting a physician or could be lulled into inaction based on their results. However, we have seen neither data nor scientific literature to support this view. Indeed, the current scientific literature, combined with our own experience, shows that people do not take rash or unconsidered actions.

Moreover, 23andMe's service is consistent with the FDA's long history of approving at-home over-the-counter laboratory tests for HIV, hepatitis and other diseases, in addition to permitting consumers direct access to tests for other conditions, such as high cholesterol and pregnancy.

We believe the current regulatory landscape is ready for improvements, and we welcome your interest and leadership in this area.

Thank you, and I look forward to your questions.

[The prepared statement of Ms. Gould follows:]

Testimony of Ashley C. Gould, General Counsel, 23andMe, Inc.
"Direct-To-Consumer Genetic Testing and Consequences to the Public Health"
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations, U.S. House of Representatives
July 22, 2010

Chairman Stupak, Ranking Member Burgess, and Members of the Subcommittee: Good morning, and thank you for inviting me to discuss this important issue.

My name is Ashley Gould, and I am the General Counsel of 23andMe, Inc., a leading personal genetics company dedicated to research and helping individuals understand their own genetic information through DNA analysis technologies and web-based interactive tools. I ask that the full written testimony be submitted for the record.

I. Overview

Direct-to-consumer (DTC) genetic testing leverages the findings from the Human Genome Project. Genetic testing has the potential to allow individuals to access their genetic information – the building blocks of their genome. Customers empowered with this information have made lifestyle changes aimed at reducing their risks of developing disease and have provided information to their doctors to aid in diagnosis and treatment. These actions have improved and even saved lives. Consumers can only be helped if such services operate at the highest levels of both science and ethics. We thus greatly appreciate the Subcommittee's interest in this increasingly important area of personal health, and we support sensible U.S. Food and Drug Administration (FDA) regulation of genetic and other forms of direct-to-consumer testing.

Before explaining our DTC genetic testing services more specifically, we would like to explain that 23andMe operates pursuant to the following core beliefs and facts:

A. Consumers have a fundamental right to access their personal genetic information;

B. 23andMe takes a holistic approach in providing genetic information to customers. Customers are provided with as much scientifically-sound information as is available so that they can learn as much as possible;

C. 23andMe provides a platform for customers to participate in the research process, so that we can all learn more about genetics and diseases;

D. Genomics has reached the stage where 23andMe can provide personal genetic information to consumers in a cost-effective manner. 23andMe relies on experts, both internally and on an outside board of prominent science advisors, to provide its services based firmly on peer-reviewed science;

E. 23andMe provides genetic testing results to consumers in a secure, confidential, and privacy-protected environment;

F. 23andMe encourages our customers to consult with medical professionals before taking any medical action based on DTC results; and

G. 23andMe supports federal standard-setting or other sensible regulatory activities to protect consumers and increase transparency.

II. Background

23andMe met with the FDA even before we launched our service, explained the full scope of our proposed services, and were encouraged to continue with our service by the then-FDA commissioner. Even while we have not been actively regulated by the FDA, we have embraced the scientific standards normally applied in a regulated environment. Based on FDA and Clinical Laboratory Improvement Amendments (CLIA) standards, we have created a sophisticated, high-quality testing process.

To process and analyze our customers' saliva samples, 23andMe contracts with the National Genetics Institute (NGI) – a wholly owned subsidiary of the Laboratory Corporation of America. NGI is a CLIA Program-certified laboratory that provides advanced clinical genetics testing services for blood screening, medical testing, and clinical research. Licensed as a clinical laboratory provider by both state and federal agencies, NGI participates in a number of approved quality control programs, and holds active Biologics Licenses from the FDA for screening of plasma for blood-borne infectious agents. It also provides advanced genetic testing services to physicians, hospitals, and clinics, and has supported numerous pharmaceutical and biotechnology companies in the clinical development of new infectious disease and oncology therapies. (See Attachment A). We believe that NGI complies with the highest professional, regulatory, and corporate quality-assurance standards.

NGI processes customer saliva samples using a chip that analyzes nearly 600,000 data points – the building blocks of the genome that I referred to above. After NGI completes the analysis, the collected data for each sample is encrypted using leading technologies to protect privacy, and sent electronically to 23andMe, which then uploads the data to the customer's individual account. 23andMe then notifies its customers that their data are loaded and ready for viewing.

Throughout this process, 23andMe provides strong safeguards for our customers' privacy and confidentiality. We have invested in a sophisticated technical environment for the storage and security of customer data and have had independent security audits to verify that security is state-of-the-art. As a part of our Terms of Service, we educate customers about our service and what will be provided – including how to use their information, how their information is protected, and the scientific limitations. During account registration, each customer is required to focus his or her attention on relevant highlighted sections of our Terms of Service and agree to them. In addition, we have

consulted on privacy issues with leading experts in the field, including the Electronic Frontier Foundation, to adopt the highest standards and best practices for storing and safeguarding our customer data.

Equally important, 23andMe grounds its service in five core elements: (A) informed consent; (B) educating customers about personal considerations they should take into account when using our service; (C) educating customers about the science and methodologies behind our service; (D) updating customers with new information as the science advances; and (E) emphasizing that customers should consult with health care professionals before taking any medically-related actions based on our reports.

A. Informed Consent and Privacy

We require informed consent from customers before they use our services so that they understand our permitted uses of their data and what our reports indicate – both the information and its limitations. We take extra precautions with certain reports. For example, we ask customers to be certain they want to know potentially significant information, and insert interstitial pages that must be clicked through before viewing our Parkinson's and BRCA reports. This way, a customer has the chance to reflect before making an affirmative choice to view his or her data.

No individual customer information is ever disclosed to third-parties without explicit consent (unless required by law). In addition, we recently introduced an institutional review board-approved consent document, which allows customers to decide if they would like to participate in research intended for peer-reviewed publication. In such instances, customer information will only ever be provided on an aggregate basis. As a constant reminder to our customers, our consent document, terms of service, and privacy statement are all available for review via links on every page of our website.

B. Education About Customers' Personal Considerations

Our customers come to our service because they are motivated to learn about their genes. Customers are not compelled to learn any information, and we designed the web site to allow customers to choose to learn the information that interests them. Our Terms of Service page clearly states that information customers learn could cause distress. Specifically, we disclose at length the following risks and considerations:

- "Once you obtain your Genetic Information, the knowledge is irrevocable;"
- "You may learn information about yourself that you do not anticipate;"
- "The laboratory may not be able to process your sample, and the laboratory process may result in errors;"
- "You should not change your health behaviors solely on the basis of information from 23andMe;"
- "Genetic research is not comprehensive;"

- "Genetic Information you share with others could be used against your interests;" and
- "23andMe Services are for research, informational, and educational use only. We do not provide medical advice."

For a complete and fully described list of disclosed risks and considerations, please see our Terms of Service. (See Attachment B). In addition, our public website contains a section addressing considerations before using our service or engaging in genetic testing. (See Attachment C).

C. Education and Transparency About the Science and Our Methodologies

We provide extensive information to our customers so they understand that the data we provide can change as new scientific studies are completed. We also explain the technology, algorithms, and methodology used to process and analyze their DNA. We have white papers readily accessible on our website that detail our inclusion criteria procedures and algorithms. In addition, for each trait, condition, or disease association we test, we explain whether the result is based on established research – meaning that the topic meets 23andMe's criteria for findings that are very likely to reflect real effects. The scientific community has largely reached consensus on these topics. We also explain whether the result is based on preliminary research – meaning that these studies still need to be confirmed by the scientific community. It also includes topics where there may be contradictory evidence. The results of these studies are not conclusive. We report associations based on preliminary research so that our customers know the most current information about what their genome says, but we provide the customers with contextual information so they know the research is preliminary.

When a customer receives his or her results related to a disease association, the customer receives the risk prediction in context of the average person's risk versus the risk for a customer with his or her genetic variations. We also educate our customers about the importance of the environment and other factors that also may influence their risk of disease. Disease is not determined by the genome alone. We provide extensive information about the condition and next steps, including encouraging customers to discuss their results with their physicians and to consult genetic counselors.

D. Updates on Changing Data

We are committed to keeping our customers educated on new scientific advances. After customers receive their initial results, we update them on new scientific findings. As new scientific studies uncover new information that changes our understanding of the genome and its meaning, we tell our customers how this new information changes their results. We believe customers have a right to be updated when advances in science change our understanding of their genomes, so we do not cut off our customers after one look – or a year of looks – at their information.

E. Emphasis on Physician and Genetic Counseling Support If Customers Have Questions

As stated, if customers have questions, we recommend that they should coordinate the receipt of their information with physicians or a genetic counselor. We do not offer genetic counseling services directly and in fact believe it is important for counselors to be independent of the company. We have provided links to such services previously and since early June 2010, we have offered our customers a referral to Informed Medical Decisions, Inc. (InformedDNA), an independent provider of genetic counseling services staffed by certified genetic counselors. These genetic counselors are trained professionals, who have additional training about the services and results that 23andMe provides.

To be clear, there is no financial relationship between 23andMe and InformedDNA. However, we do provide InformedDNA with background information about 23andMe's test offerings so that InformedDNA's genetic counselors will be prepared to discuss the tests we offer our customers. This service is optional for 23andMe customers, and customers who choose InformedDNA for genetic counseling services pay InformedDNA directly.

23andMe partnered with InformedDNA because it is the largest independent network of genetic counselors and is the only national provider whose services are a covered benefit for most individuals with commercial health insurance. (See Attachment D).

III. Concerns About DTC Genetic Testing

We recognize that there are concerns about customers having direct access to genetic testing, including the risk that individuals might make poor choices based on their results, and consistency of results among the different companies in this sector. We take those concerns extremely seriously.

A. Genetic Concerns

The best way to avoid poor choices is to have educated customers. Here are some of the things we are doing to educate customers: We have created educational videos that are on our public website (these have over 140,000 views on Youtube and are used by schools for genetic education). Our health reports have extensive information including description of the underlying scientific literature upon which reports are based, citations to these studies, the interplay between genes and the environment, and technical information and additional resources for those who are interested. We also educate the broader community. We have offered free genotyping to hundreds of physicians so they can learn about their data and understand their patients' needs, we are involved in medical school programs to further genetics understanding, and we are involved in numerous third-party research studies – some of which are described below.

With respect to concerns about people making poor choices, there is excellent scientific research being conducted about the impact and utility of DTC genetic testing. For example, the National Human Genome Research Institute and the National Cancer Institute of NIH, along with the Group Health Cooperative in Seattle and the Henry Ford Health System in Detroit, launched the "Multiplex Initiative" in May 2007 to study 2,000 people in Detroit who were offered a multiplex genetic test for eight common conditions. This study has shown that consumers understand that both genes and environment contribute to disease risk. As part of this research, researchers found that "[i]ndividuals who present to health care providers with online genetics information may be among the most motivated to take steps toward healthier lifestyles. These motives might be leveraged by health care providers to promote positive health outcomes." There is more to come, and it will educate all of us about what the actual issues might be and how to address them.

We want to better understand these issues ourselves, and to that end, 23andMe has worked with the Genetics and Public Policy Center at Johns Hopkins University to conduct an independent study of how 23andMe customers understand and use their results. We expect these results to be released later this summer, and we will keep you informed about them. We are also working on a related study with Stanford University.

23andMe has over 50,000 customers, and through monitoring community feedback, we are confident that DTC genetic testing has a positive impact on customers' lives.

B. The June 2010 Sample Mix-Up

Regarding concerns about accuracy and reliability, let me briefly address the reported June 2010 incident in which customers received results belonging to other people. A single human error by a certified technician at our contracted laboratory caused this incident. The technician accidentally and wrongly inverted a plate by 180 degrees, causing valid results for plate samples to be matched with the wrong person's name. This mismatching error at the laboratory led to 23andMe's receipt of mismatched results that were then transmitted to customers, affecting eighty-seven customers in all.

23andMe responded to the problem as soon as we learned of it from our community by notifying customers and removing the mismatched results in less than 24 hours. We were then able to give the customers their correct results within six days. While 23andMe regrets the error and takes the incident seriously, the company rapidly resolved it. Since the incident, both 23andMe and our laboratory have further strengthened our quality control systems to prevent such problems. The laboratory error that occurred here could have happened in any laboratory for any genetic tests coming from any hospital, doctor's office, or other laboratory client – it was not a problem uniquely related to 23andMe samples or DTC services to any extent. (See Attachment E).

C. Standards Setting

We fully appreciate the concerns that different companies can return different risk predictions, which can happen even when the tests are accurate. There are several scientific reasons for differences: companies employ slightly different criteria for the inclusion of disease-associated markers in their reports; new associations between genetic markers and diseases are being discovered at a rate faster than companies' development cycles; and companies test for an imperfectly overlapping set of genetic variants for reasons including the ability of different genotyping technologies to assay certain variants. We have asked NIH and FDA to help on this point. In addition, the industry is already looking to other reputable, independent entities that could take up this challenge, such as NIST, an independent standard setting entity.

IV. How DTC Genetic Testing and 23andMe Helps Consumers Improve Their Lives

Over the past decade, scientists have discovered that an increasing number of diseases can be linked to variations in an individual's DNA. These discoveries have launched the revolution in personal health, empowering individuals as never before to manage their personal health before they get sick. Thanks to such advances, we now understand that each of us is born with genetic predispositions for developing diseases.

In some cases, this information can truly save a life. A striking example is that of Kirk Citron. Kirk found out from 23andMe that he had about three times the normal risk for venous thromboembolism – something he never would have suspected. Knowing this information, Kirk did a little digging and found out his father's father had a blood clotting condition that had him on blood thinners for the last 20 years of his life. A few weeks later, Kirk tore his ACL and was told he needed to have knee surgery (which is one of the risk factors for blood clots).

Kirk went to his primary doctor and his orthopedist and told them he was worried about the risk, given his family history and his DNA test. Both doctors were somewhat dismissive of Kirk's concerns, but Kirk was insistent enough that they agreed to change the post-surgery protocol to give Kirk five days of blood thinner.

Kirk had the surgery and had the five days of blood thinner. Five days later, he suddenly felt short of breath. Kirk saw his doctor and was immediately admitted to the hospital – he had experienced a pulmonary embolism – a blood clot that traveled to his lung.

In discussing it afterwards, Kirk's doctor said two things: first, the fact that Kirk had been on the blood thinner for five days almost certainly meant that the attack was much less severe than it might have been (it could have been fatal). Second, having the information ahead of time allowed Kirk's doctor to make the diagnosis much faster than otherwise would have been the case. Once Kirk was in the hospital, and on a new round of blood thinners, he was out of danger, and now is home and doing just fine.

Our tests also detect genetic variations that have been linked with heart attacks, Crohn's Disease, macular degeneration, Parkinson's disease, Type 2 diabetes, and many others. As scientists continue to make breakthroughs, the number of diseases we can test for will only increase. Because new, reliable studies are being published weekly, even daily, we are regularly adding traits, diseases, and conditions to our testing. As we do so, we educate our customers on these latest scientific discoveries as they happen, but we only link them to our customers' personal data after we determine that they meet our standards of reliability.

23andMe's DTC service is consistent with the FDA's long history of approving at-home, over-the-counter tests for HIV, hepatitis, and fecal blood (which might be caused by colon cancer). In addition, FDA already permits customers to have direct access to tests for potentially less worrisome conditions, such as high cholesterol and pregnancy. As the FDA explains on its website, these tests help consumers "detect possible health conditions when [they] have no symptoms, so [they] can get early treatment and lower [their] chance of developing later complications ... [and] detect specific conditions when there are no signs so that [they] can take immediate action." (See Attachment F). Although the results of the FDA-approved, over-the-counter tests may lead to customers receiving potentially distressing information, the FDA has permitted consumers to have direct access to these tests. Our tests are even less worrisome, as they do not diagnose a disease but rather only provide more limited data.

V. How DTC Genetic Testing and 23andMe Help Develop and Accelerate Medical Research

Besides the direct consequences of genetic testing on healthcare, 23andMe is also strongly rooted in the development of innovative solutions for accelerating medical research. One of the unique features of 23andMe's DTC genotyping service is the company's focus on 23andWe, a community-centered research effort in which consumers are encouraged to contribute to medical science by answering surveys.

To date, through 23andWe surveys, 23andMe has amassed one of the largest databases of genetic and health information in existence. This database includes over 50,000 customers, of whom more than half have participated in at least one survey, and of whom roughly 10% have participated in at least 20 surveys in total. Our customers have answered over 10 million research questions. Last month, we published our first paper describing the results of a number of replications and several novel findings based on our customer data in the open access, peer-reviewed journal PLoS Genetics, and many more publications covering novel associations with more serious medical conditions are on the way.

We believe that this model of research has the potential to transform research in this field in two specific ways. First, unlike most research studies to date where the primary source of funding has been a government agency such as the NIH, our research model has been primarily driven by consumer interest. Second, our active cohort of

engaged customers has enabled us to pursue research into over 600 health conditions simultaneously, in contrast to traditional approach of funding a genotyping study for a single health condition at a time. This allows research to proceed at a much faster pace than possible in more traditional settings. For example, in March 2009, we began a project to study the genetics of Parkinson's disease. In less than a year, we were able to assemble a database of nearly 4,000 genotyped patients with Parkinson's disease, which enabled us to replicate previous findings as well as to discover a number of novel associations that had not previously been reported in the scientific literature. These novel associations are not yet reported to our customers because they have not yet been published in a peer-reviewed journal, which is one of our standards for inclusion.

Because we have such a large research database and engaged customers, we are able to assess the clinical significance of genome associations. We are in a unique position to tell our customers, and the community, how clinically significant this information is.

VI. 23andMe Supports a Strengthened Regulatory Framework for DTC Genetic Testing

23andMe has been working with federal authorities – and looks forward to continuing to work with them – on improving the regulatory framework for all diagnostic testing, including genetic testing. These are complicated issues, as evidenced by the fact that FDA just held a two-day meeting this week and heard from numerous medical, laboratory, academic, and industry groups about how to change the regulation of laboratory testing. We have met with the FDA several times and have had discussions with them on how they might regulate this new industry that does not fit squarely into any existing regulatory paradigm. We have also engaged with other officials at the U.S. Department of Health and Human Services and NIH.

We have been working on a proposed framework that we will present to the FDA tomorrow. This framework takes into account rapid technological innovation, and will ensure the analytical and clinical validity of all laboratory tests. We hope that the framework will lead to a scalable regulatory system for the FDA to adopt.

VII. Conclusion

Thank you again, Chairman Stupak, Ranking Member Burgess, and Members of the Subcommittee for giving me the opportunity to speak with you today and for your work on these issues.

Attachment A

National Genetics Institute

HOME COMPANY TESTING SERVICES LIBRARY CONTACT

Testing Services Overview

National Genetics Institute (NGI) provides advanced clinical genetics testing services for blood screening, medical testing, and clinical research. The company offers industry leading assays for human immunodeficiency virus (HIV), hepatitis A, B, and C (HAV, HBV, and HCV) viruses and other infectious agents and has pioneered robust, sensitive, and high throughput methods for pooled specimen nucleic acid testing.

NGI is a leading provider of nucleic acid screening services to the global biotechnology industry and screens millions of plasma donations a year for blood borne infectious agents (Screening Services). The company also provides its advanced genetic testing services to physicians, hospitals, and clinics (Medical Testing) and has supported numerous pharmaceutical and biotechnology companies in the clinical development of new infectious disease and oncology therapies (Clinical Research Services).

NGI is licensed as a clinical laboratory provider by both state and federal agencies, participates in a number of approved quality control programs, and holds active Biologics Licenses from the US Food and Drug Administration (FDA) for screening of plasma for blood borne infectious agents.

Test Menu

NGI offers a range of advanced genetics assays. Select a specific test below to obtain additional test information.

Please select one..

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LabCorp

Attachment B

terms of service

1. Definitions

- **"23andMe"** means 23andMe, Inc., whose principal place of business is at 1390 Shorebird Way, Mountain View, CA 94043.
- **"23andWe Research"** means scientific research that 23andMe performs with the intent to publish in a peer-reviewed scientific journal. 23andWe Research only uses Genetic and Self-Reported Information from users who have given consent according to the applicable Consent Document. 23andWe Research activities do not include R&D.
- **"R&D"** means research and development activities performed by 23andMe on user data. These activities may include, among other things, improving our Services and/or offering new products or services to you; performing quality control activities; conducting data analysis that may lead to and/or include commercialization with a third party.
- **"Service"** or **"Services** means 23andMe's products, software, services, and website (including but not limited to text, graphics, images, and other material and information) as accessed from time to time by the user, regardless if the use is in connection with an account or not.
- **"Personal Information"** is information that can be used to identify you, either alone or in combination with other information. 23andMe collects and stores the following types of Personal Information:
  - **"Registration Information"** is the information you provide about yourself when registering for and/or purchasing our Services (e.g. name, email, address, user ID and password, and payment information).
  - **"Genetic Information"** is information regarding your genotype (e.g. the As, Ts, Cs, and Gs at particular locations in your genome), generated through processing of your saliva by 23andMe or by its contractors, successors, and assignees; or otherwise processed by and/or contributed to 23andMe.
  - **"Self-Reported Information"** is all information about yourself, including your disease conditions, other health-related information, personal traits, ethnicity, family history, and other information that you enter into surveys, forms, or features while signed in to your 23andMe account. Self-Reported Information is included in 23andWe Research only if it has been indicated for 23andWe Research use on the website and if you have given consent as described in the applicable Consent Document.
  - **"User Content"** is all information, data, text, software, music, audio, photographs, graphics, video, messages, or other materials - *other than* Genetic Information and Self-Reported Information-generated by users of 23andMe Services and transmitted, whether publicly or privately, to or through 23andMe.
  - **"Web Behavior Information"** is information on how you use the 23andMe website (e.g. browser type, domains, page views) collected through log files, cookies, and web beacon technology.

- **"Aggregated Genetic and Self-Reported Information"** is Genetic and Self-Reported Information that has been stripped of Registration Information and combined with data from a number of other users sufficient to minimize the possibility of exposing individual-level information while still providing scientific evidence.

2. Acceptance of Terms

Your use of 23andMe's Services (excluding any services provided by 23andMe under a separate agreement) is subject to the terms of the legal agreement between you and 23andMe set forth in these Terms of Service (**"TOS"**). Except as specified herein, these TOS apply to any use of the Services, including but not limited to a) submitting a saliva sample for DNA extraction and processing, b) uploading a digital version of your Genetic Information and interacting with it on the 23andMe website, and/or c) creating and using a free 23andMe account without providing your saliva sample or Genetic Information. In order to use the Services, you must first agree to the TOS. You may not use the Services if you do not accept the TOS. You can accept the TOS by (1) clicking to accept or agree to the TOS, where this option is made available to you by 23andMe for any Service; or by (2) actually using the Services. In this case, you acknowledge and agree that 23andMe will treat your use of the Services as acceptance of the TOS from that point onwards. In addition, when using particular 23andMe Services, you shall be subject to any guidelines or rules applicable to such services that may be posted from time to time. All such guidelines or rules are hereby incorporated by reference into the TOS. 23andMe also may offer other services from time to time that are governed by different terms of service.

3. Prerequisites

a. Whether you submit your own saliva sample, a saliva sample for anyone for whom you have legal authority to agree, or otherwise provide your own Genetic Information, you may not use the Services and may not accept the TOS if (1) you are not of legal age to form a binding contract with 23andMe, or (2) you are a person barred from receiving the Services under the laws of the jurisdiction in which you are resident or from which you use the Services.
b. In addition to the conditions above, if you contribute or otherwise provide your own Genetic Information, you must be eighteen (18) years of age or older to agree to these TOS on behalf of yourself or those for whom you have legal authority to agree.
c. If your use of the Services includes creating a 23andMe account, without submitting a saliva sample or otherwise providing Genetic Information, you must be thirteen (13) years of age or older to use the Services and accept the TOS.

4. Description of the Services

The Services include access to the 23andMe public website and personal genotyping services, including the collection and analysis of your saliva sample. Unless explicitly stated otherwise, each new feature that augments or enhances the current Service shall be subject to the TOS. You acknowledge and agree that the Services are provided "AS-IS" and are based on the current state of the art of genetic research and technology in use by 23andMe at the time of the purchase or viewing. As research progresses and scientific knowledge and technology evolve, 23andMe is constantly innovating in order to provide the best possible experience for its users. You acknowledge and agree that the

form and nature of the Services which 23andMe provides may change from time to time without prior notice to you. As part of this continuing innovation, you acknowledge and agree that 23andMe may stop (permanently or temporarily) providing some Services (or any features within the Services) to you or to users generally at 23andMe's sole discretion, without prior notice to you. You may stop using the Services at any time. You do not need to specifically inform 23andMe when you stop using the Services unless you are requesting closure of your account. 23andMe assumes no responsibility for the use of Services outside the terms of this TOS or other applicable terms.

In order to use the Services, you must obtain Internet access, either directly or through devices that access web-based content, and pay any service fees associated with such access. You are solely responsible for paying such fees. In addition, you must provide all equipment necessary to make such Internet connection, including a computer and modem or other access device. You are solely responsible for providing such equipment. You acknowledge and agree that while 23andMe may not currently have set a fixed upper limit on the number of transmissions you may send or receive through the Services or on the amount of storage space used for the provision of any Service, such fixed upper limits may be set by 23andMe at any time, at 23andMe's discretion.

5. Risks and Considerations Regarding 23andMe Services

Once you obtain your Genetic Information, the knowledge is irrevocable. You should not assume that any information we may be able to provide to you, whether now or as genetic research advances, will be welcome or positive. You should also understand that as research advances, in order for you to assess the meaning of your DNA in the context of such advances, you may need to obtain further services from 23andMe or from your physician or other health care provider.

You may learn information about yourself that you do not anticipate. This information may evoke strong emotions and has the potential to alter your life and worldview. You may discover things about yourself that trouble you and that you may not have the ability to control or change (e.g., your father is not genetically your father, surprising facts related to your ancestry, or that someone with your genotype may have a higher than average chance of developing a specific condition or disease). These outcomes could have social, legal, or economic implications.

The laboratory may not be able to process your sample, and the laboratory process may result in errors. The laboratory may not be able to process your sample if your saliva does not contain a sufficient volume of DNA, you do not provide enough saliva, or the results from processing do not meet our standards for accuracy. If the initial processing fails for any of these reasons, 23andMe will reprocess the same sample at no charge to the user. If the second attempt to process the same sample fails, 23andMe will offer to send another kit to the user to collect a second sample at no charge. If the user declines this option, the user is entitled solely and exclusively to a complete refund of the amount paid to 23andMe, less shipping and handling, provided that the user shall not resubmit another sample through a future purchase of the service. If the user opts to receive another sample collection kit and 23andMe's attempts to process the second sample are unsuccessful, 23andMe will not send additional sample collection kits and the user will be entitled solely and exclusively to a complete refund of the amount paid to 23andMe, less shipping and handling, provided the user shall not resubmit another sample through a future purchase of the service. If the user breaches this policy agreement and resubmits another sample through a future purchase of the service and processing is not successful, 23andMe will not offer to reprocess the sample or provide the user a refund. Even for processing that meets our high standards, a small, unknown fraction of the data generated during the laboratory process may be un-interpretable or incorrect (referred to as "Errors"). As this possibility is known in advance, users are not entitled to refunds where these Errors occur.

You should not change your health behaviors solely on the basis of information from 23andMe. Make sure to discuss your Genetic Information with a physician or other health care provider before you act upon the Genetic Information resulting from 23andMe Services. For most common diseases, the genes we know about are only responsible for a small fraction of the risk. There may be unknown genes, environmental factors, or lifestyle choices that are far more important predictors. If your data indicate that you are not at elevated genetic risk for a particular disease or condition, you should not feel that you are protected. The opposite is also true; if your data indicate you are at an elevated genetic risk for a particular disease or condition, it does not mean you will definitively develop the disease or condition. In either case, if you have concerns or questions about what you learn through 23andMe, you should contact your physician or other health care provider.

Genetic research is not comprehensive. While we measure many hundreds of thousands of data points from your DNA, only a small percentage of them are known to be related to human traits or health conditions. The research community is rapidly learning more about genetics, and an important mission of 23andMe is to conduct and contribute to this research. In addition, many ethnic groups are not included in genetic studies. Because interpretations provided in our service rely on these published studies, some interpretations may not apply to you. Future scientific research may change the interpretation of your DNA. In the future, the scientific community may show previous research to be incomplete or inaccurate.

Genetic Information you share with others could be used against your interests. You should be careful about sharing your Genetic Information with others. In the future, businesses or insurance companies may request Genetic Information. The Genetic Information Nondiscrimination Act was signed into law in the United States in 2008, and some, but not all, states and countries have laws that protect individuals with regard to their Genetic Information. You may want to consult a lawyer to understand the extent of legal protection of your Genetic Information before you share it with anybody.

Furthermore, Genetic Information that you choose to share with your physician or other health care provider may become part of your medical record and through that route be accessible to other health care providers and/or insurance companies in the future. Genetic Information that you share with family, friends or employers may be used against your interests. Even if you share Genetic Information that has no or limited meaning today, that information could have greater meaning in the future as new discoveries are made. If you are asked by an insurance company whether you have learned Genetic Information about health conditions and you do not disclose this to them, this may be considered to be fraud.

23andMe Services are for research, informational, and educational use only. We do not provide medical advice. The Genetic Information provided by 23andMe is for research, informational, and educational use only. This means two things. First, many of the genetic discoveries that we report have not been clinically validated, and the technology we use, which is the same technology used by the research community, to date has not been widely used for clinical testing. Second, in order to expand and accelerate the understanding and practical application of genetic knowledge in health care, we invite all genotyped users to participate in 23andWe Research. Participation in such research is voluntary and based upon an IRB-approved consent document. As a result of the current state of genetic knowledge and understanding, our Services are for research, informational, and educational purposes only. The Services are not intended to be used by the customer for any diagnostic purpose and are not a substitute for professional medical advice. You should always seek the advice of your

physician or other health care provider with any questions you may have regarding diagnosis, cure, treatment, mitigation, or prevention of any disease or other medical condition or impairment or the status of your health.

23andMe does not recommend or endorse any specific course of action, resources, tests, physician or other health care providers, drugs, biologics, medical devices or other products, procedures, opinions, or other information that may be mentioned on our website. As explained on our website, 23andMe believes that (a) genetics is only part of the picture of any individual's state of being, (b) the state of the understanding of Genetic Information is rapidly evolving and at any given time we only comprehend part of the picture of the role of genetics, and (c) only a trained physician or other health care provider can assess your current state of health or disease, taking into account many factors, including in some cases your genetics as well as your current symptoms, if any. Reliance on any information provided by 23andMe, 23andMe employees, others appearing on our website at the invitation of 23andMe, or other visitors to our website is solely at your own risk.

While we are licensed in California as a clinical laboratory, not all jurisdictions require our Services to be subject to license. Therefore, we are not universally licensed by all state, federal, or international authorities for genetic testing conducted for health and disease-related purposes. In addition, there are certain jurisdictions in which we do not offer our Services because we do not have required licenses.

6. User Representations

By accessing 23andMe Services, you agree to, acknowledge, and represent as follows:

a. You understand that information you learn from 23andMe is not designed to diagnose, prevent, or treat any condition or disease or to ascertain the state of your health and that you understand that the 23andMe services are intended for research, informational, and educational purposes only. You acknowledge that 23andMe urges you to seek the advice of your physician or other health care provider if you have questions or concerns arising from your Genetic Information.
b. You give permission to 23andMe, its contractors, successors and assignees to perform genotyping services on the DNA extracted from your saliva sample and to disclose the results of analyses performed on your DNA to you and to others you specifically authorize.
c. You represent that you are eighteen (18) years of age or older if you are providing a saliva sample or accessing your Genetic Information.
d. You are guaranteeing that any sample you provide is your saliva; if you are agreeing to these TOS on behalf of a person for whom you have legal authorization, you are confirming that the sample provided will be the sample of that person.
e. If you are a customer outside the U.S. providing a saliva sample, you confirm that this act is not subject to any export ban or restriction in the country in which you reside.
f. You agree that any saliva sample you provide and all resulting data may be transferred and/or processed outside the country in which you reside.
g. You are warranting that you are not an insurance company or an employer attempting to obtain information about an insured person or an employee.
h. You are aware that some of the information you receive may provoke strong emotion.
i. You take responsibility for all possible consequences resulting from your sharing with others access to your Genetic Information and your Self-Reported Information.
j. You understand that all your Personal Information will be stored in 23andMe databases and will be processed in accordance with the 23andMe Privacy Statement.
k. Waiver of Property Rights: You understand that by providing any sample, having your Genetic Information processed, accessing your Genetic Information, or providing Self-Reported Information, you acquire no rights in any research or commercial products that may be developed by 23andMe or its collaborating partners. You specifically understand that you will not receive compensation for any research or commercial products that include or result from your Genetic Information or Self-Reported Information.

You agree that you have the authority, under the laws of the state or jurisdiction in which you reside, to provide these representations. In case of breach of any one of these representations 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Services (or any portion thereof) and you will defend and indemnify 23andMe and its affiliates against any liability, costs, or damages arising out of the breach of the representation.

7. Account Creation, Customer Account, Password, and Security Obligations

In consideration of your use of the Services, you agree to: (a) provide true, accurate, current, and complete Registration Information about yourself as prompted by the Service; and (b) maintain and promptly update the Registration Information to keep it true, accurate, current, and complete. If you provide any Registration Information that is untrue, inaccurate, not current, or incomplete, or if 23andMe has a reasonable ground to suspect that such information is untrue, inaccurate, not current, or incomplete, 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Service (or any portion thereof).

After you have purchased our Service, you will create a password and account designation. You are responsible for maintaining the confidentiality of the password and account, and are fully responsible for all activities that occur under your password or account. If you allow third parties to access 23andMe's website through your username and password, you will defend and indemnify 23andMe and its affiliates against any liability, costs, or damages, including attorney fees, arising out of claims or suits by such third parties based upon or relating to such access and use. You agree to (a) immediately notify 23andMe of any unauthorized use of your password or account or any other breach of security, and (b) ensure that you exit from your account at the end of each session. 23andMe cannot and will not be liable for any loss or damage arising from your failure to comply with this Section.

8. 23andMe Privacy Statement and Disclosure of Information

In order to use the Services, you must first acknowledge and agree to the Privacy Statement. You may not use the Services if you do not accept the Privacy Statement. You can acknowledge and agree to the Privacy Statement by (1) clicking to accept or agree to the Privacy Statement, where this option is made available to you by 23andMe for any Service; or by (2) actually using the Services.

You acknowledge and agree that 23andMe has the right to monitor any use of its systems by its personnel at any time and maintain copies documenting such monitoring. Our Privacy Statement sets forth the only expectations of privacy any individual should have in terms of usage of the 23andMe Services, website, or other systems. If you have given consent for your Genetic Information and Self-Reported Information to be used in 23andWe Research as described in the applicable Consent Document, we may include your information in the

Aggregated Genetic Information and Self-Reported Information we disclose to third parties for the purpose of publication in a peer-reviewed scientific journal. 23andMe may also include your information in Aggregated Genetic and Self-Reported Information disclosed to third-party non-profit and/or commercial research partners who will not publish that information in a peer-reviewed scientific journal. 23andMe will never release your individual-level Genetic Information and/or Self-Reported Information to any third party without asking for and receiving your explicit consent to do so, unless required by law. Further, you acknowledge and agree that 23andMe is free to preserve and disclose any and all Personal Information to law enforcement agencies or others if required to do so by law or in the good faith belief that such preservation or disclosure is reasonably necessary to: (a) comply with legal process (such as a judicial proceeding, court order, or government inquiry) or obligations that 23andMe may owe pursuant to ethical and other professional rules, laws, and regulations; (b) enforce the 23andMe TOS; (c) respond to claims that any content violates the rights of third parties; or (d) protect the rights, property, or personal safety of 23andMe, its employees, its users, its clients, and the public. In such event we will notify you through the contact information you have provided to us in advance, unless doing so would violate the law or a court order. You understand that the technical processing and transmission of the Services, including your Personal Information, may involve (a) transmissions over various networks; and (b) changes to conform and adapt to technical requirements of connecting networks, or devices. Finally, 23andMe may, in its sole discretion, restrict access to the website for any reason.

Please refer to our Privacy Statement to read about data protection related to your information. See our complete Privacy Statement here.

9. Limited License

You acknowledge that all User Content, whether publicly posted or privately transmitted, is the sole responsibility of the person from which such User Content originated. This means that you, and not 23andMe, are entirely responsible for all User Content that you upload, post, email, or otherwise transmit via the Service.

You acknowledge that the Services content presented to you as part of the Services, whether original 23andMe Services content or sponsored content within the Services, is protected by copyright and/or other intellectual property rights that are owned by 23andMe and/or the sponsors who provide that content to 23andMe (or by other persons or companies on their behalf). 23andMe grants you a Limited License to copy and distribute free of charge, for non-commercial purposes only, any of the Services content with the exception of content from "MD's Perspectives" in the "For the Experts" section of the website and any other content marked as not subject to this Limited License on the website, provided you: (i) provide the Services content as it appears on the 23andMe website with no changes including but not limited to presenting selections which might tend to misrepresent the substance of the Services content; (ii) include the following attribution on the first page of any materials you distribute: © 23andMe, Inc. 2008-2010. All rights reserved; distributed pursuant to a Limited License from 23andMe; (iii) agree you have no right to offer anyone else any further right with respect to this Services content. Aside from the Limited License provided in this paragraph, you may not modify, rent, lease, loan, sell, distribute, or create derivative works based on this Services content (either in whole or in part) unless you have been specifically told that you may do so by 23andMe or by the owners of that content, in a separate agreement.

10. Customer Conduct - Unlawful and Prohibited Use

As a condition of your use of the Services, you warrant to 23andMe that you will not use the Services for any purpose that is unlawful or prohibited by these terms, conditions, or notices. You may not use the Services in any manner that could damage, disable, overburden, or impair the Services or interfere with any other party's use and enjoyment of the Services. You may not obtain or attempt to obtain any materials or information through any means not intentionally made available or provided for through the Services. Furthermore you agree not to use the Services to: (1) upload, post, email, or otherwise transmit any material that is derogatory, defamatory, obscene, or offensive, such as slurs, epithets, or anything that might reasonably be construed as harassment or disparagement based on race, color, national origin, sex, sexual orientation, age, disability, religious or political beliefs, or other statutorily protected status; (2) impersonate any person or entity, including, but not limited to, anyone affiliated with 23andMe, or falsely state or otherwise misrepresent your affiliation with a person or entity; (3) add your own headers, forge headers, or otherwise manipulate identifiers in order to disguise the origin of any content transmitted through the Service; (4) "stalk" or otherwise harass another; (5) upload, post, email, or otherwise transmit any content that you do not have a right to transmit under any law or under contractual or fiduciary relationships (such as inside information, proprietary and confidential information learned or disclosed as part of employment relationships or under nondisclosure agreements); (6) download any file posted by another user of the Service that you know, or reasonably should know, cannot legally be distributed in such manner; (7) upload, post, email or otherwise transmit any content that infringes any patent, trademark, trade secret, copyright, or other proprietary rights ("Rights") of 23andMe or any other party; (8) harm minors in any way; (9) advertise or offer to sell or buy any goods or services for any business purpose, unless such area specifically allows such messages; (10) upload, post, email, or otherwise transmit any unsolicited or unauthorized advertising, promotional materials, "junk mail," "spam," "chain letters," "pyramid schemes," or any other form of solicitation, except in those areas that are designated for such purpose and only to the extent such content is authorized by law; (11) upload, post, email, or otherwise transmit any material that contains software viruses or any other computer code, files, or programs designed to interrupt, destroy, or limit the functionality of any computer software or hardware or telecommunications equipment; (12) interfere with or disrupt the Service or servers or networks connected to the Service, or disobey any requirements, procedures, policies, or regulations of networks connected to the Service; (13) violate these Terms of Service, any code of conduct or other guidelines which may be applicable for any particular area of the Service or have been communicated to you by anyone affiliated with 23andMe; or (14) intentionally or unintentionally violate any applicable local, state, national, or international law, or any regulations having the force of law.

You acknowledge and agree that you are solely responsible for (and that 23andMe has no responsibility to you or to any third party for) any breach of your obligations under the TOS and for the consequences (including any loss or damage which 23andMe may suffer) of any such breach. In case of breach of any one of these agreements 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Services (or any portion thereof) and you will defend and indemnify 23andMe and its affiliates against any liability, costs, or damages arising out of the breach of the representation.

If you violate the terms of this Section and/or 23andMe has a reasonable ground to suspect that you have violated the terms of this Section, 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Service (or any portion thereof).

11. Export Control and Applicable Laws and Regulations

Recognizing the global nature of the Internet, you agree to comply with all local rules regarding online conduct and acceptable content. Specifically, you agree 1) that providing your sample is not subject to any export ban or restriction in the country in which you reside, 2) that

your sample and data may be transferred and/or processed outside the country in which you reside, and 3) that you will comply with all applicable laws regarding the transmission of technical data exported from the United States or the country from which you access 23andMe's Services online.

12. Material Posted Through The Service

23andMe will not, at all times, control any of the User Content posted via the Service and, as such, does not guarantee the accuracy, integrity, or quality of such non-23andMe content. You understand that by using the Services, you may be exposed to content that is offensive, indecent, or objectionable. Under no circumstances will 23andMe be liable in any way for any non-23andMe content, including, but not limited to, any errors or omissions in any such content, or for any loss or damage of any kind incurred as a result of the use of any such content posted, emailed, or otherwise transmitted via the Services.

You acknowledge that 23andMe and its designees shall have the right (but not the obligation) in their sole discretion to pre-screen, review, filter, modify, refuse, or move any content that is available via the Services. Without limiting the foregoing, 23andMe and its designees shall have the right to remove any content that violates the TOS or is deemed by 23andMe, in its sole discretion, to be otherwise objectionable. You acknowledge and agree that you must evaluate, and bear all risks associated with, the use of any content, including any reliance on the accuracy, completeness, or usefulness of such content.

13. Material Provided to 23andMe - Your Proprietary Rights

User Content. 23andMe does not claim ownership of the User Content you provide to 23andMe (including feedback and suggestions) or post, upload, input, or submit to the Service. Unless otherwise specified, you retain copyright and any other rights you already hold over User Content that you create and submit, post, or display on or through the Services. However, by submitting, posting, or displaying User Content, you give 23andMe, its affiliated companies, sublicensees (including but not limited to sublicensees who avail themselves of the Limited License granted in Section 9 above) and successors and assigns a perpetual, irrevocable, worldwide, royalty-free, and non-exclusive license to reproduce, adapt, modify, translate, publish, publicly perform, publicly display, distribute, reproduce, edit, reformat, and create derivative works from any User Content that you submit, post, or display on or through the Services. You acknowledge and agree that this license includes a right for 23andMe to make such User Content available to other companies, organizations, or individuals with whom 23andMe has relationships, and to use such User Content in connection with the provision of those services.

You understand that 23andMe, in performing the required technical steps to provide the Services to our users, may (a) transmit or distribute your User Content over various public networks and in various media; and (b) make such changes to your content as are necessary to conform and adapt that content to the technical requirements of connecting networks, devices, services, or media. You acknowledge and agree that this license shall permit 23andMe to take these actions. You represent and warrant to 23andMe that you have all the rights, power, and authority necessary to grant the above license.

Genetic and/or Self-Reported Information. Disclosure of individual-level Genetic and/or Self-Reported Information to third parties will not occur without explicit consent, unless required by law. Note that 23andMe cannot control any further distribution of Genetic and/or Self-Reported Information that you share publicly on the 23andMe website. You acknowledge and agree that you are responsible for protecting and enforcing those rights and that 23andMe has no obligation to do so on your behalf.

Your saliva sample, once submitted to and analyzed by us, is processed in an irreversible manner and cannot be returned to you. See our website for more information on sample processing. Any Genetic Information derived from your saliva remains your information, subject to rights we retain as set forth in these TOS. You understand that you should not expect any financial benefit from 23andMe as a result of having your Genetic Information processed; made available to you; or, as provided in our Privacy Statement and Terms of Service, shared with or included in Aggregated Genetic and Self-Reported Information shared with research partners, including commercial partners.

Waiver of Property Rights. As stated above, you understand that by providing any sample, having your Genetic Information processed, accessing your Genetic Information, or providing Self-Reported Information, you acquire no rights in any research or commercial products that may be developed by 23andMe or its collaborating partners. You specifically understand that you will not receive compensation for any research or commercial products that include or result from your Genetic Information or Self-Reported Information.

14. Indemnity

You agree to defend and hold 23andMe, and its subsidiaries, affiliates, officers, agents, contractors, partners, employees, successors, and assigns harmless from any claim, or demand, including reasonable attorneys' fees, made by any third party due to or arising out of User Content you submit, post to, or transmit through the Service; your use of the Service; your connection to the Service; your violation of the TOS; or your violation of any rights of another.

If you have submitted a saliva sample or otherwise provided your own Genetic Information, you will defend and hold harmless 23andMe, its employees, contractors, successors, and assigns from any liability arising out of the use or disclosure of any information obtained from genotyping your saliva sample and/or analyzing your Genetic Information, which is disclosed to you consistent with our Privacy Statement or results from any third-party add-ons to tools we provide. In addition, if you choose to provide your Genetic and/or Self-Reported Information to third parties - whether individuals to whom you facilitate access, intentionally or inadvertently, or to third parties for diagnostic or other purposes - you agree to defend and hold harmless 23andMe, its employees, contractors, successors, and assigns from any and all liability arising from such disclosure or use of your Genetic and/or Self-Reported Information.

15. No Resale of Service

Other than pursuant to the terms of the Limited License in Section 9 of this TOS or unless otherwise agreed in a separate agreement between you and 23andMe, you agree not to display, distribute, license, perform, publish, reproduce, duplicate, copy, create derivative works from, modify, sell, resell, exploit, transfer, or transmit for any commercial purposes, all or any portion of the Service, use of the Service, or access to the Service.

16. General Practices Regarding Use and Storage

You acknowledge that 23andMe may establish general practices and limits concerning use of the Services, including without limitation the maximum number of days that Personal Information and Services content will be retained by the Service, the maximum disk space that will be allotted on 23andMe's servers on your behalf, and the maximum number of times (and the maximum duration for which) you may access

the Services in a given period of time. You acknowledge and agree that 23andMe has no responsibility or liability for the deletion of or failure to store any messages, other communications, or other content maintained or transmitted by the Services; or for the loss of Genetic Information due to malfunction or destruction of data servers or other catastrophic events. You further acknowledge that 23andMe reserves the right to change these general practices and limits in its sole discretion.

17. Modifications to Service

23andMe reserves the right at any time and from time to time to modify or discontinue, temporarily or permanently, the Services (or any part thereof) with or without notice. You acknowledge and agree that 23andMe shall not be liable to you or to any third party for any modification, suspension, or discontinuance of the Services.

The Software that you use may from time to time automatically download and install updates from 23andMe. These updates are designed to improve, enhance, and further develop the Services and may take the form of bug fixes, enhanced functions, new software modules, and completely new versions. You agree to receive such updates (and permit 23andMe to deliver these to you) as part of your use of the Services.

You acknowledge that 23andMe may offer different or additional technologies to collect and/or interpret Genetic Information in the future and that your initial purchase of the Service does not entitle you to any different or additional technologies for collection or interpretation of your Genetic Information without fee, and that you will have to pay additional fees in order to have your Genetic Information collected, processed, and/or interpreted using any future or additional technologies.

18. Termination

The TOS will continue to apply until terminated by either you or 23andMe as set out in this Section.

If you want to terminate your legal agreement with 23andMe, you may do so by notifying 23andMe at any time in writing, which will entail closing your accounts for all of the Services that you use. Your notice should be sent, in writing, to 23andMe's address, which is set out at the beginning of the TOS.

23andMe may at any time, terminate its legal agreement with you (and in conjunction therewith, your password and account(s)) if: (1) you have breached any provision of the TOS (or have acted in manner which shows that you do not intend to, or are unable to comply with, the provisions of the TOS); (2) 23andMe is required to do so by law (for example, where the provision of the Services to you is, or becomes, unlawful); (3) the partner with whom 23andMe offered the Services to you has terminated its relationship with 23andMe or ceased to offer the Services to you; (4) 23andMe is transitioning to no longer providing the Services to users in the country or state in which you reside or from which you use the Services; or (5) the provision of the Services to you by 23andMe is, in 23andMe's opinion, no longer commercially viable.

Any suspected fraudulent, abusive, or illegal activity that may be grounds for termination of your use of the Services may be referred to appropriate law enforcement authorities. You acknowledge and agree that 23andMe shall not be liable to you or any third party for any termination of your access to the Services.

19. Survival of Terms

When the TOS come to an end, all of the legal rights, obligations, and liabilities that you and 23andMe have benefited from, been subject to (or which have accrued over time while the TOS have been in force) or which are expressed to continue indefinitely, shall be unaffected by this cessation, and the provisions of sections 1.(Definitions); 2.(Acceptance of Terms); 3.(Prerequisites); 4.(Description of the Services); 5.(Risks and Considerations Regarding 23andMe Services); 6.(Representations); 7.(Account Creation, Customer Account, Password and Security Obligations); 8.(23andMe Privacy Statement); 10.(Customer Conduct - Unlawful and Prohibited Use); 11.(Export Control and Applicable Laws and Regulations); 12.(Material Posted through the Service); 13.(Material Provided to 23andMe - Your Proprietary Rights); 14.(Indemnity); 15.(No resale of Services);18.(Termination); 19.(Survival of Terms); 20.(Dealings with Information Providers and Listed Resources); 21.(Hyperlinks and 23andMe Website); 22.(23andMe Proprietary Rights); 23.(DISCLAIMER OF WARRANTIES); 24.(LIMITATION OF LIABILITY); 25.(Notice); 27.(Violation or Suspected Violation of TOS); and 28.(Miscellaneous) shall continue to apply to such rights, obligations, and liabilities indefinitely.

20. Dealings with Information Providers and Listed Resources

Your correspondence or business dealings with-or participation in promotions of-information providers, vendors, and/or resources found on or through the Service, including payment and delivery of related goods or services, and any other terms, conditions, warranties, or representations associated with such dealings, are solely between you and such information provider or resource. You acknowledge and agree that 23andMe shall not be responsible or liable for any loss or damage of any sort incurred as the result of any such dealings or as the result of the presence of such information provider or resources on the Service.

21. Hyperlinks and the 23andMe Website

The Service provides, and third parties may provide, links to other sites and resources on the Internet. Because 23andMe has no control over such sites and resources, you acknowledge and agree that 23andMe is not responsible for the availability of such external sites or resources, and does not endorse and is not responsible or liable for any content, advertising, products, or other materials on or available from such sites or resources. You further acknowledge and agree that 23andMe shall not be responsible or liable, directly or indirectly, for any damage or loss caused or alleged to be caused by or in connection with use of or reliance on any such content, goods, or services available on or through any such hyperlinked site or resource.

22. 23andMe's Proprietary Rights

You acknowledge and agree that 23andMe (or 23andMe's licensors, as applicable) own all legal right, title, and interest in and to the Services, including any intellectual property rights which subsist in the Services (whether those rights happen to be registered or not, and wherever in the world those rights may exist). You further acknowledge that the Services may contain information which is designated confidential by 23andMe and that you shall not disclose such information without 23andMe's prior written consent.

You further acknowledge and agree that the Services and any necessary software used in connection with the Services ("Software") contain proprietary and confidential information that is protected by applicable intellectual property and other laws. You further acknowledge and

agree that information presented to you through the Services or sponsors is protected by copyrights, trademarks, service marks, patents, or other proprietary rights and laws. Except as expressly authorized by 23andMe, you agree not to-and not to permit anyone else to-modify, rent, lease, loan, sell, distribute, or create derivative works of, reverse engineer, decompile, or otherwise attempt to extract the source code of the Services or Software or any part thereof, in whole or in part. Software, if any, that is made available to download from the Services, excluding software that may be made available by end-users through the Services, is the copyrighted work of 23andMe and/or its suppliers. Your use of the Software is governed by the terms of the end user license agreement, if any, which accompanies or is included with the Software ("License Agreement"). You may not install or use any Software that is accompanied by or includes a License Agreement unless you first agree to the License Agreement terms.

23andMe, Inc., 23andMe, and other 23andMe logos and product and service names are trademarks of 23andMe and these marks together with any other 23andMe trade names, service marks, logos, domain names, and other distinctive brand features are the **"23andMe Marks"**. Unless you have agreed otherwise in writing with 23andMe, other than through the Limited License in Section 9, nothing in the TOS gives you a right to use any 23andMe Marks and you agree not to display, or use in any manner, 23andMe Marks.

You agree that you shall not remove, obscure, or alter any proprietary rights notices (including copyright and trade mark notices) that may be affixed to or contained within the Services.

Unless you have been expressly authorized to do so in writing by 23andMe, you agree that in using the Services, you will not use any trade mark, service mark, trade name, logo of any company or organization in a way that is likely or intended to cause confusion about the owner or authorized user of such marks, names, or logos.

For any Software not accompanied by a License Agreement, 23andMe grants you a personal, non-transferable, and non-exclusive right and license to use the object code of its Software on a single computer. You may not (and may not allow any third party to) copy, modify, create a derivative work of, reverse engineer, reverse assemble, or otherwise attempt to discover any source code, sell, assign, sublicense, grant a security interest in, or otherwise transfer any right in the Software unless this is expressly permitted or required by law, or unless you have been specifically told that you may do so by 23andMe, in writing. This license is for the sole purpose of enabling you to use and enjoy the benefit of the Services as provided by 23andMe, in the manner permitted by the TOS. Unless 23andMe has given you specific written permission to do so, you may not assign (or grant a sublicense of) your rights to use the Software, grant a security interest in or over your rights to use the Software, or otherwise transfer any part of your rights to use the Software. You agree not to modify the Software in any manner or form, or to use modified versions of the Software, including (without limitation) for the purpose of obtaining unauthorized access to the Service. You agree not to access the Service by any means other than through the interface that is provided by 23andMe for use in accessing the Service. Any rights not expressly granted herein are reserved.

23. Disclaimer of Warranties

YOU EXPRESSLY ACKNOWLEDGE AND AGREE THAT: (1) YOUR USE OF THE SERVICES ARE AT YOUR SOLE RISK. THE SERVICES ARE PROVIDED ON AN "AS IS" AND "AS AVAILABLE" BASIS. 23ANDME EXPRESSLY DISCLAIMS ALL WARRANTIES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT. (2) 23ANDME MAKES NO WARRANTY THAT (a) THE SERVICES WILL MEET YOUR REQUIREMENTS; (b) THE SERVICES WILL BE UNINTERRUPTED, TIMELY, UNFAILINGLY SECURE, OR ERROR-FREE; (c) THE RESULTS THAT MAY BE OBTAINED FROM THE USE OF THE SERVICES WILL BE ACCURATE OR RELIABLE; (d) THE QUALITY OF ANY PRODUCTS, SERVICES, INFORMATION, OR OTHER MATERIAL PURCHASED OR OBTAINED BY YOU THROUGH THE SERVICES WILL MEET YOUR EXPECTATIONS AND (e) ANY ERRORS IN THE SOFTWARE WILL BE CORRECTED. (3) ANY MATERIAL DOWNLOADED OR OTHERWISE OBTAINED THROUGH THE USE OF THE SERVICES IS DONE AT YOUR OWN DISCRETION AND RISK AND THAT YOU WILL BE SOLELY RESPONSIBLE FOR ANY DAMAGE TO YOUR COMPUTER SYSTEM OR LOSS OF DATA THAT RESULTS FROM THE DOWNLOAD OF ANY SUCH MATERIAL. (4) NO ADVICE OR INFORMATION, WHETHER ORAL OR WRITTEN, OBTAINED BY YOU FROM 23ANDME OR THROUGH OR FROM THE SERVICES SHALL CREATE ANY WARRANTY NOT EXPRESSLY STATED IN THE TOS. (5) YOU SHOULD ALWAYS USE CAUTION WHEN GIVING OUT ANY PERSONALLY IDENTIFYING INFORMATION ABOUT YOURSELF OR THOSE FOR WHOM YOU HAVE LEGAL AUTHORITY. 23ANDME DOES NOT CONTROL OR ENDORSE ANY ACTIONS RESULTING FROM YOUR PARTICIPATION IN THE SERVICES AND, THEREFORE, 23ANDME SPECIFICALLY DISCLAIMS ANY LIABILITY WITH REGARD TO ANY ACTIONS RESULTING FROM YOUR PARTICIPATION IN THE SERVICES.

24. Limitation of Liability

WITHIN THE LIMITS ALLOWED BY APPLICABLE LAWS, YOU EXPRESSLY ACKNOWLEDGE AND AGREE THAT 23ANDME SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES, INCLUDING BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFITS, GOODWILL, USE, DATA OR OTHER INTANGIBLE LOSSES (EVEN IF 23ANDME HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES), RESULTING FROM: (a) THE USE OR THE INABILITY TO USE THE SERVICES; (b) ANY ACTION YOU TAKE BASED ON THE INFORMATION YOU RECEIVE IN THROUGH OR FROM THE SERVICES, (v) YOUR FAILURE TO KEEP YOUR PASSWORD OR ACCOUNT DETAILS SECURE AND CONFIDENTIAL, (d) THE COST OF PROCUREMENT OF SUBSTITUTE GOODS AND SERVICES RESULTING FROM ANY GOODS, DATA, INFORMATION, OR SERVICES PURCHASED OR OBTAINED OR MESSAGES RECEIVED OR TRANSACTIONS ENTERED INTO THROUGH OR FROM THE SERVICES; (e) UNAUTHORIZED ACCESS TO OR ALTERATION OF YOUR TRANSMISSIONS OR DATA; (f) THE IMPROPER AUTHORIZATION FOR THE SERVICES BY SOMEONE CLAIMING SUCH AUTHORITY; or (g) STATEMENTS OR CONDUCT OF ANY THIRD PARTY ON THE SERVICES.

25. Notice

Notices to you may be made via either email or regular mail. 23andMe may also provide notices of changes to the TOS or other matters by displaying notices or links to notices to you generally on or through the Services.

Official notices related to this TOS must be sent to us at: 23andMe, Inc.
ATTN: General Counsel
1390 Shorebird Way
Mountain View, CA 94043

Any notices that you provide without compliance with this section on Notices shall have no legal effect.

26. Changes to the Terms of Service

23andMe may make changes to the TOS from time to time. When these changes are made, 23andMe will make a new copy of the TOS available on its website and any new additional terms will be made available to you from within, or through, the affected Services.

You acknowledge and agree that if you use the Services after the date on which the TOS have changed, 23andMe will treat your use as acceptance of the updated TOS.

27. Violation or Suspected Violation of Terms of Service

If you violate the terms of these TOS and/or 23andMe has a reasonable ground to suspect that you have violated the terms of these TOS, 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Services (or any portion thereof).

28. Miscellaneous

a. **Entire Agreement.** The TOS constitute the entire agreement between you and 23andMe and govern your use of the Services, superseding any prior agreements between you and 23andMe on this subject. You also may be subject to additional terms and conditions that may apply when you use affiliate services, third-party content, or third-party software
b. **Applicable law and arbitration.** Except for any disputes relating to intellectual property rights, obligations, or any infringement claims, any disputes with 23andMe arising out of or relating to the Agreement (**"Disputes"**) shall be governed by California law regardless of your country of origin or where you access 23andMe, and notwithstanding of any conflicts of law principles and the United Nations Convention for the International Sale of Goods. Any Disputes shall be resolved by final and binding arbitration under the rules and auspices of the American Arbitration Association, to be held in San Francisco, California, in English, with a written decision stating legal reasoning issued by the arbitrator(s) at either party's request, and with arbitration costs and reasonable documented attorneys' costs of both parties to be borne by the party that ultimately loses. Either party may obtain injunctive relief (preliminary or permanent) and orders to compel arbitration or enforce arbitral awards in any court of competent jurisdiction.
c. **Waiver.** The failure of 23andMe to exercise or enforce any right or provision of the TOS shall not constitute a waiver of such right or provision. If any provision of the TOS is found by a court of competent jurisdiction to be invalid, the parties nevertheless agree that the court should endeavor to give effect to the parties' intentions as reflected in the provision, and the other provisions of the TOS remain in full force and effect.
d. **Term for cause of action.** You agree that regardless of any statute or law to the contrary, any claim or cause of action arising out of or related to use of the Services or the TOS must be filed within one (1) year after such claim or cause of action arose or be forever barred.
e. **Admissibility of printed version.** A printed version of this agreement and of any notice given in electronic form shall be admissible in judicial or administrative proceedings based upon or relating to this agreement to the same extent and subject to the same conditions as other business documents and records originally generated and maintained in printed form.
f. **Section titles.** The section titles in the TOS are for convenience only and have no legal or contractual effect.
g. **Severability Clause.** If any portion of these TOS is found to be unenforceable, the remaining portion will remain in full force and effect.
h. **Amendments.** We reserve the right to modify, supplement or replace the terms of the Agreement, effective upon posting at www.23andMe.com or notifying you otherwise. If you do not want to agree to changes to the Agreement, you can terminate the Agreement at any time per Section 18 (Termination).
i. **Assignment:** You may not assign or delegate any rights or obligations under the Agreement. Any purported assignment and delegation shall be ineffective. We may freely assign or delegate all rights and obligations under the Agreement, fully or partially without notice to you. We may also substitute, by way of unilateral novation, effective upon notice to you, 23andMe for any third party that assumes our rights and obligations under this Agreement.

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Attachment C

considerations

23andMe believes there is great promise in helping people access and understand their genetic information, but the advent of personal genetics is not without risk. To help you understand the benefits and potential drawbacks of accessing your own genetic information, we present a few issues you should consider before joining 23andMe.

You may learn surprising things about yourself.

There is a chance you could be surprised by what you learn about your genome. For example, you could discover that your father is not your biological parent. You could learn that individuals with your genetic profile are at increased risk of developing a currently incurable disease. You might learn something unexpected about your ancestry. In certain cases, these discoveries could have social, legal or economic implications.

The laboratory process can result in errors.

Our samples are processed by a federally licensed laboratory using processes that are designed to deliver the highest quality data possible. However, a small, unknown fraction of the data generated during the laboratory process may be inconclusive or incorrect.

Genetics is not destiny.

Your genes are only one factor among many that influence who you are. It is important to recognize that your diet, lifestyle, environment and even luck can be equally or more important than genes in determining your future.

It is also important to understand that 23andMe assesses the genetic chances of developing a given disease or condition by consulting scientific reports that associate certain genetic profiles with increased or decreased risk and comparing your results to them. Though we are confident in the quality of both our laboratory procedures and the scientific research we choose to include in our analyses, these aspects are currently the only information our service takes into account. That means we cannot and do not diagnose diseases or medical conditions, provide medical advice or otherwise assess your health. You should always contact your physician, a genetic counselor or other professional if you have any questions or concerns about what you learn through 23andMe.

Genetic research is not yet complete.

Studies associating genes with traits and conditions have not yet been performed in all ethnic groups. Because we can only present the results of whatever studies have been done, what you learn may not apply to someone with your ethnic background. However, 23andMe could overcome this obstacle over time–if enough people of various ethnic backgrounds are willing to anonymously share their genetic data and basic information about their traits and medical conditions, we may be able to fill in some of those gaps.

Future scientific research may change the interpretation of your DNA.

It is possible that future research may render current information incomplete or inaccurate. The good news is that significant progress is being made in the field of genetic association research, and we will keep you abreast of the latest developments.

You should consider how others may use your genetic data before sharing it.

Purchasing 23andMe's service does not require you to share your genetic information with anyone, but it does offer you the option of making your data available to others. Before you decide to share your information, you should consider how those parties might use your genetic data now and in the future. For example, a motivated party with whom you share your data might be able to use our tools to discover things that you had not anticipated. It is also possible that future scientific research will shed new light on data you reveal today, giving it new significance that you would rather not share with others.

Please see our policy forum if you would like to learn more about these important considerations.

Attachment D

news

23andMe press release

23andMe Enlists Informed Medical Decisions to Make Independent Genetic Counseling Services Available to Customers

MOUNTAIN VIEW, CA – June 3, 2010 – 23andMe, Inc., a leading personal genetics company, has engaged Informed Medical Decisions, Inc. (InformedDNA), a nationwide network of board-certified genetics experts, to offer independent genetic counseling services to new and existing customers of its Personal Genome Service™.

"This new initiative with InformedDNA means that 23andMe customers now have the option to talk about their results with a board-certified genetic counselor who has been specially trained in 23andMe's unique reports and processes," said Anne Wojcicki, 23andMe President and Co-Founder.

"We chose to work with InformedDNA because they are a leading national independent provider of genetic counseling services," stated Wojcicki. "We wanted to ensure that the information our customers receive is completely objective."

23andMe customers interested in talking with a genetic counselor from InformedDNA can choose from two levels of service. For those with general questions related to their 23andMe results, an informational Personal Genome Service (PGS) is available. Customers who want a counselor to conduct a more thorough review of their family and medical histories, and those whose results show that they carry variants with potentially serious implications, can choose Comprehensive Clinical Genetic Counseling. Determining whether the Comprehensive Clinical Genetic Counseling option is appropriate is based on national clinical guidelines for genetic counseling referral.

23andMe customers who choose to utilize the services of InformedDNA will connect with a genetic counselor by phone. Convenient appointments are available seven days a week and can be scheduled online or by calling a dedicated toll-free phone line. InformedDNA Patient Care Coordinators are available to assist customers in choosing the level of service that is right for them. All information will be kept strictly confidential. A guide to the pricing for 23andMe customers who wish to utilize the genetic counseling services is listed on InformedDNA's website.

"Informed Medical Decisions is pleased to be working with 23andMe to expand access to genetics experts, especially for people who know of or suspect they may be at risk for hereditary disease. We salute 23andMe for offering customers convenient access to our genetic counselors," said David Patrick Nixon, Informed Medical Decisions Chief Executive Officer.

About 23andMe

23andMe, Inc. is a leading personal genetics company dedicated to helping individuals understand their own genetic information through DNA analysis technologies and web-based interactive tools. The company's Personal Genome Service™ enables individuals to gain deeper insights into their ancestry and inherited traits. The vision for 23andMe is to personalize healthcare by making and supporting meaningful discoveries through genetic research. 23andMe, Inc., was founded in 2006, and the company is advised by a group of renowned experts in the fields of human genetics, bioinformatics and computer science. Its investors include Genentech, Inc., Google Inc. (NASDAQ: GOOG) and New Enterprise Associates. More information is available at www.23andme.com.

About Informed Medical Decisions, Inc. (InformedDNA)

InformedDNA includes the largest independent network of genetic counselors and is the only national provider whose services are a covered benefit for most individuals with commercial health insurance. Its pioneering telephonic service delivery model removes barriers to care (geography, language, cultural and clinical specialty) for patients and has been recognized by the Institute of Medicine and Surgeons Generals' National Call to Action on Cancer for innovations and clinical excellence.

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Press Releases

June 24, 2010 23andMe Makes New Discoveries in Genetics Using Novel, Web-based, Participant-driven Methods
June 3, 2010 23andMe Enlists Informed Medical Decisions to Make Independent Genetic Counseling Services Available to Customers
October 13, 2009 23andMe Tests NFL Players' DNA for Athletic Genetic Factors
April 27, 2009 23andMe and Palomar Pomerado Health Partner to Give PPH Members Access to Their Genetic Information
March 31, 2009 23andMe Launches Free Online Community For Moms and Moms-to-Be
March 12, 2009 23andMe Launches Parkinson's Disease Genetics Initiative
January 28, 2009 23andMe and mondoBIOTECH Partner to Advance Research of Rare Diseases
December 18, 2008 Silicon Valley Veterans Sarah Imbach and Larry Tesler Join 23andMe Management Team
December 8, 2008 23andMe Announces Holiday Season Multi-Pack Discount
October 30, 2008 TIME Magazine Names 23andMe's Personal Genome Service 2008 Invention of the Year
October 2, 2008 23andMe Announces Breast Cancer Initiative
September 9, 2008 23andMe Democratizes Personal Genetics
September 9, 2008 23andMe and Ancestry.com Partner to Extend Access to Genetic Ancestry Expertise
May 29, 2008 23andMe Launches Consumer-Enabled Research Program to Actively Engage Individuals in Genetics Research
May 14, 2008 23andMe and The Parkinson's Institute Announce Initiative to Advance Parkinson's Disease Research
January 22, 2008 23andMe Launches Web-Based Personal Genome Service™ Outside U.S.
November 29, 2007 23andMe Selected as a 2008 Technology Pioneer by the World Economic Forum
November 19, 2007 23andMe Launches Web-Based Service Empowering Individuals to Access and Understand Their Own Genetic Information
November 16, 2007 23andMe to Hold Webcast Media Briefing
May 22, 2007 23andMe, Inc. Completes Series A Financing

Attachment E

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June 28, 2010

Michael J. Madigan
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mmadigan@orrick.com

Hon. Henry A. Waxman, Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Hon. Joe Barton, Ranking Member
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Hon. Bart Stupak, Chairman
Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Washington, DC 20515-6115

Hon. Michael C. Burgess, Ranking Member
Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Washington, DC 20515-6115

Re: June 14, 2010 letter request to Anne Wojcicki, President, 23andMe, Inc.

Dear Chairman Waxman, Ranking Member Barton, Chairman Stupak and Ranking Member Burgess:

On June 14, 2010, you sent a letter request to Anne Wojcicki, President of 23andMe, Inc. ("23andMe" or "the Company"), seeking information related to a June 8, 2010 announcement by the Company relating to a number of customer DNA samples. While we are in the process of producing responsive documents, the Company would like to take this opportunity to explain the incident. At the outset, we understand that a representative of the laboratory processing and analysis company that 23andMe uses will meet with you this week and will certainly be in the best position to discuss the issues that occurred within their facility. Our description of events at the laboratory is limited to 23andMe's own understanding of what happened there.

I. How 23andMe's Collection of Customer DNA Samples and NGI's Processing and Analysis Operate

Preliminarily, we thought it would help to provide a step-by-step explanation of how 23andMe operates with respect to the collection of customer DNA samples and their processing and analysis by the Company's third-party laboratory vendor, the National Genetics Institute ("NGI") a wholly owned subsidiary of the Laboratory Corporation of America.

First, customers visit the 23andMe website and purchase one of three products for personalized genetic testing. 23andMe then sends to each customer a kit to collect a DNA sample, including a vial for saliva marked with a unique barcode, from which customer DNA will be

extracted and analyzed by NGI. The customer deposits a sample of saliva in the vial and then sends it directly to NGI. The Company uses the unique barcode on each saliva collection vial to track and distinguish each customer's unique data while maintaining customer privacy.

NGI is a Clinical Laboratory Improvement Amendments Program-certified laboratory that provides advanced clinical genetics testing services for blood screening, medical testing, and clinical research. Licensed as a clinical laboratory provider by both state and federal agencies, NGI participates in a number of approved quality control programs, and holds active Biologics Licenses from the U.S. Food and Drug Administration for screening of plasma for blood borne infectious agents. It also provides advanced genetic testing services to physicians, hospitals, and clinics and has supported numerous pharmaceutical and biotechnology companies in the clinical development of new infectious disease and oncology therapies. (see http://www.ngi.com/services/index.asp). We understand NGI complies with strict professional, regulatory, and corporate quality-assurance standards. 23andMe employees and consultants do not participate in the processing and analysis of data at NGI, although we rely on the data returned.

Upon receipt of the saliva samples, NGI logs them by their assigned bar codes into NGI's system, and then processes them through "amplification," extracting the customers' DNA from their saliva samples. Each customer's DNA is then placed by pipette into an assigned slot contained on a well plate. The well plates used by NGI for testing of 23andMe customer samples are 5"x7", and contain 96 slots to allow for the processing of up to 96 customer DNA samples per plate. These well plates are then inserted into Illumina-platform equipment for analysis of nearly 600,000 data points that 23andMe provides to its customers.

After NGI completes the analysis, the collected data for each sample is linked to its accompanying bar code, and NGI electronically sends the data encrypted to 23andMe through a secure FTP site. A single electronic file contains the data from one well plate. Upon receiving this data, 23andMe matches each barcode to the customer it belongs to, and then uploads the data from each barcode to the customer's individual account. Finally, 23andMe sends emails to its customers notifying them that their data are loaded and ready for viewing.

II. Factual Background of the June 2010 Incident

Summary

In brief, the June 2010 incident was caused by the human error of one of NGI's certified technicians accidentally and wrongly inverting one well plate, which contained 96 customer DNA samples, nine of which failed processing by 180 degrees. This led to the Company's receipt of incorrect results, which were then transmitted to customers. However, 23andMe responded rapidly to the problem, advised consumers of the problem, removed the inaccurate results in less than 24 hours, and provided those impacted with their correct results within six (6) days. While 23andMe

takes the incident seriously, the Company rapidly resolved it. Since the incident, both 23andMe and NGI have further strengthened their quality control systems to avoid any further such problems.

Detailed Account

The aforementioned inversion of the well plate by 180 degrees caused NGI's computer to assign DNA information to incorrect barcodes, as the slots were assigned to barcodes in the computer before plate insertion. I note that the plate inversion could have happened in any such lab for any such tests coming from any hospital, doctor's office, or other NGI client – it was not a problem uniquely related to 23andMe samples. Unfortunately, NGI did not detect the error before it transmitted the erroneous electronic data file from the inverted plate to 23andMe. The Company received the NGI-generated, faulty data and uploaded it to each customer's individual account and emailed those customers that their data was available. Customers received these emails between 6 and 9 p.m. on the evening of June 1.

Early in the morning of June 2, 23andMe's Director of Engineering, Alex Khomenko, checked his email and was alerted that several 23andMe customers had apparently received inaccurate genetic reports. For example, in at least one instance, a customer had received genetic data indicating that the customer was the wrong sex. That same morning, Mr. Khomenko contacted the Company's Customer Service Manager, Michelle Klucsor, who said she had received similar customer complaints via email.

To identify what happened, Mr. Khomenko ran a program covering 100% of the samples received from NGI on June 1. This program provided the names (which the customers provided when signing up with 23andMe) and sex (which the lab identified in its DNA analysis) of these customers. He then compared a customer's name against the lab-identified sex of the customer. He noticed that, in some instances, the gender of a customer's name (for example, "Sarah") did not match the sex (for example, "male") contained in the lab report. He compiled a list of all such inconsistencies. Mr. Khomenko then reviewed the original electronic files sent from NGI on June 1, 2010 and determined that all of the inconsistencies stemmed from a single electronic file, and, thus, he concluded, from one well plate.

As Mr. Khomenko conducted his investigation, 23andMe alerted NGI of the error. NGI also conducted its own investigation. Around 1 pm on June 2, 2010, 23andMe concluded that the data from the single file containing 87 customer data sets contained inaccuracies and began the process of removing this data from the accompanying accounts. During this period, 23andMe continued discussions with NGI. At approximately 4 pm on June 2, 2010 – less than 24 hours after customers had received the incorrect data – 23andMe deleted the erroneous data from the affected customers' databases and sent emails to each affected customer alerting them of the error.

On June 5, NGI confirmed that its investigation had concluded that the issue stemmed from an error on a single well plate. NGI's investigation showed that the well plate had been inverted, causing the inaccurate customer data. NGI had reprocessed the data of all impacted customers while its investigation was ongoing. NGI re-ran the entire plate from both the amplified DNA samples and the original saliva samples provided by the customers. In doing so, NGI was able to confirm the accuracy of the updated data. 23andMe was able to upload correct reports into the affected customers' accounts on June 8, 2010.

III. Steps Taken by 23andMe and NGI to Ensure No Future Errors

Since this incident, NGI has informed 23andMe that NGI has taken steps to help ensure that such errors do not recur. Specifically, 23andMe understands that NGI has modified the physical shape of its well plates to prevent them from being inverted in the machine that conducts the analysis. Attached please find a photograph of the old well plate and one of the newly-designed well plates that are now in use.

For its part, 23andMe has implemented improved quality-control procedures to double-check the accuracy of NGI's returned lab results before providing them to customers. For the period of June 8 through June 23, 23andMe cross-referenced a customer's name (which 23andMe predicts to be either male or female based on traditional name use) with the customer's sex information pulled from lab data. Doing so allowed 23andMe to identify potential errors, where the gender of a customer's name is inconsistent with lab-identified sex data for that customer.

Starting June 24, 23andMe implemented a similar quality check with additional data. As of June 10, 2010, 23andMe has been collecting customer date of birth and sex information pursuant to requirements that NGI is following. 23andMe's new process cross-references this customer-provided sex data with that generated by the lab data. Potential errors will be flagged where there are inconsistencies.

ORRICK

We look forward to speaking with you further about this issue. If you have any questions in the meantime, please call me at (202) 339-8523.

Sincerely,

Michael J. Madigan
Joshua P. Galper
Stephanie Maya Cowles

Attachment F

U.S. Food and Drug Administration

Home> Medical Devices> Products and Medical Procedures> In Vitro Diagnostics

Medical Devices

Home Use Tests

Home use tests allow you to test for some diseases or conditions at home. These tests are cost-effective, quick, and confidential. Home use tests can help:

- detect possible health conditions when you have no symptoms, so that you can get early treatment and lower your chance of developing later complications (i.e. cholesterol testing, hepatitis testing).
- detect specific conditions when there are no signs so that you can take immediate action (i.e. pregnancy testing).
- monitor conditions to allow frequent changes in treatment (i.e. glucose testing to monitor blood sugar levels in diabetes).

Despite the benefits of home testing, you should take precautions when using home-use tests. Home use tests are intended to help you with your health care, but they should not replace periodic visits to your doctor. Many times, you should talk to your doctor even if you get normal test results. Most tests are best evaluated together with your medical history, a physical exam, and other testing. Always see your doctor if you are feeling sick, are worried about a possible medical condition, or if the test instructions recommend you do so.

Approvals

- Find All FDA-Approved Home and Lab Tests[1]

Related Links

- How You Can Get the Best Results With Home Use Tests[2]
- How You Can Know If FDA Regulates an Over-The-Counter Test[3]

Links on this page:

1. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/LabTest/ucm126079.htm
2. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/HomeUseTests/ucm125664.htm
3. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/HomeUseTests/ucm125666.htm

Mr. STUPAK. Thank you.

Dr. Vanier, President and CEO of Navigenics. Would you testify, please?

TESTIMONY OF DR. VANCE VANIER

Dr. VANIER. Chairman Stupak, Ranking Member Burgess, Chairman Waxman, and members of the subcommittee, thank you for inviting me here today to testify regarding the role of personal genetics in prevention and wellness.

I am Dr. Vance Vanier, the CEO of Navigenics, a personal genetic testing company in California. I am trained originally in emergency medicine and have been extraordinarily privileged to have been on the front lines of patient care for over 10 years now.

I am currently on the faculty at Stanford Medical Center. I received my medical degree from Johns Hopkins. I did my residency training at the University of California at San Francisco.

While my medical career has taken me certainly to many places, there is one thing that I have seen over and over again; it doesn't matter whether you are in the inner cities of Baltimore or Oakland. It doesn't matter whether you are in the more privileged neighborhoods of San Francisco or Stanford. We have an epidemic of preventible chronic disease that crosses all walks of life, that crosses all geographies.

So, every time that I diagnose or treat a heart attack in the emergency department, it is a failure of prevention and wellness. Every time that I diagnose diabetes in a person due to their obesity, it is a failure of prevention and wellness. Every time I diagnose a late stage colon cancer case because that patient never got around to getting their colonoscopy, it is a failure of prevention and wellness.

Most of us in the room here today know what we are supposed to do for our health, but we as a society are challenged by the fact that we can't seem to be motivated to engage in healthy lifestyles or follow our physician's recommendations, and that failure is the cornerstone of why millions of Americans suffer from preventible disease today.

So it is in this context of tremendous unmet need that genomics is emerging as a powerful behavioral tool to motivate action. There is a body of evidence that shows that when people understand their genetic information, they are more motivated to act to make positive lifestyle choices.

There is a body of evidence that shows that this sort of testing is safe and does not cause long-term, undue psychological harm. And, clearly, there is a high interest in the American public for testing like this.

And so, given the scope of the unmet need, given the potential power of this information, and given the fact that there is high societal interest, we have an extraordinary opportunity in this room today to lay the foundation for standards of how we can responsibly deliver this information with appropriate safeguards. And I can certainly think of no better way to set the stage of this dialogue than with this subcommittee and the FDA.

As you hear my testimony today, there are five main points that I would like to reinforce.

First, not all genetic testing companies are the same. There is a huge variance in standards that different companies bring to bear.

Second, since we were founded by Dr. David Agus, an oncologist of national repute, and Dr. Dietrich Stephan, who is a human geneticist who trained under Francis Collins at the NIH, we have sought to have the most stringent qualities of science. Indeed, our genetic selection criteria meets or exceeds standards put out by the CDC.

Third is the fact that we are passionately clinically focused. We believe that you should only test for clinically actionable information. Every one of our customers is supported by genetic counselors since our founding. And we primarily work through physician groups—national physician groups, as well as medical centers such as Duke, Scripps, Cleveland Clinic, Mayo Clinic, international affiliates of Johns Hopkins. Indeed, virtually all of our tests come from physician groups or prevention and wellness programs such as ones you might find in the corporate channel.

Fourth is the extremely high standard of our lab operations. We are one of the very few companies in our space that own and operate our own lab. We are CLIA-certified, and we are the only company in our space to be approved by all 50 States, including the State of New York, which has some of the most stringent regulatory standards of any State in the U.S.

Finally, fifth, we believe that a customer's genetic information should be completely private and secure. We do not resell or share this information to any third parties, such as pharmaceutical companies.

So, in summary, we believe that a responsible approach, coupled with a thoughtful regulatory framework, can set a successful foundation for this transformational innovation that is happening in prevention and wellness today. And we certainly look forward to discussing it with you at length.

Thank you.

[The prepared statement of Dr. Vanier follows:]

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
United States House of Representatives
Hearing on
"Direct-to-Consumer Genetic Testing
And the Consequences to the Public Health"
Written Testimony of
Vance Vanier, M.D.
Chief Executive Officer
Navigenics, Inc.
July 22, 2010

Chairman Stupak, Ranking Member Burgess, and Members of the Subcommittee, thank you for the opportunity to testify on the important role that personalized genetic testing can play in prevention and wellness with the overall goal of improving public health.

I am Vance Vanier, M.D., Chief Executive Officer at Navigenics, a genetic testing company based in Foster City, California. I am trained in emergency medicine and have worked on the front lines of patient care where I have observed first-hand the overwhelming need for new preventive technologies. I continue to serve on the clinical faculty of Stanford Medical Center, received my medical degree from the Johns Hopkins School of Medicine and completed my residency training at the University of California, San Francisco, and Highland Hospital in Oakland, California.

We welcome the Subcommittee's interest in personalized genetic testing, which is rooted in a long history of congressional promotion of innovation and balanced, science-based regulation. From the 1975 Asilomar Conference on the regulation of recombinant DNA (rDNA) research through this Committee's biotechnology hearings led by Chairman *emeritus* Dingell and then-Subcommittee Chairman Waxman in the 1980s, to the recent, extraordinary success of the historic Human Genome Project, Congress has worked collaboratively with regulatory agencies, academe and industry to create the conditions that allow American researchers and companies to lead the world in creating new life-saving and life-improving health solutions.

About Navigenics

Mr. Chairman, Navigenics is a company that simply would not exist without the long-term commitment to the Human Genome Project that this Committee and this Congress made and sustained. As you know, the Human Genome Project was an unprecedented 13-year, $3 billion project completed in 2003, coordinated by the United States Department of Energy and the National Institutes of Health (NIH). Our co-founders, and each one of our dedicated employees at Navigenics, have been committed to pursuing the scientific possibilities created

by the first complete mapping of the human genome, which NIH rightly described as one of "the great feats of exploration in human history, an inward voyage of discovery rather than an outward exploration of the planet or the cosmos...which has given us the ability, for the first time, to read nature's complete genetic blueprint for building a human being."

Achieving this spectacular goal, and opening the door to the promise of personalized health and medicine, led David Agus, M.D., a leading oncologist, and Dietrich Stephan, Ph.D., a leading human geneticist, to found Navigenics in 2006. The company's overall goal is to improve health outcomes in individuals across the population. Navigenics educates and empowers individuals and their physicians with knowledge of their genetic predispositions, and then motivates them to act on the information to prevent the onset of disease, achieve earlier diagnosis, appropriately manage disease, or otherwise lessen its impact.

Navigenics offers clinically-guided personal genetic analysis exclusively through two professional channels: 1) medical centers and physicians, with clinical research partners like the Mayo Clinic, Duke Medicine, Scripps, Cleveland Clinic, the American Academy of Private Physicians, and MDVIP, the nation's largest network of physicians practicing preventive and personalized healthcare, and 2) as a benefit through employer wellness programs at Fortune 100 companies. Progressive companies who wish to promote prevention awareness have offered the Navigenics Health Compass to employees as one tool within a broader health and wellness program without ever gaining access to their employee's personal genetic data. It is important to note that consumers currently cannot enroll in Navigenics services simply through visiting our website. Navigenics will only test consumers who confirm that they are over the age of eighteen.

We firmly believe that a healthcare professional should be an integral part of the personal genetic analysis process, which is why we have our own team of genetic counselors who are available to educate and support both healthcare providers and our customers. Each of our genetic counselors is board certified by the American Board of Genetic Counseling and has received extensive specialty training in personal genomic counseling. All individuals who are interested in testing or have received genetic testing through Navigenics have access to these genetics experts to address questions and enable informed decision-making. Our members' personal physicians have unlimited access to our staff of genetic counselors as well. It is worth noting that these professionals adhere to a rigorous set of bioethical standards and receive no incentives to guide individuals to test when it may not be appropriate. Every individual who chooses to test with Navigenics is personally contacted to schedule a genetic counseling consultation to discuss the results, identify resources, and facilitate the dialogue with their healthcare providers. The majority chooses to engage in this service and report feeling empowered and better informed by the interaction.

Over the past three years, a fundamental focus of our service has been developing physician education programs and clinical tools to facilitate clinical integration for both private and corporate physicians. Navigenics' genetic counselors focus a significant portion of their efforts on working with physicians to provide end-to-end support from basic education to

clinically-guided information about specific patient results in the context of their personal and family history. The Navigenics Physician Portal is a security-enabled, centralized tool that enables ordering physicians to receive and manage their patients' Navigenics results and access ongoing clinical updates.

Unlike other companies that test for untreatable and degenerative diseases, such as Lou Gehrig's Disease (ALS), or traits such as eye and hair color or ancestral lineages, Navigenics solely focuses on medically-relevant health conditions and medication sensitivities that can help motivate behavior change and inform healthcare decisions in conjunction with a healthcare provider. Identifying an individual's genetic risk for common conditions like celiac disease and heart disease, or an increased likelihood of having an adverse reaction to a specific medication, can help them take action towards improved health. Additionally, we provide extensive health information in patient-friendly language. Navigenics thereby provides a foundation of highly-vetted resources on key prevention steps and established medical guidelines that can help avoid or lessen high morbidity chronic illnesses such as diabetes, heart disease, and high blood pressure. All of these afflictions, as you know, alone lead to seven in ten deaths in the United States and a staggering 75 percent of our national health care costs.

Navigenics operates in full compliance with all existing state and federal regulations and is the only consumer genomics company that is approved by state regulators to operate in every state, including the state of New York. We own and operate our own CLIA-certified laboratory in West Sacramento, California, which is currently regulated by CMS. We are dedicated to maintaining the privacy and security of all of our customers' genetic information, never selling nor sharing individuals' personal genetic information with third parties and ensuring that all of our all our operations are consistent with the Health Insurance Portability and Accountability Act (HIPAA).

Importance of Personalized Genetic Testing

Personalized genetic testing is already demonstrating significant value for individual consumers and patients. At an historic time when our country has passed healthcare reform to systemically address our health crisis, we have been counseling one patient at a time on strategies they may wish to consider discussing with their doctors in the pursuit of improved health.

Over the past several years we have worked with a broad range of individuals in which personal genomic testing positively impacted their health – whether it be from early identification of macular degeneration that resulted in halting visual loss before it progressed, to initiating and maintaining long-avoided lifestyle modifications to minimize the risk for diabetes and cardiovascular disease, to helping a physician select the right type of statin to yield the desired therapeutic effect. The promise of personalized medicine is not yet fully realized, but both patients and providers have already experienced its beneficial effects.

We are seeing positive results not just on an individual basis and within our partner groups but also within study populations. In cooperation with Eric Topol, M.D., of the Scripps Research Institute, Navigenics launched the Scripps Genomic Health Initiative (SGHI) in October 2008. This research study, independently approved by Scripps own Institutional Review Board (IRB) is the first large-scale research study in our country to assess consumer response to personalized genomic risk assessment over a period of 20 years. Early results from have indicated that customers are eager to learn more about their genetic predispositions to disease and do not show increases in anxiety or distress after receiving their results. A total of 82.4 percent respondents indicated that they would want to know their genetic risk and over 80 percent said they would recommend genetic testing for friends and family. Along with the research team in Dr. Topol's lab, we will be eagerly awaiting and analyzing the results from this—and other relevant studies—in the future.

These are just some of the meaningful benefits emerging within personalized medicine. Customized therapies are becoming "best practices" in hospitals, ensuring patients receive optimum treatment from the start of care. This been particularly effective for cancer treatment, but personalized medicine is also is informing treatment for cardiovascular disease, infectious disease, psychiatric disorders and transplantation medicine.

These benefits are accruing on personal as well as financial fronts. For example, genetic testing is performed to properly dose the blood thinner, warfarin. If this testing were accomplished for all patients in the United States at a cost of $125-$500 per test, the approximately 17,000 strokes, 85,000 serious bleeding incidents and as many as 43,000 emergency room visits could be avoided. This alone could represent a savings of $1.1 billion annually. We know that many drugs are only effective for 50 percent of patients for whom they are prescribed. Not only is genetic testing widely utilized with breast cancer patients to ensure that they receive the appropriate drug, but these technologies reduce trial-and-error prescribing. Personalized medicine also allows providers to minimize the side effects of drugs, increasing patient compliance. This is particularly important for conditions like asthma and diabetes, which are exacerbated by patient non-compliance.

Future Regulation of Personalized Genetic Testing

We stand at a critical juncture in our country's ability to realize the true potential of personalized medicine and of the landmark Human Genome Project. While our nation's human and financial resource investments to date have yielded impressive genomic information and data, the true value of this monumental project will be in how this knowledge will be applied in improving the quality of life and health of all Americans. Furthermore, our own national leadership in the life sciences is at risk. Abrupt or overbroad regulation can chill genomic discoveries and applications in this country, driving innovation and investment to other countries and attracting with it thousands of high value jobs in this key growth industry.

At issue is the best regulatory pathway for services like ours. As you know, just this week, the Food and Drug Administration (FDA) began a comprehensive process of reviewing

regulatory approaches to laboratory developed tests (LDTs) with a two-day public meeting. At the same time, the FDA is being criticized for, and is undertaking self-scrutiny of, the rigor and appropriateness of the entire medical device premarket clearance pathway, under section 510(K) of the Federal Food, Drug and Cosmetic Act, which potentially applies to LDTs.

Despite this continuing uncertainty, we have pursued a proactive dialogue with the FDA for more than three years, and we continue to welcome balanced federal oversight. Even before we launched our service, Navigenics was a leader in encouraging collaboration, dialogue, and compliance with regulatory authorities – at both the state and federal levels – and in seeking to develop uniform standards for the industry's technologies and services.

Navigenics has been a leader in working with industry groups, patient advocates, and other interested parties in promoting industry standard-setting and encouraging the cooperation of our industry colleagues. Because genotype-based risk prediction for common, multifactor diseases is an area of continued innovation, more work must be done to standardize markers used; to better explain the contribution of genetics to common, complex diseases; and to incorporate common genetic variants into clinical practice. We are happy to provide the Subcommittee with additional information regarding these important efforts to assure and strengthen the transparency and standards in our important new sector.

Mr. Chairman, we have great confidence in the government's ability to find a balanced path forward—one that allows for innovation while protecting the public. We are, of course, committed to complying with any and all regulatory requirements as the Agency, States and Congress work towards an effective consensus. Congress has already succeeded in protecting personal genetic data through enactment of the Genetic Information Non-Discrimination Act in 2008, which prohibits the improper use of genetic information in health insurance and employment. We believe this Subcommittee can help assure the same information is protected and safely applied in the service of safeguarding human health.

To this end, we would support the creation of an outside advisory committee to guide the FDA as it determines how to regulate LDTs and personal genetic testing services. This week's public meeting should be just the beginning of an open dialogue with the community of stakeholders that will be critical to the Agency's ability to reach consensus on the best way forward. A major hurdle for us and other test developers has been the lack of clarity about the process. This lack of clarity has affected our ability to maintain and grow our business. The economy is still in a fragile period and the federal government should continue to pursue policy that will help small businesses grow and generate new high skill and high wage jobs, and speed our economic recovery.

Conclusion

Mr. Chairman, thank you for the opportunity to testify today. Personalized genetic testing offers important benefits in strengthening prevention and wellness, improving health literacy, and reducing health care costs for the American public. I urge this Subcommittee and

Congress to work closely with the FDA, academic scientists, and companies like Navigenics, to develop reasonable, risk-based and science-based standards that will assure the continued availability of innovative health services like personalized genetic testing.

Mr. STUPAK. Thank you, Doctor.

Next we will hear from Dr. David Becker, chief scientific officer with Pathway Genomics Corporation.

Dr. Becker.

TESTIMONY OF DAVID BECKER, PH.D.

Mr. BECKER. Mr. Chairman, thank you so much. And thank you for the opportunity to testify here today.

I am the chief scientific officer at Pathway Genomics, a San Diego-based genetic testing company. Pathway operates its own on-site, CLIA-certified, and California State-licensed laboratory. We provide physicians and their patients with reports based on advanced genetic testing technology and validated genetic information, allowing them to make informed health decisions.

Pathway has validated its laboratory-developed genetic tests and established quality assurance protocols according to Federal standards and guidelines to ensure the accuracy of the data we provide.

The discovery and analysis of the human genome represent the dawn of a new era in health care delivery. With this expanded knowledge, individuals can develop personalized prevention and therapeutic strategies. At the current rate, we can expect significant additional discoveries that will allow health care providers to provide their patients with more effective personalized care, delivered at lower cost, with fewer complications.

Some have taken the position that our understanding and association with health outcomes is not yet strong enough to be interpreted and/or integrated into clinical care. We would concur that the research has to be analyzed objectively and reported responsibly. It is not true that consumers, however, are unable to benefit from access to this information.

Pathway currently offers three health-related reports, as well as a genetic ancestry report. These reports provide an assessment of genetic risk for as many as 25 different health conditions, indicate the presence of genetic markers associated with 37 different recessive genetic diseases or conditions, and project the likely response to nine different medications.

In addition to providing understandable genetic reports, Pathway offers access to clinical experts to ensure that our customers and their physicians understand their test results. Pathway's staff physicians and genetic counselors are available for guidance and support, both pre- and post-testing. These qualified experts review every health report prior to delivery, looking for indications that warrant separate communication, encouraging the customer to speak with one of our counselors—genetic counselors, that is—or physicians at no additional charge.

Pathway believes that genetic testing can be offered directly to customers in ways that help them improve their health without creating unacceptable risks. Nevertheless, we voluntarily suspended consumer ordering via the Internet and retail as we work with FDA to address their concerns over direct-to-consumer genetic testing.

Pathway is committed to improving the health and wellbeing of our customers. We are also committed to ensuring that everything

we do is based on rigorous scientific standards and complies with all applicable laws and regulations.

Genetic testing holds great promise to help people live more healthy and productive lives. Allowing consumers, in consultation with health care professionals, to access their genetic information empowers healthy and positive choices. We are excited about the future of genetic testing and look forward to continuing our work with FDA, Congress, and our colleagues to ensure the services we offer are of the highest quality and value to the American public.

Let me conclude by thanking the committee for focusing attention on both the challenges and opportunities that this new industry presents. I look forward to answering your questions.

[The prepared statement of Mr. Becker follows:]

PREPARED STATEMENT OF

DAVID BECKER Ph.D.
CHIEF SCIENTIFIC OFFICER, PATHWAY GENOMICS

BEFORE THE
U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
July 22, 2010

Mr. Chairman and Committee members,

Thank you for the opportunity to testify to you today. My name is Dr. David Becker, I am the Chief Scientific Officer at Pathway Genomics, a San Diego based genetic testing company.

Pathway Genomics utilizes advanced genetic testing technology and validated genetic information to give individuals and physicians the best available information about their genetics, allowing them to make informed health decisions. It should be noted that although Pathway provided genetic tests directly to consumers like many of our competitors, we voluntarily suspended that practice as we work with the U.S. Food and Drug Administration (FDA) to ensure that our tests are offered in a manner consistent with regulatory requirements.

Pathway operates its own on-site laboratory that is certified by the U.S. Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Act (CLIA) and licensed by the state of California. The company employs 70 geneticists, scientists, bioinformaticists, physicians, and genetic counselors, as well as software engineers, customer support representatives, and others to ensure that we offer our customers accurate information that is properly understood.

Benefits of Genetic Testing

Since the completion of the Human Genome Project in 2003, scientists, physicians, policy makers and consumers have eagerly anticipated the era of "Personalized Medicine," which means providing targeted preventive care and therapeutic treatment based on an individual's genetic makeup.

Today, billions of dollars in research are being dedicated to building on our current knowledge of the human genome. Almost daily, new and exciting discoveries about the relationships between genetics and our health are transforming traditional medicine.

Empowering consumers with information about their genes holds tremendous promise to promote health and improve lives. We at Pathway can attest to the positive value that genetic information has provided to the lives of our customers. Moreover, Dr. Francis

Collins, MD, PhD, the current Director of the National Institutes of Health (NIH), cited several instances in his book *The Language of Life* where individuals have learned from genetic reports and proactively made changes to prevent or manage disease. As a physician, Dr. Collins knew he needed to incorporate a healthy diet and regular exercise in his life, and his genetic testing finally motivated him to make these changes.

Some have argued that consumers should not be provided with information about their genes, based on a fear that the information would not be used appropriately, or that genetic testing might create unnecessary anxiety amongst patients who feel that they are destined to get certain diseases based on their genes. However, we believe that consumers are capable of understanding both the benefits of having information about their genes, as well as the fact that genetics are only one piece of the puzzle of living a healthy life.

Moreover, in 2009, Boston University School of Medicine's Risk Evaluation and Education for Alzheimer's disease (REVEAL) study found that asymptomatic first-degree relatives of Alzheimer's patients who received genetic testing results regarding a possible propensity for Alzheimer's disease (presence of an APOE ε4 allele) did not have a change in the levels of anxiety, depression or overall general distress. While this study certainly highlights the need for responsible delivery of this information, it also indicates that patients are able to process genetic information effectively and use it to make better health decisions, even with respect to diseases like Alzheimer's.

Companies like Pathway are allowing individuals and their physicians to accurately determine their personal genetic makeup. As new genetic findings are made and validated, Pathway updates individuals about these discoveries and in consultation with their physician, individuals can use this information to improve the quality of their health care.

Pathway Genomics' Testing Services

Pathway currently offers three different health-related reports, as well as a genetic ancestry report. The three health related reports are:

- Health Conditions – This report provides a customer with an assessment of their genetic risk for as many as 25 different health conditions. The number of conditions will vary by the reported ethnicity of the individual, as a result of the quantity and quality of genetic research available.

- Pre-Pregnancy Planning (Carrier Status) – This report indicates the presence of genetic markers associated with 37 recessive genetic diseases. This information can be used to detect conditions that are unlikely to affect the tested individual, but can be passed to their children.

- Drug Response – This report suggests the likely response to as many as 10 different medications. This information may facilitate optimal medication

decisions, avoiding drugs that may be harmful or dangerous or assisting in establishing proper dosing.

Similar to our competitors, genetic risk is determined by applying the odds ratios associated with an individual's genetic markers against a population average to calculate a genetically adjusted risk of disease. However, as Dr. Francis Collins highlights in his book, quantifying the risk of contracting specific diseases may not incorporate other factors like family history, lifestyle and environment that for some diseases can be more significant factors than genetics. In consideration of these concerns, we want to highlight some significant differences in the way that Pathway reports risk information. After extensive internal discussions among our scientific and medical staff, we felt that a specific percentage based calculation implies a degree of precision that is not justified by the current state of genetic information. Therefore, we instead elected to categorize the genetic results into categories meant to motivate positive health behaviors appropriate to current genetic knowledge. From lowest to highest level of genetic risk, these categories are named, "Maintain a Healthy Lifestyle," "Learn More," "Be Proactive," and "Take Action."

Further, every customer is encouraged to fill out a health survey that collects relevant data on lifestyle, environment, and family history, and we use that to calculate a lifestyle risk score using a similar categorization system. This allows us to inform an overweight customer who smokes a pack of cigarettes a day that, even if they do not have genetic risks for lung cancer and hypertension, they may be at significant risk based on their lifestyle. We feel that this approach provides a more comprehensive assessment and makes it easier for our customers to understand how to properly use the information provided to improve their health.

Physician Oversight and Genetic Counseling Services

In addition to providing understandable genetic reports, Pathway felt that it was important to provide consumers with access to professionals trained in genetics to ensure that our customers and their physicians understand what their genetic reports say, and just as importantly the limitations of genetic information.

All of Pathway's physicians and genetic counselors are Board-certified or Board-eligible with the American Board of Genetic Counseling and have significant training and expertise supporting patients with understanding of genetic information. Our genetic counselors and physicians are available for guidance and support both before any services are ordered and post-testing at no additional charge to the customer.

These qualified experts review all health report results prior to delivery, looking for indications that warrant a separate communication encouraging the customer to speak with one of our genetic counselors or physicians. Performed at no additional charge, these personal consultations explain the results and appropriate next steps, including, as appropriate, consulting with their physician.

Existing Regulation

Laboratories are already under significant regulatory oversight. This regulation includes CLIA, state regulations, and, in some cases, regulation by the FDA. Additionally, there are voluntary certifications like College of American Pathology (CAP), which certify laboratories with high standards of validation, proficiency, and quality assurance. Pathway Genomics operates its own on-site, CLIA-certified and California state-licensed laboratory, and is pursuing CAP Certification. These programs require us to follow very specific rules to ensure the quality and accuracy of our services, and affect not just our laboratory operations, but also all of our business functions.

Pathway also understands the critical importance of data privacy and data security. Consumers who have entrusted us with their personal information can be assured that Pathway utilizes administrative, technical, and physical controls to secure their genetic information. One element of these controls is our maintenance of a closed, secure system -- all of our testing takes place in-house in our own on-site laboratory mitigating many potential privacy and security risks. Pathway has a Chief Privacy Officer who administers the company's comprehensive privacy policy and security program. Each consumer receives a consent agreement as well as a user-friendly shortened summary of the privacy policy in addition to the full privacy policy.

Regulatory Changes

Pathway feels that bona fide genetic testing companies such as ours would benefit from a stable regulatory environment. Earlier this week, FDA held a public meeting to allow industry experts and laboratory providers, including Pathway, to discuss ways that FDA might regulate laboratory developed tests to ensure that high standards of accuracy and quality are maintained, while not creating an undue burden on innovation and advancing medical care.

While FDA's efforts to clarify the regulatory requirements for laboratory developed testing are still in progress, here are some areas that we believe could use additional guidance or clarification:

- Risk-based classification system for genetic tests
- Minimum scientific study criteria
- Standardized definitions for population risk
- List of the strongest effect marker for each condition
- Standardized labeling and website disclosures
- Genetic test registry with required disclosures
- Mandatory CLIA and CAP certifications
- Publicized and standardized compliance procedures, regarding incident management and reporting, customer complaints, etc.

While it is critical to ensure public safety, it is also important that new regulations do not stifle innovation or restrict an individual's access to information that impacts their health. With a stable and supportive regulatory structure, the field of genetics can not just improve the delivery of health care, but become a driver of high paying green jobs, investment, and advanced education. Failure to do so will cede America's leadership position in this emerging field of science to other countries.

Conclusion

Pathway is committed to improving the health and well-being of our customers. We are also committed to ensuring that everything we do is based on rigorous scientific standards and complies with all applicable laws and regulations. Genetic testing holds great promise to help people live more healthy and productive lives. Allowing consumers, in consultation with health care professionals, to access their genetic information empowers healthy and proactive choices. We are excited about the future of genetic testing, and look forward to working with FDA to ensure that the services we offer are of the highest quality and value to the American public.

Pathway Genomics appreciates the opportunity to testify at this hearing, and appreciates the Committee's consideration of this important issue.

Mr. STUPAK. Thank you. And thanks for your testimony.

I will start questions.

Ms. Gould, Dr. Vanier, and Dr. Becker, to get a sample on each of you, you would spit in a little vial and the customer would send it back to you, correct? None of you use the cotton swab?

Mr. BECKER. That's correct.

Mr. STUPAK. OK.

Let me put up on the board, then, GAO's report. You know, Dr. Evans said that he thought it was entertainment versus medicine. You all are telling us that your sampling is accurate, that you use markers, you assure quality.

Then why, on Mr. Kutz—he is the 48-year-old male here. And I believe Company No. 1 is 23andMe, Company No. 3 is Pathway, Company No. 4 is Navigenics.

So if you just take prostate cancer, if you're all accurate and you're all using markers and you take the same kind of saliva as your source, why would we have three different results for prostate cancer for Mr. Kutz?

Or even if you go to high blood pressure, Navigenics didn't test it, but we got different results. Go to diabetes, with the companies, you got different results if you tested for it.

So how do you explain that? Same person. You all say you have quality assurance. You all make sure the markers, and you do all this testing. Why do we have three different results with three different companies?

Ms. Gould, do you want to start with you?

Ms. GOULD. Sure. Thank you.

So we did ask for the GAO testimony in advance and didn't receive it. So it would be difficult to respond with specificity to these particular conditions, although we are happy to follow up to do that.

And I want to stress that we feel extremely confident in the analytical validity of the tests that we have, and——

Mr. STUPAK. But then why wouldn't you all have the same result? If you're all so analytical, you're all so accurate, you're all so using the markers——

Ms. GOULD. Right. So, for risk predictions, which is a subset of the things that the companies test for, we use a predictive model. And the predictive model among the companies is different based on the standards within the company, which is why we agree standards are necessary across the company.

So we are relatively conservative in the standards that we have. We require for these an initial study that has 700——

Mr. STUPAK. So you're saying you're all using different standards?

Ms. GOULD. So, there are different standards for inclusions of which SNPs are looked at and what weight is given to them. And there are differences among which variants can be tested among the technologies that are used by the different companies.

So we agree that it is not acceptable to get the different results and that we need standards. We have written a letter to the head of NIH and FDA requesting their help. We have worked with our colleagues and will continue to do that to set these standards.

Mr. STUPAK. OK. So what you are saying, then, is you don't have standards yet to accurately inform a customer whether or not they have prostate cancer, high blood pressure, or diabetes. There's no standards yet, so we don't know.

Ms. GOULD. So, 23andMe has standards, and the other companies have different standards. There's not a——

Mr. STUPAK. So as long as you all have different standards, the customer can't rely—he could get different results from every company, then. So there is no reliability then, accuracy.

Ms. GOULD. We believe there is accuracy. We agree there need to be uniform standards. I think it's important——

Mr. STUPAK. So the accuracy really depends on whose standards you're talking about.

Ms. GOULD. I don't think the accuracy depends on the standards. I think it is important to note these are risk predictions; these are not diagnoses.

Mr. STUPAK. OK. Well, even call it risk predictions, call it whatever you want to call it. We get three different results from the same saliva, from the same person, and you all claim you got accurate results. How are we to believe any of you can accurately do it?

And Dr. Evans is right, it is entertainment, not medicine.

Ms. GOULD. Again, I agree that we need uniform standards, and we are interested in working on that. We agree this is a——

Mr. STUPAK. So consumers should not trust any of these results until we have uniform standards put forth by NIH and the FDA.

Ms. GOULD. We provide a lot of context on our Web site. We are fully transparent about exactly what we are looking at in these. We do believe that our customers understand what they are getting when they see our reports.

Mr. STUPAK. Sure.

Ms. GOULD. We also discuss the interplay between genes and environment, that this is a risk prediction. And we do believe that customers can rely on the data.

Mr. STUPAK. For entertainment purposes only, not for medical reasons.

Ms. GOULD. Our service is for information and educational use. We continually remind customers that, if they have questions about these health reports, they should seek their health care professional or a genetic counselor. And we make genetic counseling available through an independent third party.

Mr. STUPAK. But Dr. Shuren and Dr. Evans testified that even the results we've seen tells a person nothing.

Ms. GOULD. Excuse me?

Mr. STUPAK. That the results medically are useless to them. Dr. Shuren testified to that, and Dr. Evans testified to that, too.

Ms. GOULD. Well, Francis Collins, in his book, "The Language of Life," when he was discussing his Type 2 diabetes results, he found that information compelling. And based on that information, he lost, I think, 20 pounds.

So we have other examples in our written testimony——

Mr. STUPAK. Well, I'm not a doctor, but I know if I'm overweight I have a chance of diabetes going up. I mean, I know that. I could even write a book about it and say that, you know?

Ms. GOULD. Right. It gave him the impetus to do something about it, which is exactly what Dr. Vanier was talking about.

So, we also have another example in our written testimony. We do believe and have stories of customers who have received information, taken it to their physicians, and had improved health outcomes. And——

Mr. STUPAK. I guess—if we can put that chart back up. I wouldn't believe anything until all those results were the same. If we got three good companies, all doing this testing, the same type of saliva, from the same person, your results should be the same. Until you can do that—and you're right, we need standards. And, hopefully, from this hearing, we will move along with that.

And my time is up, so let me go to Mr. Burgess for questions.

Mr. BURGESS. Thank you, Mr. Chairman.

And, actually, as a full-service member of this committee, I'm going to answer your question that you asked of the panel. And, actually, I'm not going to answer it; Dr. Collins is.

And you referenced, Ms. Gould, his book, "The Language of Life." And he describes the discrepancy that has been put to us on the prostate cancer. He said, when he got his results—his father had actually had the disease. 23andMe results arrived. "I was relieved to see a prediction of lower-than-average risk. But deCODE disagreed, saying my risk was slightly elevated. Navigenics upped the ante substantially, placing me at 40 percent higher than the average male."

His question, "What on earth is going here? To sort this out, I had to drill down into the details of the lab studies." And here is the explanation. 23andMe tested for five variants known to confer prostate cancer; deCODE tested for 13; Navigenics had tested for nine. There was considerable overlap between the DNA markers tested, but no company had actually tested for the complete set of 16.

So I guess my question, then, to our three panelists—and at least two of the three of you, I heard, use CLIA-certified labs to get your results, and that is good. So the results of each of those SNPs was accurate. But it is an evolving science as to which ones you include in the panel and how you make predictions based upon that.

How do you handle new information as it comes forward? Once you decide, Ms. Gould, on that five that you're going to use for prostate cancer risk, does that never change? Or, as new information comes forward, you've still got the DNA in the database, so you could go back and look at any of the other 16 and make a determination if you decide that a different set needs to be used.

And if there were scientific consensus—and here is where the FDA could help—if there was standardization, then perhaps there wouldn't be this discrepancy we see on the slide.

So, my time is limited, but would each of you briefly comment on that?

Ms. GOULD. Yes. So we do regularly update our reports, at no charge to our customers. And we include new studies as they meet our inclusion criteria set forth in our white papers, which are on our Web site. So the answer is, yes, we absolutely update.

Dr. VANIER. We do the same.

I would also mention, as to standards, first of all, I think that Dr. Shuren's articulation of a way going forward for standards is going to be an excellent one for our industry. In the interim, however, I would point out that there are branches of government that has put forth standards, such as the CDC with their Venice criteria. And that is specifically a set of criteria that we have used.

But, indeed, it is an evolving science. And as new standards meet that criteria, they are added to our panels.

Mr. BECKER. We also have a trained staff of geneticists, of physicians, and Ph.D. Scientists that review and help to update our service on a regular basis.

Mr. BURGESS. Dr. Vanier, one of the clips that they played for us was a woman who was given advice that you probably, pretty certainly, might definitely have an increased risk. I mean, that was a terrible clip. And, again, as I said, that sounded like a telemarketer giving genetic counseling.

Have you done anything to tighten up those standards within your company? Because, of all the things we heard this morning, that was probably the most startling.

Dr. VANIER. So, there are two clips. And so, first of all—actually, let me begin by saying that, regardless of which company are the sources for any of those audio clips, it is obviously extraordinarily disappointing, both as a physician and as a company that is helping lead this industry.

And until the GAO can tell us which clips belong to which company—that would certainly be helpful. I suspect the clip of the woman asking for her fiance as a gift, because it references ancestry, is not our company because we do not do that sort of testing.

Mr. BURGESS. Right. I think your company was identified as the one that gave the breast cancer advice.

And all I would ask is that you've got to tighten that up. I mean, regardless of what we do, regardless of what legislation, regardless of what regulations the FDA puts out, that is unacceptable and truly frightening, that someone with no medical background, with just having been given some talking points on how to respond to a question, would be answering a question of that importance.

I mean, that is a 30-minute discussion between a patient or a primary care doctor. I mean, I know that, because I have had those discussions. That is not something you can answer over the telephone. And that conversation in no way provided that patient any real insight and, in fact, probably provided a great deal of worry.

Dr. Evans, let me just ask you a couple of things. Now, you talked about the entertainment value of medicine. We shouldn't discount that. I'm an OB/GYN doctor by profession. And, certainly, the boutique sonogram, Baby's First Picture, that was available in lots of malls during the years that I was practicing, I would all the time be asked to comment on the pictures that were made on some substandard machine at a shopping mall.

So it is probably no surprise that there is an entertainment value for this——

Mr. WAXMAN. Mr. Chairman? We have votes on the floor. If there is a chance for some of us to ask questions—the gentleman's time has expired. He is still in the middle of his question.

I wonder if you would allow me to have a couple of minutes, because I'm not going to be able to return to be able to ask questions of this panel. His time has expired.

Mr. BURGESS. Very well.

Mr. STUPAK. All right. We'll go a second round.

Chairman Waxman, for questions.

Mr. WAXMAN. Thank you. That will give him a chance to go further. And I want to get a chance to ask some questions.

If we are going to have these consumer tests, there ought to be some standards. Ms. Gould, you said there ought to be some standards.

Dr. Vanier, Dr. Becker, do you agree there ought to be some standards?

Dr. VANIER. Clearly, Chairman Waxman.

Mr. WAXMAN. OK. So we heard from the first panel that the FDA ought to regulate this, because they handle medical devices. Do the three of you think that you ought to be regulated as medical devices?

Ms. Gould?

Ms. GOULD. We have not agreed in the past with FDA's characterization of our service as a medical device. We are meeting with them tomorrow and look forward to hearing more about why they believe that. That——

Mr. WAXMAN. Well, who should set the standards if it's not FDA?

Ms. GOULD. That said, I think FDA should be involved in the standards. I was pleased to note Dr. Shuren talking about a new framework for genetic testing, and we think that that is really needed.

NIH has also put out comments for a registry. We have provided comments for that. We think that is a great thing, as well.

Mr. WAXMAN. Uh-huh.

Dr. Vanier, a quick answer to that? Do you think you ought to be a medical device regulated by the FDA?

Dr. VANIER. I would agree, the insight that I have into this, as I was invited to speak at the FDA's panel regarding all laboratory-developed tests early this week, and I think the consensus you heard from the hundreds of companies that attended was the FDA clearly has a role to regulate the quality of the science and the quality of the markers that were used on our panel.

Mr. WAXMAN. And, Dr. Becker, do you agree with that?

Mr. BECKER. I do agree with my colleagues. And I think Pathway is committed to working with FDA to help develop appropriate standards that are prudent in this area but do not completely stifle innovation, as well as affect overall laboratory-developed tests.

Mr. WAXMAN. How would it stifle innovation? If you have to live up to certain standards and if you're going to give people predictions about their health, upon which they are going to act, how would that stifle innovation, to ask——

Mr. BECKER. I don't believe that that will stifle innovation. But the current structure of FDA regulation, if applied the way it is today, could completely not only—if it is applied to all laboratory-developed tests, could significantly affect the testing industry, not just genetic testing.

Mr. WAXMAN. Dr. Evans, you're a physician. If a patient came to you with the result of one of these tests that said they had a 13 percent risk or a 20 percent risk or a greater risk, something like that, either quantified or not, of breast cancer, how would you respond to that patient who is alarmed and wants to know what it means?

Dr. EVANS. Right. I would tell them several things. First of all, I would tell them that, as evidenced by that elegant experiment that the GAO did, we have no idea, and neither does anybody in those companies, really how to interpret and analyze those risks. We simply don't know. And that is obviously quite clear.

Secondly, I would tell them that the magnitude of the increased or decreased risk really doesn't matter for them. All right? What they need to do, as Representative Stupak said, for general health promotion is to do the things we have already known for a long time are important in health promotion.

Thirdly, I would tell you that, when it comes to parsing risks, even if we could do that—there are many claims made about prevention and the power of prevention. But, number one, there isn't a bit of evidence that genetic data is magical in its ability to get people to change their behavior.

And, number two, even if it were—so let me grant for a second this fantasy that genetic information is going to induce people to change their behavior. If that is the case, we have a bigger problem. Because, for every person I identify who is at increased risk for a given malady, I will mathematically certainly identify another individual who is at a decreased risk. If this information is so powerful in changing behavior, then I have set the stage for counterproductive behavior in those people.

Mr. WAXMAN. Now, what would be more valuable to you as a physician and your patient, family history or this assessment that——

Dr. EVANS. Oh, we actually have tremendous data on that. One can take all of the risk factors that we know about for diabetes, heart disease, breast cancer, what have you, they add nothing to our ability to predict risk if one simply puts a patient on a scale, asks them a few questions about their family history.

Maybe someday we will get to the point where we can do that, but we are nowhere near that point now. And there is tons of data to support my statement.

Mr. WAXMAN. Mr. Chairman, if the companies are selling a product that promises to improve health, then its scientific validity should be established. I don't think we ought to leave it to them to decide that question, because they have a financial interest to decide it in their way.

Government has to have some standards and enforce them. We do this all the time. FDA seems the appropriate place. The question is whether it should be the rigid formulation of a medical device or something else. But we need standards, and we need them enforced.

Thank you.

Mr. STUPAK. Thank you, Mr. Chairman.

We have two votes on the floor. We are going to stand in recess for 20 minutes. We will come back with this panel in 20 minutes.

We are in recess.

[Recess.]

Mr. STUPAK. The hearing will come back to order.

I'd remind the witnesses that they're under oath.

When we left off, I think Chairman Waxman had finished. So it would be to Mr. Gingrey for questions, please.

Mr. GINGREY. Mr. Chairman, thank you.

I'm going to start by asking a few questions of Dr. Evans.

Dr. Evans, in your testimony, you state how important it is that the information patients receive be of high quality. From what you have seen and heard today from the previous panel and from your co-witnesses on this panel, do you have confidence that patients are, indeed, receiving high-quality information from these companies?

Dr. EVANS. I think there's two parts to that answer.

With regard to what physicians call analytic validity—that is, if they tell you that you have an A, one of the DNA building blocks, at disposition, I believe it. OK? Absolutely, they do quality work from an analytic standpoint.

However, with regard to quality related to what we call clinical validity—that is, what does this tell you about your risk of this disease—I would say, absolutely not. And the GAO experiment shows that in a beautiful way. No one knows how to interpret these data. And that is quite clear.

So, quality information, to be of quality, must be meaningful. It is not meaningful. And, therefore, I would say, no, this isn't quality information.

Mr. GINGREY. So, measuring one's blood pressure and finding that it is elevated, or measuring one's cholesterol and finding that it is elevated, or measuring one's blood sugar and finding that it is elevated, these are not comparable, then, to this information that you would get in regard to this genetic testing?

Dr. EVANS. That is absolutely correct. Because there are two reasons. One is that I can go to three different doctors, and if these doctors are doing their job right, my blood pressure is going to be reflected the same at each place. My cholesterol should be essentially the same, you know, give or take some degree of variation.

But as we have seen here——

Mr. GINGREY. Yes, from the slide that Chairman Stupak presented in the first panel——

Dr. EVANS. Yes, so this is not comparable information.

Mr. GINGREY. Well, you know, it reminds me of—and thank you for that response. There are scans that companies do to detect the amount of calcium in one's blood vessels, whether it is the aorta or the coronary arteries, whatever. I mean, you just get a report back. And if it is a lot, I guess you'd say it is 3-plus.

And I have a brother who's a year and a half older than me. He doesn't like to admit that. But he had one of these tests done, and it said, oh, yes, you've got a lot of calcium, and you'd better go see your cardiologist. Well, it took him 2 months to get an appointment. It is a wonder he didn't have a heart attack in that time from anxiety.

But he ended up seeing—but, finally, he ended up on the operating table for a coronary angiogram, which showed that, you

know, he didn't have as much as 60 percent blockage in any vessel. And it was just a curiosity, really. And he ended up probably spending about $10,000 in the process. And, of course, the coronary angiogram is not without risk. He could've had a heart attack on the table.

Dr. EVANS. That's right.

Mr. GINGREY. So, I mean, this is the kind of thing that, as a former physician—well, I'm still a physician. I've got an active license, thank goodness. But I am concerned, I am concerned about this.

Dr. EVANS. Well, yes, Dr. Gingrey, your comparison is absolutely apt. The advent of this type of testing is, I think, entirely comparable to these scans which we simply don't know how to interpret and which, when misinterpreted and not understood in context, can lead to harm.

Mr. GINGREY. Well, you even, in your testimony, Dr. Evans, suggested that it is kind of an entertainment thing. It is sort of like Dr. Burgess, earlier in his questioning, was talking about these ultrasounds that are done in the shopping malls, and they're—I don't know—they're more than 3–D, they're 4–D. And they're for entertainment purposes.

Dr. EVANS. Sure.

Mr. GINGREY. I want to switch quickly in my remaining time, Mr. Chairman, to ask maybe the triumvirate of Ms. Gould and Dr. Vanier and Dr. Becker, do you agree that what you are providing to these patients, if you will, or direct-to-the-consumer information about their genome is more for entertainment than it is for a real therapeutic, possibly, and diagnostic value?

Dr. VANIER. Dr. Gingrey, I would like to respond to that.

First, I appreciate and think it is very important that Dr. Evans is on this panel. But I want to make it clear that there is no uniformity in the academic medical world around issues like this. There is indeed, for instance, research that shows that behavior does change.

Second, I think your analogies to high cholesterol and hypertension are apt, because the genetic risk information that is imparted is relatively of the same predictive value of hypertension and high cholesterol. And just as we know many people who may drop dead at the age of 90 despite having high blood pressure and we know people that, you know, have many risk factors and continue to live on and on, these are probabilistic; they are not predeterministic. And so the information that genetics is uncovering is analogous to the risk factors that you used in your practice and I use in my practice today.

There are often analogies made to the body scan industry, for instance. And we don't believe they're apt, as long as you have a health care professional to support and interpret the information. Most of the body scan industry came out of the fact that you had vulnerable consumers that were getting these CAT scans and then the information was handed over to the physicians and they didn't know what to do with them.

There is clearly an educational gap in the physician base. More physicians need to be educated about genetics. But the ones that are—for instance, we work with a couple hundred physicians—very

much know what to do with the information because it is akin to the risk information they've been using for all of their practice.

Mr. GINGREY. Dr. Vanier, I'm going to have to let your response be suffice for the other two, because I am 2 minutes over, or a minute and a half.

And I will yield back.

Mr. STUPAK. Thank you, Mr. Gingrey.

I know there's more questions. I know Mr. Burgess has some. Let's go another round here.

Dr. Evans, could you grab that book right there? I've got a couple of questions I want to ask you.

Could someone hand it to him? Thank you.

You know, we've talked a lot about direct-to-consumer testing companies that offer a variety of products for their clients. One type of test looks at how a person reacts to and breaks down certain prescription medications. This obviously can be very useful when a person is diagnosed with an illness and the physician is developing a treatment plan.

But I want to ask you to take a look at Exhibit No. 6 there. When it is done with direct-to-consumer testing, in that world, it really raises some questions. Because if you look at Exhibit No. 6, this is an internal Navigenics document that shows a consumer's test result for the processing of a drug. I need your help there.

Dr. EVANS. Irinotecan.

Mr. STUPAK. OK. Irinotecan. That drug is commonly used for treating colorectal and other cancers.

The document shows us that this consumer has a low risk of the side effects for this drug. The document then goes on to say that, if he or she is being treated for cancer, then their medical team may want to prescribe irinotecan.

Dr. Evans, in your opinion as a physician, do you think this document provides medical advice?

Dr. EVANS. Well, clearly. Yes, it is providing advice, in my opinion.

Mr. STUPAK. Good.

Dr. Vanier, this is your company, right?

Dr. VANIER. Correct.

Mr. STUPAK. So are you giving medical advice for this patient here?

Dr. VANIER. In fact, the statement you read suggests that the patient should do anything in consultation with their physician. In no case do we recommend that anyone take independent action. This is specifically why we have genetic counseling support and why we primarily work through physicians.

Mr. STUPAK. Right, but isn't your document—if you take a look at it, if you want to see it, it says your patient's risk of side effects—you have a high risk here, it says. I want to make sure I'm on the right one here, No. 6. OK, this is the drug. Your side effect is low risk.

And so, are you not giving medical advice? I mean, where does it say there, "Consult your physician"?

Dr. VANIER. The statement, Chairman Stupak, if I understand what you are reading, is, "Based on your genetic markers, you're likely to have low risk of side effects."

Mr. STUPAK. Right. So, based upon—OK. Go ahead.

Dr. VANIER. Those sorts of statements are pulled directly from the pharmacogenomic literature. And, in fact, the pharmacogenomic markers on our panel, in many or most cases, come from the FDA list of qualified markers.

Mr. STUPAK. Sure. And then it says right underneath that where you read, it says, "We determine your risk by analyzing your genetic code." So, by looking at the little vial of spit that they gave you, you made the determination that this individual should take this drug for cancer, right? It would be good for them if they had cancer, right? They should take that?

Dr. VANIER. We specifically point out that it would be helpful for the medical team to know that they are at low risk. And, in fact, irinotecan testing, along with, for instance, Plavix testing, is an area of great interest for oncologists and cardiologists today because the data is robust.

Mr. STUPAK. OK, well, let's go to the next one. Let's go to Exhibit No. 5 in that book there, OK?

The document is given to physicians whose patients recently had genetic testing done by, again, your company. The document notifies the physician that his or her patient is likely to have a high risk of side effects of the drug abacavir, a drug commonly used for treating HIV infection. The document goes on to inform the physician they may want to tailor the patient's therapy to reduce the chance of abacavir hypersensitivity and lists four treatment options.

Again, isn't this giving medical advice?

Dr. VANIER. No. The bright line that is often drawn here is we do not specifically state, because the data does not support it, which drug the physician should use, which dosing that they should consider, et cetera.

Mr. STUPAK. Well, then why do you bring up this drug, then, if you're not telling the doctor which drug to use?

Dr. VANIER. It is information that simply should be taken into account. For instance, the FDA has recently put a black label warning on Plavix that there are different genetic responders. In no case, for instance, for Plavix do we tell the physicians what to do. It is simply raising an awareness, just the way the FDA did with their labeling.

Mr. STUPAK. And, Dr. Evans, you think they are giving any medical treatment here?

Dr. EVANS. Well, it certainly seems to me to be medical advice. And I think that this is an example—these two examples are very good exemplars of the fact that some of the information contained in these scans has robust genetic and medical implications. Therefore, this is, you know, I think by any commonsense interpretation, medical advice.

Mr. STUPAK. Dr. Vanier, do you certify all these letters that go out, as the doctor, then, for Navigenics?

Dr. VANIER. Yes, we have a medical advisory board that looks them over.

Mr. STUPAK. OK. Do you, though? Do you personally?

Dr. VANIER. Yes.

Mr. STUPAK. OK. So if, as Exhibit No. 5 or No. 6 there, Dr. Evans, if I came to you as a patient and gave you this, what could you take from this information that I brought to you as I received this letter from Navigenics?

Dr. EVANS. Right, I would probably do two things. One is, especially in the case of abacavir, the data are so robust that show that if one has a particular version of this HLA gene, that they are much more likely to have a serious reaction to abacavir, I would take that very seriously.

I would be very tempted to repeat the test because of all of the tests that have been done at the same time. But I have no great quibble with the analytical validity. I trust that result.

My quibble with that particular issue is that it's medical advice.

Mr. STUPAK. My time has expired.

Mr. Burgess for questions.

Mr. BURGESS. Thank you.

Dr. Evans, in your written testimony, you—and I think you addressed it in response to a question, the issue of being at increased and decreased risk, and if someone is at increased risk, there's someone out there at decreased risk, and the advice might be inappropriate in both instances.

Now, there was quite a flap created in this committee a little less than a year ago, when the United States Preventive Health Task Force came with some revised recommendations on mammography, that individuals between 40 and 50 no longer need them. Well, it turns out they walked back from that.

And there was also some concern that the health bill, as it was being written, would incorporate some of those things, such that people covered under specific plans might end up not being covered if those guidelines fell outside the U.S. Preventive Health Task Force.

Would it not be worthwhile—if that world was the one that had persisted and existed today when the bill was signed into law, might this type of testing not be helpful for a woman between 40 and 50 to assess whether she go out and purchase on her own the screening test that might be life-saving?

Dr. EVANS. Actually, no, for a couple of reasons, Congressman.

Number one, the degree of risk determination that these types of tests generally provide is so lacking in robustness that we really don't know whether a woman should be getting mammograms early or not based on these kinds of results.

It is very different from the situation for, say, BRCA–1 or 2, the genes that, as you know, confer an exceedingly high risk of breast cancer, in which we've got pretty good data to suggest that those women need to be treated very, very differently. These results, however, aren't of sufficient robustness to really guide who in the population should get mammograms early or not.

And I would also, again, go back to the GAO experiment, which shows that we don't know how to interpret them. In other words, we will be misassigning women right and left, if we try that, that to high-risk or low-risk.

Mr. BURGESS. Well, but the U.S. Preventive Health Task Force may have just misassigned everyone in that age bloc.

Dr. EVANS. Yes. Unfortunately, the reality is that, in medicine, we—although from a wishful-thinking standpoint we might want to be able to assign people a very precise risk, the reality is that we are not good at it, as the GAO report shows, and that we are asking for trouble, in my opinion, if we start telling a woman, "You don't need mammograms until X date because of your genetic profile."

Mr. BURGESS. Well, but that is not the issue. And I would just submit—and I've got some of the same concerns that everyone else up here on the dais has. But I would just submit that, in a world that at one point seemed to be rapidly moving to one-size-fits-all, government-controlled medicine, I would think the consumer could see real value in being able to assess whether they individually might need to make a different decision than their government would make. In which case, this type of testing, I think, could be extremely effective.

Dr. EVANS. If this type of testing were consistently—if it were consistent between labs, and——

Mr. BURGESS. Right. And we have a Federal agency who is responsible for that.

Dr. EVANS [continuing]. And if it were meaningful——

Mr. BURGESS. And my hope is that they will now respond and provide the background and the guidance that the consumer needs, not so much the provider needs.

Dr. EVANS. Right. The——

Mr. BURGESS. Let me just ask Ms. Gould a question before my time runs out.

Now, you reference in your written testimony an individual who had an increased likelihood of a deep-vein thrombosis, a blood clot, an increased propensity for blood clots, and wasn't aware of this until the testing was done.

I mean, I will just tell you, as a practicing OB/GYN, nothing strikes more fear in your heart that you might do a relatively minor procedure on a very young and healthy person and have them spend weeks in the hospital recovering from a deep-vein thrombosis or, worse yet, die of a pulmonary embolism. And that is one of the most frightening things that we can face in medicine. You can imagine, from a medical/legal standpoint, it is extremely concerning.

I was intrigued by that story that you included there. We went from a world where, early in my career, you just accepted that as a risk until, later on, everyone got a low dose of heparin right before surgery because we lived in a medical/legal environment that you just couldn't tolerate the one in 10,000 who would have that complication.

So what has the experience been at 23andMe? Are you guys following this? I mean, that is a compelling story, but an anecdote doesn't a series make. You need at least two anecdotes to make a series. Have you been following that?

Ms. GOULD. Yes. And we do have several customer stories. And I think this goes to—you know, there was the word used, "fantasy," before. You know, we strongly disagree with that. Colleen McBride at NIH has written that, when people get access to their online genetics, it can be very empowering, and it can be a great oppor-

tunity for a physician to leverage that to help them make better lifestyle choices.

We have had a number of examples where people were getting access to this information that they would otherwise really not have known, and talked to their physicians and health care providers and have seen better health outcomes.

Mr. BURGESS. Well, I will just say, from a clinician's standpoint, I mean, you welcome all information that comes from any source, especially if it is going to keep you out of that kind of trouble.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Burgess.

Ms. DeGette for questions.

Ms. DEGETTE. Thank you, Mr. Chairman.

Thank you for your comments. Mrs. Christensen and I had to run over and vote in the Resources Committee.

I have a couple of follow-up questions that I wanted to ask. The first one is on the privacy issues. And, as you know, we only have 5 minutes, so if people can be relatively short in their answers, I would appreciate it.

Ms. Gould, does your company believe that we should protect the privacy of medical information of the people who undergo this testing?

Ms. GOULD. Yes, we absolutely believe——

Ms. DEGETTE. Thank you.

Dr. Vanier. You need to answer verbally.

Dr. VANIER. Oh. Yes.

Ms. DEGETTE. And, Dr. Becker, do you believe that, as well?

Mr. BECKER. We absolutely believe in that.

Ms. DEGETTE. OK.

Now, for Dr. Vanier and Dr. Becker, I realize you did not see the GAO report until this morning. But, in the previous panel, Mr. Kutz testified that the two companies that told the young woman online that her fiance could send in their medical information to surprise him with his genetic background were your two companies. And I would assume from both of you that you have specific policies against this practice.

Correct, Dr. Vanier?

Mr. BECKER. If you will, Congresswoman——

Ms. DEGETTE. Well, I asked Dr. Vanier, and then I will ask you.

Does your company have a specific policy against this practice?

Dr. VANIER. We do. And I would——

Ms. DEGETTE. Thank you.

Dr. VANIER [continuing]. Also like to correct the assertion that that was our company, because it was involved in ancestry, and we do not offer it.

Ms. DEGETTE. OK. Well, no, I wasn't referring to that specific audio clip. He said—and, again, this is a little unfair to you, I realize, because you haven't seen the GAO report. But he said the two companies that told them that they could send in the fiance's information were your two companies.

But if that was the case, that would be against your company policies, correct?

Dr. VANIER. Correct. I would strongly like that information corrected.

Ms. DEGETTE. Yes, I bet you would, and we'll make sure you get it.

Dr. Becker.

Mr. BECKER. That is correct. That is against our policies. We take responsibility for that particular action and feel—that action was reported. I'm aware of that.

Ms. DEGETTE. OK.

Mr. BECKER. That was reported very quickly after that discussion with the customer service person happened. We took the appropriate——

Ms. DEGETTE. So that clip was from your company.

Mr. BECKER. It was.

Ms. DEGETTE. And that is against your policy, right?

Mr. BECKER. That is against our policy.

Ms. DEGETTE. So this leads to another question, because all three of the companies represented here are companies that are trying to do important work. And I don't think anybody—well, maybe somebody on this panel, certainly not me—would object to this type of information being gathered and given to consumers.

What we are all concerned about is the same thing you're concerned about, is that it be done to a high degree of medical certainty and that people's privacy is ensured and, also, that they get adequate medical advice. I think we can all agree with that.

And so, my question would be, to all three of you, how do you think that we could protect confidential patient information if you have essentially telemarketing individuals on the phones talking to folks about these tests?

Mr. BECKER. If I will——

Ms. DEGETTE. Sure.

Mr. BECKER [continuing]. Congresswoman, thank you very much for the question.

We did take action to train that person and correct the ability of that to happen. So this was a customer service agent. We take it very seriously, this particular incident. And we have—we no longer will do that.

Ms. DEGETTE. OK. Well, that's good.

Dr. Vanier, do you have anything to add to that?

Dr. VANIER. I do. I think we can look at the Genetic Information Nondiscrimination Act as a first step of an important series of legislation that would include genetic protections for consumers.

Ms. DEGETTE. But that is already in effect, that act.

Dr. VANIER. But it speaks to the fact that, obviously, individuals—that health plans and companies should not have access to that individual genetic data. I think that is a model on how you can begin to understand other legislation that would protect individuals'——

Ms. DEGETTE. So you think we might need additional legislation because of the narrowness of that act. Is that what you are saying?

Dr. VANIER. Yes.

Ms. DEGETTE. OK.

Ms. Gould, what would your view be on that?

Ms. GOULD. Well, we have strong both policy and technical safeguards to protect customer information. And we agree that privacy

is of utmost concern. We think GINA is a great start and agree that likely more will be needed in the future.

Ms. DEGETTE. Thank you.

Mr. Stupak, I think everyone else has had two rounds but Dr. Christensen. So should we have her question and then I'll take my second round?

Mr. STUPAK. Sure.

Ms. DEGETTE. Thank you.

Mr. STUPAK. Mrs. Christensen for questions.

Mrs. CHRISTENSEN. Thank you both.

My question, I guess, would first go to Dr. Becker. And if you could turn to Exhibit 11 in the binder. Mr. Kutz testified earlier that none of the companies was able to provide a complete genetic analysis for the DNA samples they submitted with African American and Asian profiles. And this is apparently due to limitations in the ethnic composition of the studies that the companies use to predict their customers' genetic risk.

Exhibit 11, at the bottom of the page is an internal e-mail dated November 12, 2009, that Pathway produced to the committee. And this document, one Pathway employee has sent another a proposed script for handling customers who self-identify as African American or Hispanic and, thus, will receive a more limited genetic analysis.

According to Pathway's document, the company first notifies customers of the limited available data when their report is almost ready to be sent. And the script for those of African descent indicates that they will only be able to provide limited information, for example, for females, just three conditions—Alzheimer's, Lupus, and Type 2 diabetes—and for males, four— Alzheimer's, lupus, Type 2 diabetes, and prostate cancer.

The script makes clear that the customer had already self-identified as African American. So why doesn't Pathway tell African American customers that the company would not be able to provide the full data before they make their payment, you know, not just when you're ready to send the results?

Mr. BECKER. Actually, Congresswoman, we do now do that activity. As you described, we do inform on our Web site, there is a clear matrix of what conditions you will get depending on what reported ethnicity you——

Mrs. CHRISTENSEN. So you now inform the clients and the customers before they make a payment what the limitations are?

Mr. BECKER. Yes, we do. And if they came on to our customer site without reviewing that information, it is our policy—and clicked on and paid, and then were disappointed with what they got, it is our policy to actually refund their money and discuss any questions or concerns they may have.

Mrs. CHRISTENSEN. OK.

Well, in the case of the Hispanic—I think it was a Hispanic—yes, the self-identified Hispanic customers, the proposed letter recommends that, quote, "we set your ethnicity to Caucasian."

Are the results accurate if you change someone's ethnicity and compare them to data for the wrong population?

Mr. BECKER. The results that we present are based on the ethnicities for—and the findings in the literature for those ethnicities. So they are accurate for those ethnicities. And we are

informing Hispanics to look at that information in that context, that this is information based on Caucasians.

Mrs. CHRISTENSEN. And you feel that it provides accurate enough information despite the fact that they're based on people of European descent rather than——

Mr. BECKER. Well, that is a very interesting question that comes down to the actual population mixture of the Hispanics. And the current literature suggests that Hispanics are actually divided into groups that are derived from Africans and Caucasians.

Mrs. CHRISTENSEN. Well, you already don't have much in the way of African information.

But, Ms. Gould, 23andMe produced to the committee an internal e-mail, also dated June 23, 2008, concerning a complaint of an Asian American customer who was unhappy that her genetic report was based on data from a European population. It is Exhibit No. 3, I think, in the binder.

Are the results your company provided to this Asian American customer as accurate as they would have been if you had data from an Asian population?

Ms. GOULD. So, we provide context in our reports where the underlying study—the populations in which the underlying studies were conducted. And we make that clear on our Web site, as well, that we can only provide data—and we provide this in the claim process before people get their data—that genetic research is not comprehensive.

And one of our core missions is actually to undertake more research. In fact, one of the projects that we are hoping to start is to try to replicate or fail to replicate existing studies in African American populations. We do think that it is critical that more research be done in order to show the applicability of the existing research in various populations. Unfortunately, most of this research, which has been NIH-funded, has primarily been done in European populations. This is one of our core missions, is to make——

Mrs. CHRISTENSEN. Well, we are very concerned about including more racial and ethnic minority populations in clinical trials and studies, as well.

But it seems, unless something has changed since, you know, we have this data, you were not, apparently, telling individuals that their data would have been limited if they were Asian or if——

Ms. GOULD. We do provide that, and we have provided that information previously.

Mrs. CHRISTENSEN. My time is up. I'll come back.

Mr. STUPAK. Thank you.

Ms. DeGette, you had some follow-up questions?

Ms. DEGETTE. Thank you. I just have a couple follow-up questions.

Dr. Becker, you had testified in your statement that you felt that FDA approval of these tests as medical devices could stifle innovation. The chairman talked a little bit to Ms. Gould about the idea of FDA approval as medical devices. And I'm wondering if you can briefly tell me why you think that would be the case.

Mr. BECKER. Well, I don't believe that it's FDA approval per se. The current structure of requiring premarket approval could actually inhibit the ability of this information to be accessible to people.

Ms. DEGETTE. And why would that be, sir?

Mr. BECKER. Well, because if pre-approval is required for all of these tests, it will take quite some time to collect, potentially, the clinical validity as defined today.

Ms. DEGETTE. So is there some alternate mechanism at the FDA that you believe could serve all the purposes we are talking about, to give a consistent level of data, to protect patient privacy, and also to regulate the kind of information they're given? Is there some alternate process at the FDA?

Mr. BECKER. Well, we do, and we do support Dr. Shuren's proposal this morning. But we also——

Ms. DEGETTE. I'm sorry, which proposal was that?

Mr. BECKER. He proposed a way forward. And I don't remember all the details exactly of that.

Ms. DEGETTE. OK.

Mr. BECKER. But he proposed a way forward that sounded very fair and reasonable, which I think is definitely the FDA's goal here. I don't want to speak for FDA, but the—well, I'm sorry. I will stop.

Ms. DEGETTE. Dr. Vanier, I wonder if you could comment on whether you think FDA approval as medical devices is the appropriate route to go?

Dr. VANIER. I think history shows over and over again that the correct, deft regulatory touch both protects the public and leaves the door open for innovation. Dr. Shuren's proposal, that it is the genetic markers that we use in our tests that need to be standardized and regulated, is something that we would certainly support.

Ms. DEGETTE. And that is great, and I support that too. The concern that I have, and I think probably many members of this committee would share that concern, that is only one component of what the problems that we have are. So how would we address those other problems in an alternate way?

Dr. VANIER. I think another component of the regulatory process, as has been discussed before, is the actual collection kit, the kit in which you, for instance, submit your saliva.

Ms. DEGETTE. Right.

Dr. VANIER. There is a history of that potentially needing to be a Class I device. And I think that is also an appropriate area to be looked at.

Ms. DEGETTE. OK. What about the privacy—well, you already talked about that.

Dr. Evans, I'm wondering if you can comment on all of this.

Dr. EVANS. You bet.

I think it is absolutely critical to apply a deft hand to regulation. Too blunt of regulation could stifle the ability of companies and academic laboratories to develop tests. So it is important.

I think the two things that I find most heartening by the FDA's approach are to take a risk-calibrated approach to testing—that is, you subject tests that have higher stakes to more regulation. And secondly, as was pointed out in the first panel, that one may be able to envision regulatory schemes which look at a subset of markers or a given platform and not have to clear every single test, so to speak.

Ms. DEGETTE. Mr. Chairman, I want to say two things. I think I can probably speak for all of us that we are pleased that this

panel has recognized that there is a need for improvement in standardization in the industry.

And I would also—it is always the practice of this committee to allow panel members to offer questions in writing. I think that is particularly important in this case, because all of us just received the GAO report this morning. So I would ask unanimous consent that we would all have additional days to submit questions in writing to this panel, but also that they would be able to supplement their answers in today's hearing based on the GAO report that they have been given.

Mr. STUPAK. As the gentlelady knows, we always have 10 days to put forth additional questions.

Would you yield on that point?

Ms. DEGETTE. Yes, I would be happy to.

Mr. STUPAK. Let me ask our panel this, then, in light of what Ms. DeGette said and what we have seen. Our hearing has shown that there is a gap between claims made by genetic testing companies and the value of the information actually given to the consumer. And, as Dr. Evans says, it is more entertainment than medicine.

So let me ask you this, then. Would you agree that until the FDA develops standards for testing, uniform standards for how you're going to test, uniform standards for genetic markers, and ensure the accuracy of the tests and standards for interpreting the test results, would you agree to stop this direct-to-consumer marketing for monetary value until the FDA has this standard set?

Ms. Gould?

Ms. GOULD. We don't think that that is the answer. We, again, believe in the accuracy of our tests. We provide——

Mr. STUPAK. So you're still going to continue marketing this test?

Ms. GOULD. We think that it is appropriate that we continue and that people have the right to access their genetic information.

Mr. STUPAK. For entertainment or for medical reasons?

Ms. GOULD. We provide our information for informational and educational use.

Mr. STUPAK. OK.

Dr. Vanier, would——

Dr. VANIER. Chairman Stupak, I think it is a great question but one put in the context of where we are as an industry. We are at the dawn of an era of personalized medicine, as the committee has pointed out. And as much early interest as there has been in the American public, I think it is important to understand that we are all small businesses. I suspect no one on this table flew in on a corporate jet this morning, for instance. And so, stopping any sort of offering in the public, typically from a venture capital perspective, means that most of the product category goes away for many years.

In our case specifically, because we distribute mostly through physicians and prevention and wellness programs, we would like to continue to be able to do so, given the health care support that we give.

Mr. STUPAK. OK. So let me phrase it like this. How much do you charge for one of your tests?

Dr. VANIER. Right now, we are at several hundred dollars.

Mr. STUPAK. OK, several hundred. How many of those several hundred is for profit?

Dr. VANIER. The gross margins range—actually, I would put it this way: We are a pre-profitable company. We are still venture-capital-funded. We are losing money every year.

Mr. STUPAK. OK. So would you stop marketing for a profit then? Would you stop marketing these tests for a profit? I know the claim you don't make a profit, but how much money do you draw off every year for this testing from Navigenics? Because that is part of the company's cost, right?

Dr. VANIER. Understood.

Mr. STUPAK. So, I mean, if you're doing this for public good, why would you charge people then? So we can build these databases and do genetic testing. But even if we did that, we need uniform standards, don't we?

Dr. VANIER. I understand. I think most of the innovation in health care business shows that you can do well by doing good. And I think hopefully that is what we are continuing and would like to do.

Mr. STUPAK. We haven't seen any good yet.

How about you, Dr. Becker? Would you stop marketing it until we get some uniform standards in testing here so we can interpret these results? I mean, the American people are spending a billion dollars a year for nothing.

Mr. BECKER. We think developing standards is absolutely critical. And being involved in that process should require the members at this table. And in order to do that, we should have the ability to have jobs——

Mr. STUPAK. Sure.

Mr. BECKER. —and continue to work hard and help FDA and Congress and——

Mr. STUPAK. So would you stop marketing it while we're helping FDA and Congress set standards?

Mr. BECKER. We would prefer not to stop marketing as we are today. And we are working, similar as Navigenics, with physicians and wellness programs. And so we have physicians involved, we have genetic counselors involved.

We feel that it is important to allow the public access to this information if they want it and present it in a responsible fashion, telling what genetics can and can't do. I think it is very important——

Mr. STUPAK. So what do you pay a physician to be involved in this? What does your company pay a physician to be involved in this?

Mr. BECKER. Yes, we would.

Mr. STUPAK. How much do you pay them?

Mr. BECKER. That is not my area. And I can get back to the committee——

Mr. STUPAK. OK, we will follow it up in writing.

Mr. Burgess?

Mr. BURGESS. Let me ask you a question. Are all three of the companies represented here today based in the United States?

Ms. GOULD. Yes.

Dr. VANIER. Yes.

Mr. BECKER. Yes, we are.

Mr. BURGESS. Now, one of the companies that is not here, deCODE, is based in Iceland. Are any of you currently marketing your products in Europe, for example, in the European Union?

Ms. GOULD. We do offer our services in Europe.

Dr. VANIER. We are mostly in Asia and Canada.

Mr. BECKER. We currently do not offer our products in Europe.

Mr. BURGESS. What is the experience with offering in Europe? What is the regulatory environment in Europe as relates to these products?

Ms. GOULD. We haven't heard any specific issues around it.

Mr. BURGESS. Europe has a similar regulatory agency to the Food and Drug Administration. There are obviously some differences. But so far, they have not shown any interest or curiosity in what is going on?

Ms. GOULD. Correct.

Mr. BURGESS. And the Canadian equivalent of the FDA, Dr. Vanier?

Dr. VANIER. Currently, no.

Mr. BURGESS. So at this point, the only regulatory efforts that you are aware of are coming from the United States?

Dr. VANIER. No, let me recharacterize my statements. While we have little commercial experience, for instance, in Europe, clearly genetic testing is an area of regulation in many countries. I know England has been taking a look at it, Germany has been taking a look at it as well, and there are clearly many personalized medicine coalitions and efforts in Canada as well.

Mr. BURGESS. And can the experiences of those bodies inform the activities that we are going to embark upon at the FDA? Is there a possibility for learned—or sharing learned experiences?

Dr. VANIER. I think that is always the case. However, in this specific case, I believe the FDA is showing leadership, compared to their counterparts abroad.

Mr. BURGESS. Well, let me just say that personalized medicine, I do believe that is the wave of the future. In fact, that is one of those things that concern me so much about this bill that we passed and got signed into law 3 months ago, was it moved us away from an environment of personalized medicine and moved us more into a regimented command and control type of structure.

So I for one am encouraged by what you are doing. I do want it done right. I do want the consumer protected, and I do want the information to be believable.

Yes, the FDA has a role to play, but I would submit that each of you and your companies has a role to play as well. And, yes, while there are some proprietary and some competitive issues to be protected, there is also the greater concept to be protected as well, which is allowing consumers to access information, just as we would a blood pressure or cholesterol or a blood glucose at a health fair that might be at any one of our churches or community centers back home.

So I think, Mr. Chairman, that is probably the extent of what I had. I did want to see if we could perhaps recall——

Mr. STUPAK. Yes, Mr. Burgess, we will do that. I owe Mrs. Christensen a round of questions, if she would like. We will wrap it up with this panel and bring back Mr. Kutz. He is still here.

Mrs. CHRISTENSEN. Thanks. Let's continue the same line of questioning I had before. Do all of the companies represented here have disclaimers regarding the limited results that would be available for people of different races and ethnicities?

Dr. VANIER. If I actually may correct an assertion made by Dr. Kutz, we do not collect any sort of ethnic information from our patients whatsoever, but we do certainly as well help educate them about the promises and limitations of the information, given the state of the ethnic literature.

Mrs. CHRISTENSEN. That is prominently displayed somewhere on your Web site?

Dr. VANIER. Yes.

Mrs. CHRISTENSEN. The answer is yes to the other two? So what if someone happens to miss that? I am hoping that it is really prominently placed on your Web site. Don't you think that someone should follow up for those? I guess I would be asking Ms. Gould and Dr. Becker since you two do ask that question, follow up.

If a person says they are Hispanic, Asian or African American or Native American, do you feel an obligation to go back and check and make sure that they understand that the information is going to be limited or don't you think there should be a checkmark or something to make sure that they see that they have seen that and noted that before they send in their payment?

Ms. GOULD. I think it is a great idea. It is something that I will definitely take back to the team, the concept of sort of a checkmark, do you understand this. We do not do follow-ups, to say do you understand, in which cases there have been only European studies.

Our service is also broad. We cover ancestry and other areas that are not as dependent upon ethnicity. So we feel like everybody has something to learn from our service. We do highlight the fact that genetic research is not comprehensive, and we want to be, again, part of learning more about that.

Mrs. CHRISTENSEN. OK. Briefly, if I could get one other question in.

Mr. BECKER. Just a quick answer. We could improve our service to follow-up. We also do not do that particular type of follow-up that you indicate.

Mrs. CHRISTENSEN. I was out for a while, so this question may have been asked in one way or another, and I am going to ask everyone, starting with Dr. Becker.

We have heard compelling testimony that the science is not there yet to meaningfully interpret the data that these kind of genetic tests product regarding risk for diseases, not even good enough to be interpreted by health professionals. As a physician, I feel comfortable though that if I took a good history, did a good physical and did some routine lab, I would get significant information on which I could predict, and useful information on risk for certain diseases.

Why then should someone order these tests, especially somebody from a racial and ethnic minority background? Dr. Becker?

Mr. BECKER. Certainly there are limitations in the state of science that are even higher relative to the other ethnic backgrounds outside of Caucasians, and we support NIH's effort to ameliorate that problem.

We think that being overlooked here is the motivational aspect of this particular service and the fact that these conditions show some increased propensity for cardiovascular disease, clearly Type 2 diabetes, things that are clearly actionable and affected by diet and exercise.

So although we recognize the fact that these conditions are not predictive at this time, and that needs to be responsibly reported to the public so that they understand clearly, we spend a lot of time developing the extensive amount of information that is provided to the customer about that specific effort.

Mrs. CHRISTENSEN. Dr. Vanier?

Dr. VANIER. There are well-known limitations to the physical exam. There are well-known limitations to the tools that we use in everyday medicine. For example, the National Cancer Institute just looked at the limitations of family history for screening for prostate cancer and breast cancer. And while indeed you have heard testimony today that the science may be early and evolving, you have also heard testimony today about the medical importance, for instance, of things like pharmaco-genomic testing. And I think when you hear the totality of the testimony today, an important point to make is none of us should be satisfied with the status quo, none of us should be satisfied with the state of the American health care system, and it is tests like these that open up a future of great use.

Ms. GOULD. I agree with what Dr. Vanier just said. In addition, we believe that people have the right to access their genetic information if they want to do that, and we think it is really important and it is a great educational tool to learn about genetics within the prism of your own data. And we think that is an important aspect to our service as well, as well as getting people in the research we are undertaking to advance our understanding of genetics overall.

Dr. EVANS. So, as my testimony has indicated, I think that the value of the bulk of this information is extremely low. I think that if one can get less meaningful, it is less meaningful for those of minorities. I think that I also agree that people should have access to their own genomes. But, again, I think that the claims made for that information should comport with reality, and I think that the idea that this adds to motivation or adds to our information is clearly demonstrably incorrect at this point.

Mrs. CHRISTENSEN. Thank you.

Mr. STUPAK. Thank you, Ms. Christensen.

Let me thank this panel for their testimony and thank you for appearing today to help us understand this problem. We all have a lot more work to do in this area. I appreciate your being here.

I excuse this panel. I am going to ask Mr. Kutz to come back for a couple of questions, if he would. Thank you.

Mr. STUPAK. Mr. Kutz, a couple of questions, if I may. Can we put up the slide of the predictions of the 48-year-old male, the one we had up earlier, the first question or two, and then Mr. Burgess has some questions on some other parts of your testimony and we will get to that.

There has been some confusion. Identify the companies, company one, two, three, four, if you would, please, for us.

Mr. KUTZ. Company number one is 23andMe; two is Decode, the one Dr. Burgess said I should look at actually; three is Pathway; and four is Navigenics.

Mr. STUPAK. OK. Decode, number two, that was the company from Iceland, I believe you said?

Mr. KUTZ. That is correct.

Mr. STUPAK. That is all I had. You wanted to clarify some parts, Mr. Burgess, with this witness?

Mr. BURGESS. Yes, sir. We had two vignettes, one that dealt with the risk factors for breast cancer and one that asked a question about obtaining a surprise for their fiance.

Mr. STUPAK. Can we get those vignettes up?

Mr. BURGESS. There you go. Can we identify the companies so we are clear on that, because there was some confusion here on the dais here.

Mr. KUTZ. Yes, sir. On the breast cancer it is Navigenics.

Mr. STUPAK. And the other one you wanted was——

Mr. BURGESS. The awesome gift. It would be an awesome gift.

Mr. KUTZ. That is Pathway.

Mr. STUPAK. Again, we just should identify for the record it is the individual who wants to give his fiance the DNA testing results, and that was Pathway. Do you have any further questions of this witness?

Mr. BURGESS. No.

Mr. STUPAK. No further questions. Thank you, and thank you for your clarification.

OK, that concludes all questioning. I want to thank all of our witnesses for coming today and for their testimony.

The committee rules provide for and as we said during the hearing, members have 10 days to submit additional questions for the record. It has also been requested and is unanimous consent that any of our witnesses who testified who wish to supplement their testimony will have 10 days to do so.

That concludes our hearing. This meeting of the subcommittee is adjourned.

[Whereupon, at 1:10 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Opening Statement of the Honorable Joe Barton
Subcommittee on Oversight and Investigations
Hearing on
"The Outbreak of Salmonella in Eggs"
September 22, 2010

Thank you, Chairman Waxman for convening this important hearing. This Committee has held over a dozen hearings on food safety over the last four years, and now we have another unfortunate outbreak to investigate: over 1,500 reported cases of salmonella illness across America traced to bad eggs.

From past investigations and what we have discovered so far during this one, we know that the weaknesses in food production and regulations sometime give rise to sudden and at times lethal outbreaks of illness, and that these flaws will never go away by themselves. Neither government nor industry can shrug these things off.

I want to say thank and welcome our first panel of witnesses, Mrs. Lewis and Mrs. Lobato. Both women were sickened by the salmonella contamination that was present in eggs produced and brought to market by Wright County Egg and Hillandale Farms.

The investigation into the ultimate source of the salmonella contamination in the eggs is ongoing, and many other important questions regarding the recall and outbreak remain unanswered.

I hope the witnesses from the two companies and the Food and Drug Administration identify and discuss both the possible breakdowns in corporate management of food safety and the lack of appropriate regulatory oversight of an industry that produces eggs, which the FDA has historically considered a "high-risk" food product.

I hope the CEOs here today will not try to defend the indefensible, especially when it comes to the failure to maintain good manufacturing and agricultural practices. Numerous documents reviewed by my Committee staff indicate possible failures in such practices. These documents include privately conducted testing reports for salmonella, FDA 483 Forms, audit reports, and sanitation reports completed by inspectors from the U.S. Department of Agriculture. Before and after everything else, it is a strong sense of responsibility by the producer that keeps our food safe. When problems are discovered, they must be examined and remedied by the producer, or people will get sick, and some may even die.

A new Egg Rule was finalized by the FDA this July and the FDA informed the Committee that they plan to begin inspecting over 600 egg production facilities later this year. Good. But why has the agency neglected this industry in the past, considering the earlier problems the agency and the public have had with salmonella in eggs. I wish that the FDA Commissioner, Dr. Hamburg, had accepted the Committee's invitation to testify here today. The Majority should have insisted that

she come and explain to Congress and to the public what's going on during her watch, at her agency.

Families need to be able to trust that the food they eat is safe. That's a fundamental measure of modern society, and it's why I supported the food safety legislation that passed this House in 2009. I strongly encourage the industry to shore-up their food safety systems and find new and better ways to increase the safety of our food supply so that we can prevent future outbreaks of food-borne illness.

Thank you Mr. Chairman, I look forward to the testimony and opportunity to ask questions.

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October 26, 2010

Gregory Kutz
Managing Director
Forensic Audits and Special Investigations
Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Kutz:

Thank you for appearing before the Subcommittee on Oversight and Investigations on July 22, 2010, at the hearing entitled "Direct-To-Consumer Genetic Testing and the Consequences to the Public Health."

Pursuant to the Committee's Rules, attached are written questions for the record directed to you from certain Members of the Committee. In preparing your answers, please address your response to the Member who submitted the questions.

Please provide your responses by November 9, 2010, to Earley Green, Chief Clerk, via e-mail to Earley.Green@mail.house.gov. Please contact Earley Green or Jennifer Berenholz at (202) 225-2927 if you have any questions.

Sincerely,

Henry A. Waxman
Chairman

Attachment

Questions for the Record from the July 22, 2010, Hearing on Direct-To-Consumer Genetic Tests

1. **What gaps do you believe exist in genetic privacy law? What recommendations do you have for addressing these gaps?**

   We cannot answer this question because it is outside the scope of our investigation.

2. **Who should develop standards (*e.g.* biomarker standards, risk algorithm standards) or other relevant criteria for genetic tests and how should they be vetted?**

   We cannot answer this question because it is outside the scope of our investigation.

3. **Should a minimum scientific evidence requirement be met before a claim or risk assessment is made in a direct-to-consumer genetic test?**

   We cannot answer this question because it is outside the scope of our investigation.

4. **Describe in detail what genetic counseling services are available to potential and current customers of the companies you investigated. In your response, include information regarding the type of counseling provided, the training and credentials of your genetic counselors, time of availability and duration of genetic counseling, and all costs associated with receiving genetic counseling including one-time and ongoing counseling.**

   As part of our investigation, we posed as fictitious consumers; purchased tests from 5 companies; and analyzed the results we received, to include a comparison of counseling services where applicable.[1] After obtaining test results for our consumers, we also interviewed company representatives about the types of services offered to consumers. The descriptions below refer to the counseling services offered by each company at the time of our investigation. Unless otherwise indicated, we do not know what services the companies currently offer.

   Company 1

   Company 1 did not offer genetic counseling services at the time of our investigation. According to a press release dated June 3, 2010, the company planned to collaborate with an independent service provider to make counseling services available to its customers. However, as of November 4, 2010, Company 1's Web site still directs

[1] We also investigated advertising methods used by 10 additional companies, but we did not purchase tests from these companies or inquire as to whether they offered genetic counseling. Although we recorded conversations with company representatives as part of this investigation of advertising methods, we do not know whether the representatives we spoke to were genetic counselors.

customers interested in genetic counseling to contact the National Society of Genetic Counselors.

Company 2

Company 2 provided our fictitious consumers with free genetic counseling services. Specifically, the company claimed that its "experts" would help interpret test results. These experts were available via phone or e-mail and there was no time limit on these conversations. However, we were unable to determine whether the company's experts were board certified in the United States because the company is located outside the country.[2] In addition, we found that the experts provided our fictitious donors with little guidance beyond the generally accepted health information contained in the test results.

Company 3

Company 3 recommended that our fictitious consumers use its on-staff genetic counselors to review test results at no additional charge. These experts were available via phone or e-mail to discuss results with customers or to answer test-related questions. There was no time limit on these conversations. In our post-test interviews, the company further claimed that its experts were genetic counselors and certified by the American Board of Genetic Counseling. However, all of our fictitious donors spoke to the same person, who admitted that she was not a board-certified genetic counselor. Company 3 has since changed its Web site to note that its counselors are "board eligible" as opposed to board certified. During post-test interviews, the company also claimed that the counselors review family history and provide consumers with additional information that is not in the test results. However, we found that the counselors provided our fictitious consumers with little guidance beyond the generally accepted health information contained in the test results.

Company 4

Company 4 counselors were available free of charge by appointment between the hours of 9 am and 5 pm Pacific Standard Time and there was no time limit on the duration of the conversations. We were able to confirm that all of Company 4's genetic counselors were U.S. board-certified. In our post-test interviews, company representatives stressed that their counselors explain the results, discuss beneficial next steps, and ensure that consumers and their physicians understand the meaning and limitations of the tests. They also said that genetic counselors can work with physicians and their patients to understand test results and facilitate a physician's informed clinical decision-making. However, even though counselors recommended

[2] Board certified indicates that they are certified by the American Board of Genetic Counseling (ABGC). The ABGC issued credential recognizes individuals who have met established standards for graduate training and clinical experience, successfully completed a comprehensive general genetics examination and genetic counseling specialty examination, and committed to maintaining their knowledge and skills in a rapidly evolving field through recertification.

customers take their results to their doctor, during our investigation, a counselor from Company 4 admitted to one of our fictitious consumers that a physician would probably not know what to do with the test results. For the most part, we found that the counselors provided our fictitious consumers with little guidance beyond the generally accepted health information contained in the test results. However, the counselors also encouraged our consumers to make dietary changes such as adopting a Mediterranean diet or eating curry to prevent Alzheimer's disease, claims that cannot be proven, according to experts that we spoke to.

Company 5

Company 5 did not offer genetic counseling services at the time of our investigation and, to our knowledge, does not currently offer any genetic counseling services.

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October 26, 2010

James P. Evans MD, PhD
Bryson Professor of Genetics and Medicine
University of North Carolina at Chapel Hill
CB#7264
Chapel Hill, NC 27599-7264

Dear Dr. Evans:

Thank you for appearing before the Subcommittee on Oversight and Investigations on July 22, 2010, at the hearing entitled "Direct-To-Consumer Genetic Testing and the Consequences to the Public Health."

Pursuant to the Committee's Rules, attached are written questions for the record directed to you from certain Members of the Committee. In preparing your answers, please address your response to the Member who submitted the questions.

Please provide your responses by November 9, 2010, to Earley Green, Chief Clerk, via e-mail to Earley.Green@mail.house.gov. Please contact Earley Green or Jennifer Berenholz at (202) 225-2927 if you have any questions.

Sincerely,

Henry A. Waxman
Chairman

Attachment

9 November 2010

Dear Congresswoman DeGette,

Thank you for your interest in the implications of direct-to-consumer genetic testing and genetic privacy, matters upon which I testified on July 22, 2010.

I am writing this letter in response to your follow-up questions, which I have reiterated below along with my responses. Please keep in mind that my expertise is in genetics and the practice of medicine. While I have spent considerable time dealing with the broad social implications of genetics and genetic testing, I am not an expert in the Law and apologize for any mistakes I might make in my answers.

I have also included with this letter a copy of my testimony from this summer.

To address your specific questions:

1. **What gaps do you believe exist in genetic privacy law? What recommendations do you have for addressing these gaps?**

   Privacy issues are of concern in the realm of genetics due to the fact that one's DNA is a uniquely identifying material, a small amount of which enables you to be differentiated from all others on the planet. Moreover, genetic analysis can reveal many things about you, ranging from your predisposition to disease your ancestry. Given the growing power of DNA analysis, its plummeting cost and the proliferation of genetic testing options being marketed to consumers, it is reasonable to think about how an individual's genetic information might be (or not be) protected when they submit a sample for analysis.

   Significant gaps in privacy protection do exist at the current time and there is no federal legislation, which broadly addresses genetic privacy. While there exist state laws of various sorts, they are highly inconsistent and vary a great deal in the degree and types of protection offered. The Genetic Information non-discrimination Act (GINA) does not address privacy issues and is therefore not relevant to this discussion.

   HIPAA has some provision within it for the protection of genetic information, but does so in the very narrow sense of only protecting the privacy of *medical* information. One might consider labeling all genetic information "medical", thereby affording broad protection to genetic information. However such a solution is problematic given that much genetic information that individuals might legitimately want protected is not of a medical nature, *per se*. Such sensitive genetic information could include one's propensity for various behaviors and personality attributes, which have clear genetic underpinnings.

   Thus one option to broadly protect the privacy of potentially sensitive genetic information would be legislation at the federal level. Such legislation would have to be nuanced in order to appropriately deal with the heterogeneous nature of genetic information. For example, certain personality characteristics and behavioral attributes

might warrant strong privacy protections whereas other types of genetic information (such as ancestry) might be seen as less needful of protection. It would seem that one way of getting to such a nuanced approach would be to give as much control as possible to the individual who is undergoing genetic testing so that she or he could control its use and dissemination to the extent they are comfortable with its release. Envisioning such an approach highlights the importance of something I emphasized this summer in my testimony: the need to regulate claims by the testing laboratories so that the public is presented with a fair and accurate picture of the true risks and benefits involved in testing.

It seems to me that the FTC has an important role to play in the protection of genetic privacy. It is my understanding that this agency has broad jurisdiction to regulate "unfair trade practices" and that if a commercial laboratory has a privacy policy they must live up to it. It is also my understanding that the FTC has expressed the (reasonable in my mind) notion that it is an unfair trade practice not to have a privacy policy. However, an apparent gap in the FTC enforcement is it doesn't give the right to an individual to pursue breeches of privacy; rather, the FTC must do it. I believe that some state laws fill this gap. Thus, I feel that the FTC could play an important role in addressing privacy issues with regard to commercial genetic testing.

Finally, a simpler approach to addressing at least some aspects of the genetic privacy issue would be to increase transparency by establishing a clearinghouse to compare and illuminate different privacy policies by different companies/entities (and perhaps track the dissemination of such information).

2. **Who should develop standards (*e.g.* biomarker standards, risk algorithm standards) or other relevant criteria for genetic tests and how should they be vetted?**

Professional organizations such as The American College of Medical Genetics, the American Society of Human Genetics, the Association of Molecular Pathologists, the College of American Pathology and industry groups all have experience in developing the kind of standards that could help put genetic testing on a more consistent, firm and protected foundation. One could envision industry standards developed by such stakeholders enhancing the reliability of testing - like a "seal of approval" which, while perhaps not mandatory, could at least serve to highlight the most legitimate entities involved in genetic testing and give the public some guidance in this highly technical and confusing field.

I also readily imagine a role for certain governmental agencies such as the FDA in regulating such tests. Indeed, I applaud the FDA's general intent to take a risk-stratified approach to the regulation of genetic tests. The devil, though, is in the details. Appropriately defining risk is difficult and both over-regulation and under-regulation could cause mischief. The solution, I believe, is for the FDA to work closely with professional organizations like those I have listed above. It is only through such close cooperation that we will develop nuanced regulation on a case-by-case basis that will

benefit the American people, simultaneously protecting them but not quenching innovation. I would also highlight the fact that the Centers for Disease Control has also been active in such pursuits and has an admirable program (EGAPP – The Evaluation of Genomic Applications in Practice and Prevention) designed to assess the reliability of genetic testing.

3. Should a minimum scientific evidence requirement be met before a claim or risk assessment is made in a direct-to-consumer genetic test?

Absolutely. Many of the claims, both implicit and explicit, now being made by DTC genetic testing companies are groundless. Such exaggerated and overtly false claims (both implicit and explicit) risk not only the health and finances of the public but risk tarnishing the entire private laboratory testing industry which, if properly behaved, could thrive and benefit us all. The GAO report elegantly revealed the lack of credibility of current tests and the vacuous nature of the claims made even by the industry leaders. Exaggerated and inaccurate claims are not only detrimental to those who purchase such tests but in the end will undermine the credibility of the entire endeavor of genetic testing.

Thus, I advocate for a requirement that claims, especially those related to health matters, be demonstrably true and backed up by evidence. It seems to me that this might be done with existing regulatory capacity in that the FTC is charged, if I am not mistaken, with ensuring that advertising claims be true. I would recommend that they be more aggressive in their scrutiny of the purveyors of such testing.

I hope that I have answered your questions. Please don't hesitate to contact me if I can be of help or if you wish further elaboration on these or related issues.

Sincerely,

James P. Evans MD, Ph.D
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November 30, 2010

Michael J. Madigan
(202) 339-8523
mmadigan@orrick.com

Hon. Henry A. Waxman, Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Re: Response to October 26, 2010 letter request to Ashley Gould, General Counsel, 23andMe, Inc.

Dear Chairman Waxman:

This letter responds on behalf of 23andMe, Inc. ("23andMe" or the "Company") to your October 26, 2010 letter request, which contained supplemental questions from Representative Diana DeGette.

1. What gaps do you believe exist in genetic privacy law? What recommendations do you have for addressing these gaps?

On the federal level, the Company believes the Genetic Information Nondiscrimination Act of 2008 ("GINA") is a good start toward protecting against genetic discrimination in the workplace and as it relates to health insurance. However, GINA does not protect against discrimination in the areas of life and disability insurance, where increased protections are needed. One of the most common questions of potential 23andMe customers is whether their genetic data could be used against them by insurance companies. As the Company believes that genetic data will be increasingly and extremely useful as part of healthcare in general and an individual's medical record, the Company believes that the protections against misuse of genetic data in the areas of healthcare access and health, life and disability insurance need to be addressed. The Company recognizes that there might be other gaps in GINA's application and that it could be years before they become clear.

2. Who should develop standards (*e.g.* biomarker standards, risk algorithm standards) or other relevant criteria for genetic tests and how should they be vetted?

The Company believes that industry should work collaboratively with federal agencies, including the U.S. Food and Drug Administration ("FDA") and the National Institutes of Health ("NIH"), to develop and maintain appropriate standards and regulatory frameworks. In this regard, the Company has been working with the FDA and has proposed a framework for regulating genetic tests that encompasses the technical challenges underlying genetic technologies and sets a high standard for transparency and openness. The FDA is currently reviewing 23andMe's proposal.

The Company also believes it is imperative that regulators appreciate the rapid pace of technological advancements and the impact they will have on any standards that are created. The Company believes that regulation must be carefully designed to avoid stifling innovation while simultaneously being realistic about the capacity of regulatory bodies to review new devices. For this reason, the Company believes that transparency and interaction with the broader scientific community are important for understanding and vetting interpretations of genetic data. For example, 23andMe presented new data examining our biomarker selection and risk estimation algorithms at the American Society of Human Genetics meeting earlier this month.

3. Should a minimum scientific evidence requirement be met before a claim or risk assessment is made in a direct-to-consumer genetic test?

Although the Company believes that all genetic testing companies should be responsible for substantiating any claims or risk assessments they make, 23andMe also believes it is important to carefully articulate the type of substantiation that should be required. For example, the Company does not believe that uniformly requiring scientific consensus on the markers used in genetic tests is an appropriate path forward as it would stifle innovation in the development of novel healthcare tools, would prevent doctors from obtaining information that could be useful in making medical decisions, and, in some cases, would be scientifically impractical.

However, the Company recognizes the importance of both ensuring that consumers understand the limitations of claims and risk assessments when scientific consensus does not exist, and, thus, strongly supports the need for transparency in the interpretation of genetic data. To date, 23andMe has published a white paper describing the scientific evidence criteria used by the Company, and, for each of its genetic interpretation reports, the Company provides detailed information on each genetic marker used. Furthermore, each of its reports emphasizes the importance of consulting with medical professionals before making medical decisions.

Fundamentally, the Company believes that all individuals have a right to their genetic information, and that companies like 23andMe should be responsible for providing the appropriate context so that individuals clearly understand the meaning and limitations of the information being presented.

4. **Describe in detail what genetic counseling services are available to potential and current customers of your company. Please include information regarding the type of counseling provided, the training and credentials of your genetic counselors, time of availability and duration of genetic counseling, and all costs associated with receiving genetic counseling, including one-time and ongoing counseling.**

23andMe does not provide genetic counseling services, and the Company believes it is important for genetic counselors to be independent of the Company. Since launching, 23andMe has provided links to such services on its website. Since June 2010, 23andMe has formed a non-monetary referral relationship with Informed Medical Decisions, Inc. ("Informed") to refer customers who seek genetic counseling services. Informed is a national, independent genetic counseling firm staffed by board-certified genetics counselors who have additional training in 23andMe's services and reports.

To be clear, there is no financial relationship between 23andMe and Informed. Interested customers sign up directly with Informed and pay Informed directly. For more information, please see the attached press release.

5. **Please describe in detail the process by which a client of your company receives a genetic evaluation. Include all steps that take place, from the point a client or physician solicits information about a genetic test to the point when a genetic report is received.**

Our customers sign up for our service online. After purchase, we ship a saliva collection kit to customers, who provide the sample and mail it directly to our contracted laboratory, National Genetics Institute ("NGI"). After NGI receives proper authorization from the Company to process a saliva sample, NGI extracts DNA from the sample and processes it using Illumina genotyping technology that analyzes nearly 600,000 data points; the number will grow to approximately one million data points analyzed on 23andMe's recently announced new version of the genotyping chip used for processing. Samples are tracked between NGI and the Company and are authorized for processing through unique barcode identifiers assigned by the Company. After NGI completes the analysis, the collected data for each sample is encrypted using leading technologies to protect privacy, and sent electronically via a secure Internet connection to 23andMe, which then uploads the data to the customer's individual account. 23andMe then notifies the customer that his or her data can be viewed. Customers use a secure log-in identification and password at the Company's website to access the data, including reports and features developed by the Company.

6. **Please describe all measures used by your company to protect client privacy and client identity. In your response, please discuss sample and data storage before and after samples are processed, and data transfer between all involved parties (*e.g.* between client and your company, between your company and contractors, between your company and medical professionals).**

23andMe provides strong safeguards for customer privacy and confidentiality. The Company has invested in a sophisticated technical environment for the storage and security of customer data and has had the Company's security systems independently audited. Genetic data is stored securely and separately from personally identifiable information, such as name and credit card information. The Company's servers and data reside at a secure data center facility that requires biometric data to gain access to the physical space in which servers are housed. In addition, the Company's research team is not permitted access to the product database through policy and technical means. And, the Company's employee handbook prohibits the misuse of customer data and notes that such misuse is subject to discipline, up to and including termination.

23andMe's website contains clear statements about customer privacy protections in two places – the Terms of Service (see Provision 8) as well as a separate "Privacy Statement" – both of which can be accessed through links on every page of the 23andMe website, including the home page. Both documents are also attached to this letter. In addition, the Company has consulted on privacy issues with leading experts in the field, including the Electronic Frontier Foundation, to adopt high standards for storing and safeguarding customer data.

Before being sent to a customer, each sample vial is labeled by the Company with only a unique barcode, and the accompanying file authorizing processing includes each customer's sex and date of birth, as required under the Clinical Laboratory Improvement Amendments. This is the only personally identifiable information NGI receives about our customers, and only 23andMe possesses the information to match it with a customer name.

After NGI processes a sample, as noted above, it encrypts a customer's genetic report and sends it electronically to 23andMe via a secure Internet connection. The report is then uploaded into the customer's account for the customer to see. Finally, the customer accesses his or her account through a personal identification and password.

No individual customer information is ever disclosed to third parties without explicit customer consent, unless required by law. Customers have the right to decide if they would like to participate in research intended for peer-reviewed publication, and they do so through a consent form. In such instances, customer information is only provided on an aggregate basis and never on

an individual level, unless the Company receives explicit customer consent. As a constant reminder to customers, 23andMe's Privacy Statement, consent document, and Terms of Service are all available for review via links on every page of the 23andMe website.

* * *

Because this letter might contain confidential or proprietary business information or records about the Company, we request that the Committee treat it as confidential, and we have marked it "CONFIDENTIAL" accordingly. In the event that the Committee intends to disclose any of this material in a public forum or to an agent, employee, or other person affiliated with any competitor, the Company requests that it be given advance notice of one week to permit it to address the issue with you.

In addition, some material in this submission might contain material that would normally be subject to the attorney-client privilege or work product doctrine. While we believe it is important for the Committee to be aware of this specific information, its submission does not constitute any present or future intent to waive any rights or privileges of the Company with respect to this matter, including any applicable attorney-client privilege, work-product doctrine, or another privilege. The Company expressly reserves any applicable privileges to which it is entitled under the law.

If you have any questions about this letter or the attachments, please contact me at (202) 339-8523.

Sincerely,

Michael J. Madigan
Joshua P. Galper

Attachments

cc: Hon. Diana DeGette

news

23andMe press release

23andMe Enlists Informed Medical Decisions to Make Independent Genetic Counseling Services Available to Customers

MOUNTAIN VIEW, CA – June 3, 2010 – 23andMe, Inc., a leading personal genetics company, has engaged Informed Medical Decisions, Inc. (InformedDNA), a nationwide network of board-certified genetics experts, to offer independent genetic counseling services to new and existing customers of its Personal Genome Service™.

"This new initiative with InformedDNA means that 23andMe customers now have the option to talk about their results with a board-certified genetic counselor who has been specially trained in 23andMe's unique reports and processes," said Anne Wojcicki, 23andMe President and Co-Founder.

"We chose to work with InformedDNA because they are a leading national independent provider of genetic counseling services," stated Wojcicki. "We wanted to ensure that the information our customers receive is completely objective."

23andMe customers interested in talking with a genetic counselor from InformedDNA can choose from two levels of service. For those with general questions related to their 23andMe results, an informational Personal Genome Service (PGS) is available. Customers who want a counselor to conduct a more thorough review of their family and medical histories, and those whose results show that they carry variants with potentially serious implications, can choose Comprehensive Clinical Genetic Counseling. Determining whether the Comprehensive Clinical Genetic Counseling option is appropriate is based on national clinical guidelines for genetic counseling referral.

23andMe customers who choose to utilize the services of InformedDNA will connect with a genetic counselor by phone. Convenient appointments are available seven days a week and can be scheduled online or by calling a dedicated toll-free phone line. InformedDNA Patient Care Coordinators are available to assist customers in choosing the level of service that is right for them. All information will be kept strictly confidential. A guide to the pricing for 23andMe customers who wish to utilize the genetic counseling services is listed on InformedDNA's website.

"Informed Medical Decisions is pleased to be working with 23andMe to expand access to genetics experts, especially for people who know of or suspect they may be at risk for hereditary disease. We salute 23andMe for offering customers convenient access to our genetic counselors," said David Patrick Nixon, Informed Medical Decisions Chief Executive Officer.

About 23andMe

23andMe, Inc. is a leading personal genetics company dedicated to helping individuals understand their own genetic information through DNA analysis technologies and web-based interactive tools. The company's Personal Genome Service™ enables individuals to gain deeper insights into their ancestry and inherited traits. The vision for 23andMe is to personalize healthcare by making and supporting meaningful discoveries through genetic research. 23andMe, Inc., was founded in 2006, and the company is advised by a group of renowned experts in the fields of human genetics, bioinformatics and computer science. Its investors include Genentech, Inc., Google Inc. (NASDAQ: GOOG) and New Enterprise Associates. More information is available at www.23andme.com.

About Informed Medical Decisions, Inc. (InformedDNA)

InformedDNA includes the largest independent network of genetic counselors and is the only national provider whose services are a covered benefit for most individuals with commercial health insurance. Its pioneering telephonic service delivery model removes barriers to care (geography, language, cultural and clinical specialty) for patients and has been recognized by the Institute of Medicine and Surgeons Generals' National Call to Action on Cancer for innovations and clinical excellence.

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Press Releases

November 24, 2010 23andMe Announces Immediate Availability of Upgraded Genotyping Array, New Testing Approximately One Million SNPs
November 9, 2010 23andMe Raises More Than $22 million in Series C Financing
June 24, 2010 23andMe Makes New Discoveries in Genetics Using Novel, Web-based, Participant-driven Methods
June 3, 2010 23andMe Enlists Informed Medical Decisions to Make Independent Genetic Counseling Services Available to Customers
October 13, 2009 23andMe Tests NFL Players' DNA for Athletic Genetic Factors
April 27, 2009 23andMe and Palomar Pomerado Health Partner to Give PPH Members Access to Their Genetic Information
March 31, 2009 23andMe Launches Free Online Community For Moms and Moms-to-Be
March 12, 2009 23andMe Launches Parkinson's Disease Genetics Initiative
January 28, 2009 23andMe and mondoBIOTECH Partner to Advance Research of Rare Diseases
December 18, 2008 Silicon Valley Veterans Sarah Imbach and Larry Tesler Join 23andMe Management Team
December 8, 2008 23andMe Announces Holiday Season Multi-Pack Discount
October 30, 2008 TIME Magazine Names 23andMe's Personal Genome Service 2008 Invention of the Year
October 2, 2008 23andMe Announces Breast Cancer Initiative
September 9, 2008 23andMe Democratizes Personal Genetics
September 9, 2008 23andMe and Ancestry.com Partner to Extend Access to Genetic Ancestry Expertise
May 29, 2008 23andMe Launches Consumer-Enabled Research Program to Actively Engage Individuals in Genetics Research
May 14, 2008 23andMe and The Parkinson's Institute Announce Initiative to Advance Parkinson's Disease Research
January 22, 2008 23andMe Launches Web-Based Personal Genome Service™ Outside U.S.
November 29, 2007 23andMe Selected as a 2008 Technology Pioneer by the World Economic Forum
November 19, 2007 23andMe Launches Web-Based Service Empowering Individuals to Access and Understand Their Own Genetic Information
November 16, 2007 23andMe to Hold Webcast Media Briefing
May 22, 2007 23andMe, Inc. Completes Series A Financing

23andMe genetics just got personal.

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1. Definitions

- **"23andMe"** means 23andMe, Inc., whose principal place of business is at 1390 Shorebird Way, Mountain View, CA 94043.
- **"23andWe Research"** means scientific research that 23andMe performs with the intent to publish in a peer-reviewed scientific journal. 23andWe Research only uses Genetic and Self-Reported Information from users who have given consent according to the applicable Consent Document. 23andWe Research activities do not include R&D.
- **"R&D"** means research and development activities performed by 23andMe on user data. These activities may include, among other things, improving our Services and/or offering new products or services to you; performing quality control activities; conducting data analysis that may lead to and/or include commercialization with a third party.
- **"Service"** or **"Services** means 23andMe's products, software, services, and website (including but not limited to text, graphics, images, and other material and information) as accessed from time to time by the user, regardless if the use is in connection with an account or not.
- **"Personal Information"** is information that can be used to identify you, either alone or in combination with other information. 23andMe collects and stores the following types of Personal Information:
  - **"Registration Information"** is the information you provide about yourself when registering for and/or purchasing our Services (e.g. name, email, address, user ID and password, and payment information).
  - **"Genetic Information"** is information regarding your genotype (e.g. the As, Ts, Cs, and Gs at particular locations in your genome), generated through processing of your saliva by 23andMe or by its contractors, successors, and assignees; or otherwise processed by and/or contributed to 23andMe.
  - **"Self-Reported Information"** is all information about yourself, including your disease conditions, other health-related information, personal traits, ethnicity, family history, and other information that you enter into surveys, forms, or features while signed in to your 23andMe account. Self-Reported Information is included in 23andWe Research only if it has been indicated for 23andWe Research use on the website and if you have given consent as described in the applicable Consent Document.
  - **"User Content"** is all information, data, text, software, music, audio, photographs, graphics, video, messages, or other materials - *other than* Genetic Information and Self-Reported Information-generated by users of 23andMe Services and transmitted, whether publicly or privately, to or through 23andMe.
  - **"Web Behavior Information"** is information on how you use the 23andMe website (e.g. browser type, domains, page views) collected through log files, cookies, and web beacon technology.
- **"Aggregated Genetic and Self-Reported Information"** is Genetic and Self-Reported Information that has been stripped of Registration Information and combined with data from a number of other users sufficient to minimize the possibility of exposing individual-level information while still providing scientific evidence.

2. Acceptance of Terms

Your use of 23andMe's Services (excluding any services provided by 23andMe under a separate agreement) is subject to the terms of the legal agreement between you and 23andMe set forth in these Terms of Service ("TOS"). Except as specified herein, these TOS apply to any use of the Services, including but not limited to a) submitting a saliva sample for DNA extraction and processing, b) uploading a digital version of your Genetic Information and interacting with it on the 23andMe website, and/or c) creating and using a free 23andMe account without providing your saliva sample or Genetic Information. In order to use the Services, you must first agree to the TOS. You may not use the Services if you do not accept the TOS. You can accept the TOS by (1) clicking to accept or agree to the TOS, where this option is made available to you by 23andMe for any Service, or by (2) actually using the Services. In this case, you acknowledge and agree that 23andMe will treat your use of the Services as acceptance of the TOS from that point onwards. In addition, when using particular 23andMe Services, you shall be subject to any guidelines or rules applicable to such services that may be posted from time to time. All such guidelines or rules are hereby incorporated by reference into the TOS. 23andMe also may offer other services from time to time that are governed by different terms of service.

3. Prerequisites

a. Whether you submit your own saliva sample, a saliva sample for anyone for whom you have legal authority to agree, or otherwise provide your own Genetic Information, you may not use the Services and may not accept the TOS if (1) you are not of legal age to form a binding contract with 23andMe, or (2) you are a person barred from receiving the Services under the laws of the jurisdiction in which you are resident or from which you use the Services.
b. In addition to the conditions above, if you contribute or otherwise provide your own Genetic Information, you must be eighteen (18) years of age or older to agree to these TOS on behalf of yourself or those for whom you have legal authority to agree.
c. If your use of the Services includes creating a 23andMe account, without submitting a saliva sample or otherwise providing Genetic Information, you must be thirteen (13) years of age or older to use the Services and accept the TOS.

4. Description of the Services

The Services include access to the 23andMe public website and personal genotyping services, including the collection and analysis of your saliva sample. Unless explicitly stated otherwise, each new feature that augments or enhances the current Service shall be subject to the TOS. You acknowledge and agree that the Services are provided "AS-IS" and are based on the current state of the art of genetic research and technology in use by 23andMe at the time of the purchase or viewing. As research progresses and scientific knowledge and technology evolve, 23andMe is constantly innovating in order to provide the best possible experience for its users. You acknowledge and agree that the form and nature of the Services which 23andMe provides may change from time to time without prior notice to you. As part of this continuing innovation, you acknowledge and agree that 23andMe may stop (permanently or temporarily) providing some Services (or any features

within the Services) to you or to users generally at 23andMe's sole discretion, without prior notice to you. You may stop using the Services at any time. You do not need to specifically inform 23andMe when you stop using the Services unless you are requesting closure of your account. 23andMe assumes no responsibility for the use of Services outside the terms of this TOS or other applicable terms.

In order to use the Services, you must obtain internet access, either directly or through devices that access web-based content, and pay any service fees associated with such access. You are solely responsible for paying such fees. In addition, you must provide all equipment necessary to make such Internet connection, including a computer and modem or other access device. You are solely responsible for providing such equipment. You acknowledge and agree that while 23andMe may not currently have set a fixed upper limit on the number of transmissions you may send or receive through the Services or on the amount of storage space used for the provision of any Service, such fixed upper limits may be set by 23andMe at any time, at 23andMe's discretion.

5. Risks and Considerations Regarding 23andMe Services

Once you obtain your Genetic Information, the knowledge is irrevocable. You should not assume that any information we may be able to provide to you, whether now or as genetic research advances, will be welcome or positive. You should also understand that as research advances, in order for you to assess the meaning of your DNA in the context of such advances, you may need to obtain further services from 23andMe or from your physician or other health care provider.

You may learn information about yourself that you do not anticipate. This information may evoke strong emotions and has the potential to alter your life and worldview. You may discover things about yourself that trouble you and that you may not have the ability to control or change (e.g., your father is not genetically your father, surprising facts related to your ancestry, or that someone with your genotype may have a higher than average chance of developing a specific condition or disease). These outcomes could have social, legal, or economic implications.

The laboratory may not be able to process your sample, and the laboratory process may result in errors. The laboratory may not be able to process your sample if your saliva does not contain a sufficient volume of DNA, you do not provide enough saliva, or the results from processing do not meet our standards for accuracy. If the initial processing fails for any of these reasons, 23andMe will reprocess the same sample at no charge to the user. If the second attempt to process the same sample fails, 23andMe will offer to send another kit to the user to collect a second sample at no charge. If the user declines this option, the user is entitled solely and exclusively to a complete refund of the amount paid to 23andMe, less shipping and handling, provided that the user shall not resubmit another sample through a future purchase of the service. If the user opts to receive another sample collection kit and 23andMe's attempts to process the second sample are unsuccessful, 23andMe will not send additional sample collection kits and the user will be entitled solely and exclusively to a complete refund of the amount paid to 23andMe, less shipping and handling, provided the user shall not resubmit another sample through a future purchase of the service. If the user breaches this policy agreement and resubmits another sample through a future purchase of the service and processing is not successful, 23andMe will not offer to reprocess the sample or provide the user a refund. Even for processing that meets our high standards, a small, unknown fraction of the data generated during the laboratory process may be un-interpretable or incorrect (referred to as "Errors"). As this possibility is known in advance, users are not entitled to refunds where these Errors occur.

You should not change your health behaviors solely on the basis of information from 23andMe. Make sure to discuss your Genetic Information with a physician or other health care provider before you act upon the Genetic Information resulting from 23andMe Services. For most common diseases, the genes we know about are only responsible for a small fraction of the risk. There may be unknown genes, environmental factors, or lifestyle choices that are far more important predictors. If your data indicate that you are not at elevated genetic risk for a particular disease or condition, you should not feel that you are protected. The opposite is also true, if your data indicate you are at an elevated genetic risk for a particular disease or condition, it does not mean you will definitively develop the disease or condition. In either case, if you have concerns or questions about what you learn through 23andMe, you should contact your physician or other health care provider.

Genetic research is not comprehensive. While we measure many hundreds of thousands of data points from your DNA, only a small percentage of them are known to be related to human traits or health conditions. The research community is rapidly learning more about genetics, and an important mission of 23andMe is to conduct and contribute to this research. In addition, many ethnic groups are not included in genetic studies. Because interpretations provided in our service rely on these published studies, some interpretations may not apply to you. Future scientific research may change the interpretation of your DNA. In the future, the scientific community may show previous research to be incomplete or inaccurate.

Genetic information you share with others could be used against your interests. You should be careful about sharing your Genetic Information with others. In the future, businesses or insurance companies may request Genetic Information. The Genetic Information Nondiscrimination Act was signed into law in the United States in 2008, and some, but not all, states and countries have laws that protect individuals with regard to their Genetic Information. You may want to consult a lawyer to understand the extent of legal protection of your Genetic Information before you share it with anybody.

Furthermore, Genetic Information that you choose to share with your physician or other health care provider may become part of your medical record and through that route be accessible to other health care providers and/or insurance companies in the future. Genetic Information that you share with family, friends or employers may be used against your interests. Even if you share Genetic Information that has no or limited meaning today, that information could have greater meaning in the future as new discoveries are made. If you are asked by an insurance company whether you have learned Genetic Information about health conditions and you do not disclose this to them, this may be considered to be fraud.

23andMe Services are for research, informational, and educational use only. We do not provide medical advice. The Genetic Information provided by 23andMe is for research, informational, and educational use only. This means two things. First, many of the genetic discoveries that we report have not been clinically validated, and the technology we use, which is the same technology used by the research community, to date has not been widely used for clinical testing. Second, in order to expand and accelerate the understanding and practical application of genetic knowledge in health care, we invite all genotyped users to participate in 23andMe Research. Participation in such research is voluntary and based upon an IRB-approved consent document. As a result of the current state of genetic knowledge and understanding, our Services are for research, informational, and educational purposes only. The Services are not intended to be used by the customer for any diagnostic purpose and are not a substitute for professional medical advice. You should always seek the advice of your physician or other health care provider with any questions you may have regarding diagnosis, cure, treatment, mitigation, or prevention of any disease or other medical condition or impairment or the status of your health.

23andMe does not recommend or endorse any specific course of action, resources, tests, physician or other health care providers, drugs, biologics, medical devices or other products, procedures, opinions, or other information that may be mentioned on our website. As explained on our website, 23andMe believes that (a) genetics is only part of the picture of any individual's state of being, (b) the state of the understanding of Genetic Information is rapidly evolving and at any given time we only comprehend part of the picture of the role of genetics, and (c) only a trained physician or other health care provider can assess your current state of health or disease, taking into account many factors, including in some cases your genetics as well as your current symptoms, if any. Reliance on any information provided by 23andMe, 23andMe employees, others appearing on our website at the invitation of 23andMe, or other visitors to our website is solely at your own risk.

While we are licensed in California as a clinical laboratory, not all jurisdictions require our Services to be subject to license. Therefore, we are not universally licensed by all state, federal, or international authorities for genetic testing conducted for health and disease-related purposes. In addition, there are certain jurisdictions in which we do not offer our Services because we do not have required licenses.

6. User Representations

By accessing 23andMe Services, you agree to, acknowledge, and represent as follows:

a. You understand that information you learn from 23andMe is not designed to diagnose, prevent, or treat any condition or disease or to ascertain the state of your health and that you understand that the 23andMe services are intended for research, informational, and educational purposes only. You acknowledge that 23andMe urges you to seek the advice of your physician or other health care provider if you have questions or concerns arising from your Genetic Information.
b. You give permission to 23andMe, its contractors, successors and assignees to perform genotyping services on the DNA extracted from your saliva sample and to disclose the results of analyses performed on your DNA to you and to others you specifically authorize.
c. You represent that you are eighteen (18) years of age or older if you are providing a saliva sample or accessing your Genetic Information.
d. You are guaranteeing that any sample you provide is your saliva; if you are agreeing to these TOS on behalf of a person for whom you have legal authorization, you are confirming that the sample provided will be the sample of that person.
e. If you are a customer outside the U.S. providing a saliva sample, you confirm that this act is not subject to any export ban or restriction in the country in which you reside.
f. You agree that any saliva sample you provide and all resulting data may be transferred and/or processed outside the country in which you reside.
g. You are warranting that you are not an insurance company or an employer attempting to obtain information about an insured person or an employee.
h. You are aware that some of the information you receive may provoke strong emotion.
i. You take responsibility for all possible consequences resulting from your sharing with others access to your Genetic Information and your Self-Reported Information.
j. You understand that all your Personal Information will be stored in 23andMe databases and will be processed in accordance with the 23andMe Privacy Statement.
k. Waiver of Property Rights You understand that by providing any sample, having your Genetic Information processed, accessing your Genetic Information, or providing Self-Reported Information, you acquire no rights in any research or commercial products that may be developed by 23andMe or its collaborating partners. You specifically understand that you will not receive compensation for any research or commercial products that include or result from your Genetic Information or Self-Reported Information.

You agree that you have the authority, under the laws of the state or jurisdiction in which you reside, to provide these representations. In case of breach of any one of these representations 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Services (or any portion thereof) and you will defend and indemnify 23andMe and its affiliates against any liability, costs, or damages arising out of the breach of the representation.

7. Account Creation, Customer Account, Password, and Security Obligations

In consideration of your use of the Services, you agree to: (a) provide true, accurate, current, and complete Registration Information about yourself as prompted by the Service; and (b) maintain and promptly update the Registration Information to keep it true, accurate, current, and complete. If you provide any Registration Information that is untrue, inaccurate, not current, or incomplete, or if 23andMe has a reasonable ground to suspect that such information is untrue, inaccurate, not current, or incomplete, 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Service (or any portion thereof).

After you have purchased our Service, you will create a password and account designation. You are responsible for maintaining the confidentiality of the password and account, and are fully responsible for all activities that occur under your password or account. If you allow third parties to access 23andMe's website through your username and password, you will defend and indemnify 23andMe and its affiliates against any liability, costs, or damages, including attorney fees, arising out of claims or suits by such third parties based upon or relating to such access and use. You agree to (a) immediately notify 23andMe of any unauthorized use of your password or account or any other breach of security, and (b) ensure that you exit from your account at the end of each session. 23andMe cannot and will not be liable for any loss or damage arising from your failure to comply with this Section.

8. 23andMe Privacy Statement and Disclosure of Information

In order to use the Services, you must first acknowledge and agree to the Privacy Statement. You may not use the Services if you do not accept the Privacy Statement. You can acknowledge and agree to the Privacy Statement by (1) clicking to accept or agree to the Privacy Statement, where this option is made available to you by 23andMe for any Service; or by (2) actually using the Services.

You acknowledge and agree that 23andMe has the right to monitor any use of its systems by its personnel at any time and maintain copies documenting such monitoring. Our Privacy Statement sets forth the only expectations of privacy any individual should have in terms of usage of the 23andMe Services, website, or other systems. If you have given consent for your Genetic Information and Self-Reported Information to be used in 23andWe Research as described in the applicable Consent Document, we may include your information in the Aggregated Genetic Information and Self-Reported Information we disclose to third parties for the purpose of publication in a peer-reviewed scientific journal. 23andMe may also include your information in Aggregated Genetic and Self-Reported Information disclosed to third-party non-profit and/or commercial research partners who will not publish that information in a peer-reviewed scientific journal. 23andMe will never release your individual-level Genetic Information and/or Self-Reported Information to any third party without asking for and receiving your explicit consent to do so, unless required by law. Further, you acknowledge and agree that 23andMe is free to preserve and disclose any

and all Personal Information to law enforcement agencies or others if required to do so by law or in the good faith belief that such preservation or disclosure is reasonably necessary to: (a) comply with legal process (such as a judicial proceeding, court order, or government inquiry) or obligations that 23andMe may owe pursuant to ethical and other professional rules, laws, and regulations; (b) enforce the 23andMe TOS; (c) respond to claims that any content violates the rights of third parties; or (d) protect the rights, property, or personal safety of 23andMe, its employees, its users, its clients, and the public. In such event we will notify you through the contact information you have provided to us in advance, unless doing so would violate the law or a court order. You understand that the technical processing and transmission of the Services, including your Personal Information, may involve (a) transmissions over various networks; and (b) changes to conform and adapt to technical requirements of connecting networks, or devices. Finally, 23andMe may, in its sole discretion, restrict access to the website for any reason.

Please refer to our Privacy Statement to read about data protection related to your information. See our complete Privacy Statement here.

9. Limited License

You acknowledge that all User Content, whether publicly posted or privately transmitted, is the sole responsibility of the person from which such User Content originated. This means that you, and not 23andMe, are entirely responsible for all User Content that you upload, post, email, or otherwise transmit via the Service.

You acknowledge that the Services content presented to you as part of the Services, whether original 23andMe Services content or sponsored content within the Services, is protected by copyright and/or other intellectual property rights that are owned by 23andMe and/or the sponsors who provide that content to 23andMe (or by other persons or companies on their behalf). 23andMe grants you a Limited License to copy and distribute free of charge, for non-commercial purposes only, any of the Services content with the exception of content from "MD's Perspectives" in the "For the Experts" section of the website and any other content marked as not subject to this Limited License on the website, provided you: (i) provide the Services content as it appears on the 23andMe website with no changes including but not limited to presenting selections which might tend to misrepresent the substance of the Services content; (ii) include the following attribution on the first page of any materials you distribute: © 23andMe, Inc. 2008-2010. All rights reserved; distributed pursuant to a Limited License from 23andMe; (iii) agree you have no right to offer anyone else any further right with respect to this Services content. Aside from the Limited License provided in this paragraph, you may not modify, rent, lease, loan, sell, distribute, or create derivative works based on this Services content (either in whole or in part) unless you have been specifically told that you may do so by 23andMe or by the owners of that content, in a separate agreement.

10. Customer Conduct - Unlawful and Prohibited Use

As a condition of your use of the Services, you warrant to 23andMe that you will not use the Services for any purpose that is unlawful or prohibited by these terms, conditions, or notices. You may not use the Services in any manner that could damage, disable, overburden, or impair the Services or interfere with any other party's use and enjoyment of the Services. You may not obtain or attempt to obtain any materials or information through any means not intentionally made available or provided for through the Services. Furthermore you agree not to use the Services to: (1) upload, post, email, or otherwise transmit any material that is derogatory, defamatory, obscene, or offensive, such as slurs, epithets, or anything that might reasonably be construed as harassment or disparagement based on race, color, national origin, sex, sexual orientation, age, disability, religious or political beliefs, or other statutorily protected status; (2) impersonate any person or entity, including, but not limited to, anyone affiliated with 23andMe, or falsely state or otherwise misrepresent your affiliation with a person or entity; (3) add your own headers, forge headers, or otherwise manipulate identifiers in order to disguise the origin of any content transmitted through the Service; (4) "stalk" or otherwise harass another; (5) upload, post, email, or otherwise transmit any content that you do not have a right to transmit under any law or under contractual or fiduciary relationships (such as inside information, proprietary and confidential information learned or disclosed as part of employment relationships or under nondisclosure agreements); (6) download any file posted by another user of the Service that you know, or reasonably should know, cannot legally be distributed in such manner; (7) upload, post, email or otherwise transmit any content that infringes any patent, trademark, trade secret, copyright, or other proprietary rights ("Rights") of 23andMe or any other party; (8) harm minors in any way; (9) advertise or offer to sell or buy any goods or services for any business purpose, unless such area specifically allows such messages; (10) upload, post, email, or otherwise transmit any unsolicited or unauthorized advertising, promotional materials, "junk mail," "spam," "chain letters," "pyramid schemes," or any other form of solicitation, except in those areas that are designated for such purpose and only to the extent such content is authorized by law; (11) upload, post, email, or otherwise transmit any material that contains software viruses or any other computer code, files, or programs designed to interrupt, destroy, or limit the functionality of any computer software or hardware or telecommunications equipment; (12) interfere with or disrupt the Service or servers or networks connected to the Service, or disobey any requirements, procedures, policies, or regulations of networks connected to the Service; (13) violate these Terms of Service, any code of conduct or other guidelines which may be applicable for any particular area of the Service or have been communicated to you by anyone affiliated with 23andMe; or (14) intentionally or unintentionally violate any applicable local, state, national, or international law, or any regulations having the force of law.

You acknowledge and agree that you are solely responsible for (and that 23andMe has no responsibility to you or to any third party for) any breach of your obligations under the TOS and for the consequences (including any loss or damage which 23andMe may suffer) of any such breach. In case of breach of any one of these agreements 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Services (or any portion thereof) and you will defend and indemnify 23andMe and its affiliates against any liability, costs, or damages arising out of the breach of the representation.

If you violate the terms of this Section and/or 23andMe has a reasonable ground to suspect that you have violated the terms of this Section, 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Service (or any portion thereof).

11. Export Control and Applicable Laws and Regulations

Recognizing the global nature of the Internet, you agree to comply with all local rules regarding online conduct and acceptable content. Specifically, you agree 1) that providing your sample is not subject to any export ban or restriction in the country in which you reside, 2) that your sample and data may be transferred and/or processed outside the country in which you reside, and 3) that you will comply with all applicable laws regarding the transmission of technical data exported from the United States or the country from which you access 23andMe's Services online.

12. Material Posted Through The Service

23andMe will not, at all times control any of the User Content posted via the Service and, as such does not guarantee the accuracy, integrity, or quality of such non-23andMe content. You understand that by using the Services, you may be exposed to content that is offensive, indecent, or objectionable. Under no circumstances will 23andMe be liable in any way for any non-23andMe content, including, but not limited to, any errors or omissions in any such content, or for any loss or damage of any kind incurred as a result of the use of any such content posted, emailed or otherwise transmitted via the Services.

You acknowledge that 23andMe and its designees shall have the right (but not the obligation) in their sole discretion to pre-screen, review, filter, modify, refuse, or move any content that is available via the Services. Without limiting the foregoing, 23andMe and its designees shall have the right to remove any content that violates the TOS or is deemed by 23andMe, in its sole discretion, to be otherwise objectionable. You acknowledge and agree that you must evaluate, and bear all risks associated with, the use of any content, including any reliance on the accuracy, completeness, or usefulness of such content.

13. Material Provided to 23andMe - Your **Proprietary Rights**

User Content. 23andMe does not claim ownership of the User Content you provide to 23andMe (including feedback and suggestions) or post, upload, input, or submit to the Service. Unless otherwise specified, you retain copyright and any other rights you already hold over User Content that you create and submit, post, or display on or through the Services. However, by submitting, posting, or displaying User Content, you give 23andMe, its affiliated companies, sublicensees (including but not limited to sublicensees who avail themselves of the Limited License granted in Section 9 above) and successors and assigns a perpetual, irrevocable, worldwide, royalty-free, and non-exclusive license to reproduce, adapt, modify, translate, publish, publicly perform, publicly display, distribute, reproduce, edit, reformat, and create derivative works from any User Content that you submit, post, or display on or through the Services. You acknowledge and agree that this license includes a right for 23andMe to make such User Content available to other companies, organizations, or individuals with whom 23andMe has relationships, and to use such User Content in connection with the provision of those services.

You understand that 23andMe, in performing the required technical steps to provide the Services to our users, may (a) transmit or distribute your User Content over various public networks and in various media; and (b) make such changes to your content as are necessary to conform and adapt that content to the technical requirements of connecting networks, devices, services, or media. You acknowledge and agree that this license shall permit 23andMe to take these actions. You represent and warrant to 23andMe that you have all the rights, power, and authority necessary to grant the above license.

Genetic and/or Self-Reported Information. Disclosure of individual-level Genetic and/or Self-Reported Information to third parties will not occur without explicit consent, unless required by law. Note that 23andMe cannot control any further distribution of Genetic and/or Self-Reported Information that you share publicly on the 23andMe website. You acknowledge and agree that you are responsible for protecting and enforcing those rights and that 23andMe has no obligation to do so on your behalf.

Your saliva sample, once submitted to and analyzed by us, is processed in an irreversible manner and cannot be returned to you. See our website for more information on sample processing. Any Genetic Information derived from your saliva remains your information, subject to rights we retain as set forth in these TOS. You understand that you should not expect any financial benefit from 23andMe as a result of having your Genetic Information processed; made available to you; or, as provided in our Privacy Statement and Terms of Service, shared with or included in Aggregated Genetic and Self-Reported Information shared with research partners, including commercial partners.

Waiver of Property Rights. As stated above, you understand that by providing any sample, having your Genetic Information processed, accessing your Genetic Information, or providing Self-Reported Information, you acquire no rights in any research or commercial products that may be developed by 23andMe or its collaborating partners. You specifically understand that you will not receive compensation for any research or commercial products that include or result from your Genetic Information or Self-Reported Information.

14. Indemnity

You agree to defend and hold 23andMe, and its subsidiaries, affiliates, officers, agents, contractors, partners, employees, successors, and assigns harmless from any claim, or demand, including reasonable attorneys' fees, made by any third party due to or arising out of User Content you submit, post to, or transmit through the Service, your use of the Service, your connection to the Service, your violation of the TOS, or your violation of any rights of another.

If you have submitted a saliva sample or otherwise provided your own Genetic Information, you will defend and hold harmless 23andMe, its employees, contractors, successors, and assigns from any liability arising out of the use or disclosure of any information obtained from genotyping your saliva sample and/or analyzing your Genetic Information, which is disclosed to you consistent with our Privacy Statement or results from any third-party add-ons to tools we provide. In addition, if you choose to provide your Genetic and/or Self-Reported Information to third parties - whether individuals to whom you facilitate access, intentionally or inadvertently, or to third parties for diagnostic or other purposes - you agree to defend and hold harmless 23andMe, its employees, contractors, successors, and assigns from any and all liability arising from such disclosure or use of your Genetic and/or Self-Reported Information.

15. No Resale of Service

Other than pursuant to the terms of the Limited License in Section 9 of this TOS or unless otherwise agreed in a separate agreement between you and 23andMe, you agree not to display, distribute, license, perform, publish, reproduce, duplicate, copy, create derivative works from, modify, sell, resell, exploit, transfer, or transmit for any commercial purposes, all or any portion of the Service, use of the Service, or access to the Service.

16. General Practices Regarding Use and Storage

You acknowledge that 23andMe may establish general practices and limits concerning use of the Services, including without limitation the maximum number of days that Personal Information and Services content will be retained by the Service, the maximum disk space that will be allotted on 23andMe's servers on your behalf, and the maximum number of times (and the maximum duration for which) you may access the Services in a given period of time. You acknowledge and agree that 23andMe has no responsibility or liability for the deletion of or failure to store any messages, other communications, or other content maintained or transmitted by the Services, or for the loss of Genetic Information due to malfunction or destruction of data servers or other catastrophic events. You further acknowledge that 23andMe reserves the right to change these general practices and limits in its sole discretion.

17. Modifications to Service

23andMe reserves the right at any time and from time to time to modify or discontinue, temporarily or permanently, the Services (or any part thereof) with or without notice. You acknowledge and agree that 23andMe shall not be liable to you or to any third party for any modification suspension, or discontinuance of the Services.

The Software that you use may from time to time automatically download and install updates from 23andMe. These updates are designed to improve, enhance, and further develop the Services and may take the form of bug fixes, enhanced functions, new software modules, and completely new versions. You agree to receive such updates (and permit 23andMe to deliver these to you) as part of your use of the Services.

You acknowledge that 23andMe may offer different or additional technologies to collect and/or interpret Genetic Information in the future and that your initial purchase of the Service does not entitle you to any different or additional technologies for collection or interpretation of your Genetic Information without fee, and that you will have to pay additional fees in order to have your Genetic Information collected, processed and/or interpreted using any future or additional technologies.

18. Termination

The TOS will continue to apply until terminated by either you or 23andMe as set out in this Section.

If you want to terminate your legal agreement with 23andMe, you may do so by notifying 23andMe at any time in writing, which will entail closing your accounts for all of the Services that you use. Your notice should be sent, in writing, to 23andMe's address, which is set out at the beginning of the TOS

23andMe may at any time, terminate its legal agreement with you (and in conjunction therewith, your password and account(s)) if: (1) you have breached any provision of the TOS (or have acted in manner which shows that you do not intend to, or are unable to comply with, the provisions of the TOS); (2) 23andMe is required to do so by law (for example, where the provision of the Services to you is, or becomes, unlawful); (3) the partner with whom 23andMe offered the Services to you has terminated its relationship with 23andMe or ceased to offer the Services to you; (4) 23andMe is transitioning to no longer providing the Services to users in the country or state in which you reside or from which you use the Services, or (5) the provision of the Services to you by 23andMe is, in 23andMe's opinion, no longer commercially viable.

Any suspected fraudulent, abusive, or illegal activity that may be grounds for termination of your use of the Services may be referred to appropriate law enforcement authorities. You acknowledge and agree that 23andMe shall not be liable to you or any third party for any termination of your access to the Services.

19. Survival of Terms

When the TOS come to an end, all of the legal rights, obligations, and liabilities that you and 23andMe have benefited from, been subject to (or which have accrued over time while the TOS have been in force) or which are expressed to continue indefinitely, shall be unaffected by this cessation, and the provisions of sections 1.(Definitions); 2.(Acceptance of Terms); 3.(Prerequisites); 4.(Description of the Services); 5. (Risks and Considerations Regarding 23andMe Services); 6.(Representations); 7.(Account Creation, Customer Account, Password and Security Obligations); 8.(23andMe Privacy Statement), 10.(Customer Conduct - Unlawful and Prohibited Use); 11.(Export Control and Applicable Laws and Regulations); 12.(Material Posted through the Service), 13.(Material Provided to 23andMe - Your Proprietary Rights); 14.(Indemnity); 15.(No resale of Services);16.(Termination); 19.(Survival of Terms); 20.(Dealings with Information Providers and Listed Resources); 21.(Hyperlinks and 23andMe Website); 22.(23andMe Proprietary Rights); 23.(DISCLAIMER OF WARRANTIES); 24. (LIMITATION OF LIABILITY), 25.(Notice); 27.(Violation or Suspected Violation of TOS); and 28.(Miscellaneous) shall continue to apply to such rights, obligations, and liabilities indefinitely.

20. Dealings with Information Providers and Listed Resources

Your correspondence or business dealings with-or participation in promotions of-information providers, vendors, and/or resources found on or through the Service, including payment and delivery of related goods or services, and any other terms, conditions, warranties, or representations associated with such dealings, are solely between you and such information provider or resource. You acknowledge and agree that 23andMe shall not be responsible or liable for any loss or damage of any sort incurred as the result of any such dealings or as the result of the presence of such information provider or resources on the Service.

21. Hyperlinks and the 23andMe Website

The Service provides, and third parties may provide, links to other sites and resources on the Internet. Because 23andMe has no control over such sites and resources, you acknowledge and agree that 23andMe is not responsible for the availability of such external sites or resources, and does not endorse and is not responsible or liable for any content, advertising, products, or other materials on or available from such sites or resources. You further acknowledge and agree that 23andMe shall not be responsible or liable, directly or indirectly, for any damage or loss caused or alleged to be caused by or in connection with use of or reliance on any such content, goods, or services available on or through any such hyperlinked site or resource.

22. 23andMe's Proprietary Rights

You acknowledge and agree that 23andMe (or 23andMe's licensors, as applicable) own all legal right, title, and interest in and to the Services, including any intellectual property rights which subsist in the Services (whether those rights happen to be registered or not, and wherever in the world those rights may exist). You further acknowledge that the Services may contain information which is designated confidential by 23andMe and that you shall not disclose such information without 23andMe's prior written consent.

You further acknowledge and agree that the Services and any necessary software used in connection with the Services ("Software") contain proprietary and confidential information that is protected by applicable intellectual property and other laws. You further acknowledge and agree that information presented to you through the Services or sponsors is protected by copyrights, trademarks, service marks, patents, or other proprietary rights and laws. Except as expressly authorized by 23andMe, you agree not to-and not to permit anyone else to-modify, rent, lease, loan, sell, distribute, or create derivative works of, reverse engineer, decompile, or otherwise attempt to extract the source code of the Services or Software or any part thereof, in whole or in part. Software, if any, that is made available to download from the Services, excluding software that may be made available by end-users through the Services, is the copyrighted work of 23andMe and/or its suppliers. Your use of the Software is governed by the terms of the end user license agreement, if any, which accompanies or is included with the

Software ("License Agreement"). You may not install or use any Software that is accompanied by or includes a License Agreement unless you first agree to the License Agreement terms

23andMe, Inc., 23andMe, and other 23andMe logos and product and service names are trademarks of 23andMe and these marks together with any other 23andMe trade names, service marks, logos, domain names, and other distinctive brand features are the "**23andMe Marks**" Unless you have agreed otherwise in writing with 23andMe, other than through the Limited License in Section 9, nothing in the TOS gives you a right to use any 23andMe Marks and you agree not to display, or use in any manner, 23andMe Marks.

You agree that you shall not remove, obscure, or alter any proprietary rights notices (including copyright and trade mark notices) that may be affixed to or contained within the Services.

Unless you have been expressly authorized to do so in writing by 23andMe, you agree that in using the Services, you will not use any trade mark, service mark, trade name, logo of any company or organization in a way that is likely or intended to cause confusion about the owner or authorized user of such marks, names, or logos.

For any Software not accompanied by a License Agreement, 23andMe grants you a personal, non-transferable, and non-exclusive right and license to use the object code of its Software on a single computer. You may not (and may not allow any third party to) copy, modify, create a derivative work of, reverse engineer, reverse assemble, or otherwise attempt to discover any source code, sell, assign, sublicense, grant a security interest in, or otherwise transfer any right in the Software unless this is expressly permitted or required by law, or unless you have been specifically told that you may do so by 23andMe, in writing. This license is for the sole purpose of enabling you to use and enjoy the benefit of the Services as provided by 23andMe, in the manner permitted by the TOS. Unless 23andMe has given you specific written permission to do so, you may not assign (or grant a sublicense of) your rights to use the Software, grant a security interest in or over your rights to use the Software, or otherwise transfer any part of your rights to use the Software. You agree not to modify the Software in any manner or form, or to use modified versions of the Software, including (without limitation) for the purpose of obtaining unauthorized access to the Service. You agree not to access the Service by any means other than through the interface that is provided by 23andMe for use in accessing the Service. Any rights not expressly granted herein are reserved

23. Disclaimer of Warranties

YOU EXPRESSLY ACKNOWLEDGE AND AGREE THAT: (1) YOUR USE OF THE SERVICES ARE AT YOUR SOLE RISK. THE SERVICES ARE PROVIDED ON AN "AS IS" AND "AS AVAILABLE" BASIS. 23ANDME EXPRESSLY DISCLAIMS ALL WARRANTIES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT. (2) 23ANDME MAKES NO WARRANTY THAT (a) THE SERVICES WILL MEET YOUR REQUIREMENTS; (b) THE SERVICES WILL BE UNINTERRUPTED, TIMELY, UNFAILINGLY SECURE, OR ERROR-FREE; (c) THE RESULTS THAT MAY BE OBTAINED FROM THE USE OF THE SERVICES WILL BE ACCURATE OR RELIABLE; (d) THE QUALITY OF ANY PRODUCTS, SERVICES, INFORMATION, OR OTHER MATERIAL PURCHASED OR OBTAINED BY YOU THROUGH THE SERVICES WILL MEET YOUR EXPECTATIONS AND (e) ANY ERRORS IN THE SOFTWARE WILL BE CORRECTED. (3) ANY MATERIAL DOWNLOADED OR OTHERWISE OBTAINED THROUGH THE USE OF THE SERVICES IS DONE AT YOUR OWN DISCRETION AND RISK AND THAT YOU WILL BE SOLELY RESPONSIBLE FOR ANY DAMAGE TO YOUR COMPUTER SYSTEM OR LOSS OF DATA THAT RESULTS FROM THE DOWNLOAD OF ANY SUCH MATERIAL. (4) NO ADVICE OR INFORMATION, WHETHER ORAL OR WRITTEN, OBTAINED BY YOU FROM 23ANDME OR THROUGH OR FROM THE SERVICES SHALL CREATE ANY WARRANTY NOT EXPRESSLY STATED IN THE TOS. (5) YOU SHOULD ALWAYS USE CAUTION WHEN GIVING OUT ANY PERSONALLY IDENTIFYING INFORMATION ABOUT YOURSELF OR THOSE FOR WHOM YOU HAVE LEGAL AUTHORITY. 23ANDME DOES NOT CONTROL OR ENDORSE ANY ACTIONS RESULTING FROM YOUR PARTICIPATION IN THE SERVICES AND, THEREFORE, 23ANDME SPECIFICALLY DISCLAIMS ANY LIABILITY WITH REGARD TO ANY ACTIONS RESULTING FROM YOUR PARTICIPATION IN THE SERVICES.

24. Limitation of Liability

WITHIN THE LIMITS ALLOWED BY APPLICABLE LAWS, YOU EXPRESSLY ACKNOWLEDGE AND AGREE THAT 23ANDME SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES, INCLUDING BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFITS, GOODWILL, USE, DATA OR OTHER INTANGIBLE LOSSES (EVEN IF 23ANDME HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES), RESULTING FROM: (a) THE USE OR THE INABILITY TO USE THE SERVICES; (b) ANY ACTION YOU TAKE BASED ON THE INFORMATION YOU RECEIVE IN THROUGH OR FROM THE SERVICES, (v) YOUR FAILURE TO KEEP YOUR PASSWORD OR ACCOUNT DETAILS SECURE AND CONFIDENTIAL, (d) THE COST OF PROCUREMENT OF SUBSTITUTE GOODS AND SERVICES RESULTING FROM ANY GOODS, DATA, INFORMATION, OR SERVICES PURCHASED OR OBTAINED OR MESSAGES RECEIVED OR TRANSACTIONS ENTERED INTO THROUGH OR FROM THE SERVICES, (e) UNAUTHORIZED ACCESS TO OR ALTERATION OF YOUR TRANSMISSIONS OR DATA; (f) THE IMPROPER AUTHORIZATION FOR THE SERVICES BY SOMEONE CLAIMING SUCH AUTHORITY; or (g) STATEMENTS OR CONDUCT OF ANY THIRD PARTY ON THE SERVICES.

25. Notice

Notices to you may be made via either email or regular mail. 23andMe may also provide notices of changes to the TOS or other matters by displaying notices or links to notices to you generally on or through the Services.

Official notices related to this TOS must be sent to us at: 23andMe, Inc.
ATTN: General Counsel
1390 Shorebird Way
Mountain View, CA 94043

Any notices that you provide without compliance with this section on Notices shall have no legal effect.

26. Changes to the Terms of Service

23andMe may make changes to the TOS from time to time. When these changes are made, 23andMe will make a new copy of the TOS available on its website and any new additional terms will be made available to you from within, or through, the affected Services.

You acknowledge and agree that if you use the Services after the date on which the TOS have changed, 23andMe will treat your use as acceptance of the updated TOS

27. Violation or Suspected Violation of Terms of Service

If you violate the terms of these TOS and/or 23andMe has a reasonable ground to suspect that you have violated the terms of these TOS, 23andMe has the right to suspend or terminate your account and refuse any and all current or future use of the Services (or any portion thereof).

28. Miscellaneous

a. **Entire Agreement.** The TOS constitute the entire agreement between you and 23andMe and govern your use of the Services, superseding any prior agreements between you and 23andMe on this subject. You also may be subject to additional terms and conditions that may apply when you use affiliate services, third-party content, or third-party software
b. **Applicable law and arbitration.** Except for any disputes relating to intellectual property rights, obligations, or any infringement claims, any disputes with 23andMe arising out of or relating to the Agreement ("Disputes") shall be governed by California law regardless of your country of origin or where you access 23andMe, and notwithstanding of any conflicts of law principles and the United Nations Convention for the International Sale of Goods. Any Disputes shall be resolved by final and binding arbitration under the rules and auspices of the American Arbitration Association, to be held in San Francisco, California, in English, with a written decision stating legal reasoning issued by the arbitrator(s) at either party's request, and with arbitration costs and reasonable documented attorneys' costs of both parties to be borne by the party that ultimately loses. Either party may obtain injunctive relief (preliminary or permanent) and orders to compel arbitration or enforce arbitral awards in any court of competent jurisdiction.
c. **Waiver.** The failure of 23andMe to exercise or enforce any right or provision of the TOS shall not constitute a waiver of such right or provision. If any provision of the TOS is found by a court of competent jurisdiction to be invalid, the parties nevertheless agree that the court should endeavor to give effect to the parties' intentions as reflected in the provision, and the other provisions of the TOS remain in full force and effect.
d. **Term for cause of action.** You agree that regardless of any statute or law to the contrary, any claim or cause of action arising out of or related to use of the Services or the TOS must be filed within one (1) year after such claim or cause of action arose or be forever barred.
e. **Admissibility of printed version.** A printed version of this agreement and of any notice given in electronic form shall be admissible in judicial or administrative proceedings based upon or relating to this agreement to the same extent and subject to the same conditions as other business documents and records originally generated and maintained in printed form.
f. **Section titles.** The section titles in the TOS are for convenience only and have no legal or contractual effect.
g. **Severability Clause.** If any portion of these TOS is found to be unenforceable, the remaining portion will remain in full force and effect
h. **Amendments.** We reserve the right to modify, supplement or replace the terms of the Agreement, effective upon posting at www.23andMe.com or notifying you otherwise. If you do not want to agree to changes to the Agreement, you can terminate the Agreement at any time per Section 18 (Termination).
i. **Assignment:** You may not assign or delegate any rights or obligations under the Agreement. Any purported assignment and delegation shall be ineffective. We may freely assign or delegate all rights and obligations under the Agreement, fully or partially without notice to you. We may also substitute, by way of unilateral novation, effective upon notice to you, 23andMe for any third party that assumes our rights and obligations under this Agreement.

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privacy statement

Summary

- 23andMe respects your privacy. 23andMe does not sell, lease, or rent your individual-level Personal Information without explicit consent
- We are committed to providing a secure, user-controlled environment for our Services.
- This summary provides highlights of our full Privacy Statement and applies to 23andMe's collection and handling of your Personal Information. We encourage you to read the full Statement.

Definitions

- **"23andMe"** means 23andMe, Inc., whose principal place of business is at 1390 Shorebird Way, Mountain View, CA 94043.
- **"23andWe Research"** means scientific research that 23andMe performs with the intent to publish in a peer-reviewed scientific journal. 23andWe Research only uses Genetic and Self-Reported Information from users who have given consent according to the applicable Consent Document. 23andWe Research activities do not include R&D.
- **"R&D"** means research and development activities performed by 23andMe on user data. These activities may include, among other things, improving our Services and/or offering new products or services to you; performing quality control activities; conducting data analysis that may lead to and/or include commercialization with a third party.
- **"Service"** or **"Services"** means 23andMe's products, software, services, and website as accessed from time to time by the user, regardless if the use is in connection with an account or not.

Which Personal Information We Collect

"Personal Information" is information that can be used to identify you, either alone or in combination with other information. 23andMe collects and stores the following types of Personal Information (see Terms of Service for a full list of related definitions):

- **"Registration Information"** is the information you provide about yourself when registering for and/or purchasing our Services (e.g. name, email, address, user ID and password, and payment information).
- **"Genetic Information"** is information regarding your genotype (e.g. the As, Ts, Cs, and Gs at particular locations in your genome), generated through processing of your saliva by 23andMe or by its contractors, successors, and assignees; or otherwise processed by and/or contributed to 23andMe.
- **"Self-Reported Information"** is all information about yourself, including your disease conditions, other health-related information, personal traits, ethnicity, family history, and other information that you enter into surveys, forms, or features while signed in to your 23andMe account. Self-Reported Information is included in 23andWe Research only if it has been indicated for 23andWe Research use on the website and if you have given consent as described in the applicable Consent Document.
- **"User Content"** is all information, data, text, software, music, audio, photographs, graphics, video, messages, or other materials - *other than* Genetic Information and Self-Reported Information - generated by users of 23andMe Services and transmitted, whether publicly or privately, to or through 23andMe.
- **"Web Behavior Information"** is information on how you use the 23andMe website (e.g. browser type, domains, page views) collected through log files, cookies, and web beacon technology.

How We Use Your Information

- 23andMe collects Personal Information from you for all purposes necessary to ensure the regular operation of your account and/or availability of our Services. These include, among other things, providing you with our Services; improving our Services and/or offering new products or services to you; performing quality control activities; conducting other R&D; and, upon your authorization, conducting 23andWe Research on diseases, traits, and other conditions.
- We use Registration Information to enable your purchase, inform you when your Genetic Information is available to you, provide you with customer service, manage our Services, and authenticate your website visits and usage. We may also use this information to offer you other products or services or to invite you to participate in specific research projects.
- We may disclose to third parties, and/or use in our Services, **"Aggregated Genetic and Self-Reported Information"**, which is Genetic and Self-Reported Information that has been stripped of Registration Information and combined with data from a number of other users sufficient to minimize the possibility of exposing individual-level information while still providing scientific evidence. If you have given consent for your Genetic and Self-Reported Information to be used in 23andWe Research as described in the applicable Consent Document, we may include such information in Aggregated Genetic and Self-Reported Information intended to be published in peer-reviewed scientific journals. If you do not give consent for your Genetic and Self-Reported Information to be used in 23andWe Research, we may still use your Genetic and/or Self-Reponed Information for R&D purposes as described above, which may include disclosure of Aggregated Genetic and Self-Reported Information to third-party non-profit and/or commercial research partners who will not publish that information in a peer-reviewed scientific journal
- We will never release your individual-level Genetic and/or Self-Reported Information to a third party without asking for and receiving your explicit consent to do so, unless required by law.
- We use Web Behavior Information to track and monitor aggregate usage of our website, for R&D, for quality control, to improve our Services, and/or to target advertising for our products and services
- We give you the ability to share your Genetic Information with other 23andMe customers through sharing features.
- We will not disclose your individual-level Personal Information to any third party, except under the following circumstances:
  - Partners or service providers (e.g. our contracted genotyping laboratory or credit card processors) use and/or store the information in order to provide you with 23andMe's Services
  - We are required to do so by law (see the section below titled "Information Disclosure Required By Law").
  - You have provided explicit consent for us to do so.

Your Choices

- Contribution of Personal Information other than Registration Information is voluntary and permission-based.
- Whether to give consent for 23andMe to use your Genetic and Self-Reported Information for 23andWe Research is voluntary
- Providing Self-Reported Information through surveys, forms, or features indicated for 23andWe Research use is voluntary
- At your written request we will close your account. As a result, all Genetic Information will be removed from the account and will no longer be accessible. 23andMe will not use your Genetic Information in research taking place starting thirty (30) days after account closure. We cannot remove Genetic Information that has previously been used for published research or shared with external collaborators before account closure. (See the section below titled "Account Closure and Correction of Personal Information".)

Additional Information

- We encourage you to read 23andMe's full Privacy Statement.

How to Contact Us

Questions about this Summary, our Privacy Statement, or about 23andMe's handling of your Personal Information may be emailed to privacy@23andme.com, or sent to:

Privacy Administrator
23andMe, Inc.
1390 Shorebird Way
Mountain View, CA 94043

Full Privacy Statement

23andMe Respects Your Privacy

23andMe recognizes the importance of privacy and respects your desire to store and access your information in a private and secure manner.

This Privacy Statement is intended to make you aware of how we handle your Personal Information. We are committed to providing you a secure, user-controlled environment for the use of our Services. At the same time, you share responsibility for maintaining privacy and security - for example, by keeping your password secure.

We encourage you to familiarize yourself with our Privacy Statement, Our Consent Form and Terms of Service explain that, by using our website and signing up for our service, you are allowing us to process your personal information according to the provisions set forth in those documents and this Privacy Statement.

Your Personal Information

In the course of your relationship with 23andMe, we collect several types of Personal Information. Personal Information is information that could be used to identify you, either alone or in combination with other information. We collect such information from you when you purchase our Services, create a personal account, complete surveys and forms, and/or when you communicate with us or request information from us. Personal Information collected online can be combined with Personal Information collected offline. We collect five primary types of Personal Information through our Service and website.

1. **"Registration Information"** is information that we collect from you when you purchase or sign up for our Services. Examples of such information include your name, credit card information, billing and shipping addresses, and contact information, such as email address and telephone number.
2. **"Genetic Information"** consists of your genotype, e.g. the As, Ts, Cs, and Gs at particular locations in your genome. Genetic Information is generated when you purchase 23andMe's Service and your saliva sample is analyzed and processed or you otherwise contribute or access your Genetic Information through our Services. Our instructions for sample collection and shipment clearly require you to send only your saliva sample to our third-party laboratory labeled with the unique barcode and no other identifier. The unique barcode identifies you to us but not to the laboratory. We are also required to provide sex and date of birth or age to the laboratory pursuant to CLIA requirements. No other Personal Information is required for the analysis. To protect your privacy, receiving personnel at the laboratory will remove and discard any identifying information (e.g. name, address) included with saliva samples before testing personnel receive the samples for genotyping. Receiving personnel do not perform testing, and testing personnel only handle samples labeled with the unique barcode. Unless you choose to store your sample in the biobank, DNA and saliva samples are destroyed after the laboratory completes its work, provided that laboratory legal and regulatory requirements no longer require the actual samples to be maintained. The laboratory securely sends the resulting Genetic Information to us along with your unique barcode. Genetic Information is stored securely on our servers; the laboratory also stores your Genetic Information, but labeled only with a sample barcode. The laboratory conducting DNA extraction and analysis does not have access to your name, other Registration Information or any other Personal Information except your sex and date of birth or age, as required by CLIA.
3. **"Self-Reported Information"** includes information you provide to us, including but not limited to information about your disease conditions (e.g. Type 2 Diabetes), other health-related information (e.g. pulse rate, cholesterol levels, visual acuity), personal traits (e.g., eye color, height), ethnicity, and/or family history (e.g. similar information about family members). We collect this information from you if and when you enter the information into surveys, forms, or features while signed in to your account. Self-Reported Information is included in 23andWe Research only if it has been indicated for 23andWe Research use on the website and if you have given consent as described in the applicable Consent Document.
4. **"User Content"** is all information *other than* Genetic Information or Self-Reported Information generated by users of 23andMe Services and transmitted, whether publicly or privately, to 23andMe. User Content may include data, text, software, music, audio, photographs, graphics, video, messages, or other materials. For example, User Content includes posts made to the 23andMe community forums or emails to Customer Support. User Content *does not* include Genetic Information or Self-Reported Information.
5. **"Web Behavior Information"** is information on how you use the 23andMe website (e.g. browser type, domains, page views) collected through log files, cookies, and web beacon technology.

How We Use Registration Information

We use your Registration Information to authenticate your website visits and usage; to enable your purchase; to communicate with you about information, services, and products that you have requested; and to manage and improve our website, software, and Services. We may also use this information to offer you services and products that may be of interest to you or invite you to participate in specific research

projects. We give you the opportunity to opt out of optional communications, either through our Service or by contacting our Privacy Administrator at privacy@23andme.com.

How We Use Genetic and Self-Reported Information

We use your Genetic and Self-Reported Information to provide you with 23andMe Services, customize the user experience, and enhance our features. IF you allow sharing, Genetic and Self-Reported Information may be displayed in other users' accounts. Self-Reported Information is used to customize your user experience - for example, by adjusting reports of genetic risk to account for your reported behaviors or environmental exposures.

If, and only if, you have given consent to participate in 23andWe Research as described in the applicable Consent Document, we may include your Genetic Information and Self-Reported Information indicated for 23andWe Research use in Aggregated Genetic and Self-Reported Information disclosed to third parties for the purpose of publication in a peer-reviewed scientific journal. 23andWe Research is intended to advance genetic knowledge and to create, commercialize, or undertake activities toward the practical applications of this learning to the improvement of health care.

If you do not give your consent to participate in 23andWe Research, 23andMe may still use your Genetic and Self-Reported Information for purposes such as quality control or other R&D activities. Genetic and Self-Reported Information used for such purposes may be included in Aggregated Genetic and Self-Reported Information disclosed to third-party research partners who will not publish the information in a peer-reviewed scientific journal. Research partners may include commercial or non-profit organizations that conduct or support scientific/medical research or conduct or support the development of drugs or devices to diagnose, predict, or treat health conditions.

How We Use User Content and Web Behavior Information

23andMe uses User Content to provide our Services and improve the overall user experience. For example, posts made to the 23andMe community forums are publicly displayed to other users. See Section 13 of the Terms of Service for a full description of your rights relating to User Content.

Web Behavior Information is collected through log files, cookies, and web beacon technology during a visit to the 23andMe website. Web Behavior Information is used to improve our Services and the overall user experience.

Log Files. When users visit our website, 23andMe gathers certain information automatically and stores it in log files. This information includes Internet Protocol (IP) addresses, browser type, Internet Service Provider, referring/exit pages, operating system, date/time stamp, and clickstream data (i.e. a list of pages or URLs visited). We use this information, which is not designed to identify individual users, to analyze trends, administer the site, track users' movements around the site, and gather demographic information about our user base as a whole. We may, in some circumstances, need to review this automatically collected data in combination with specific Registration Information to identify and resolve issues for individual users.

Cookies. The 23andMe website also uses cookies. A cookie is a small text file that is stored on a user's computer when you visit our website or any other website through your computer. We use both session cookies and persistent cookies to make it easier for you to navigate our site, improve the security of your Personal Information, enhance the functionality of certain features, and improve performance. The cookies we employ are used to enable secure access to your account when you are signed in to your account and are only applicable within the confines of our website.

A session cookie expires when you close your browser. A persistent cookie remains on your hard drive for an extended period of time. You can remove persistent cookies by following directions provided in your Internet browser's "help" file. However, if you set your browser to reject cookies, your ability to use our site will be significantly impaired. In particular, you will not be able to access any part of our site that requires a sign-in, such as your account.

Web Beacons. A web beacon is a clear graphic image that is loaded by your web browser when it accesses a website and that records a user's visit to a particular web page. We, or third parties that work for us, may place cookies and web beacons on our website, in our emails, and in our advertisements that appear on other websites or in emails sent by others that mention our products and services with our permission. The purpose of our web beacons is to support operation of our website and to offer additional products and services through targeted advertisements. For example, we may use beacons to determine when someone views a web page, count how many individuals visit our website after clicking advertisements placed on other websites, or count how many people have purchased products from our website after viewing an advertisement we placed. Web beacons may also help us determine the effectiveness of an email campaign because the beacons can count the number of individuals who open an email or forward it to others. We use this Web Behavior Information to better tailor our marketing to you and may also use this information to customize content on our website, enable a shopping cart, or conduct research. Third parties only collect anonymous Web Behavior Information through the use of web beacons, allowing statistical analysis relating to the performance of our advertising.

If you wish to disable web beacons, it is possible to prevent your browser from loading them, although there is not currently a standard method for doing so.

Information Sharing

23andMe gives you the ability to connect with other individuals who have 23andMe accounts through our community forums, relative finding features, and other sharing features. For some features, opt-out is required to avoid notifications. In addition, you may choose to disclose, through other means not associated with 23andMe, any part of your Personal Information to friends and/or family members, groups of individuals, third-party service providers, doctors or other health care professionals, and/or other individuals. We recommend that you make such choices carefully.

Personal Information, once released or shared, can be difficult to contain. 23andMe will have no responsibility or liability for any consequences that may result because you have released or shared Personal Information with a third party. Likewise, if you are reading this because you have access to the Personal Information of a 23andMe customer through a multi-profile account, we urge you to recognize your responsibility to protect the privacy of that person. It is incumbent upon customers to share Personal Information only with people they know and trust. Users with multi-profile accounts should use caution in setting profile-level privacy settings.

Information Disclosure

As a general rule, 23andMe will not disclose your individual-level Personal Information to any third party, except under the following circumstances:

- Partners or service providers (e.g. credit card processors or our contracted genotyping laboratory) process and/or store the information in order to provide you with 23andMe's Services
- We are required to do so by law (see the section below titled "Information Disclosure Required By Law")
- You have provided explicit consent for us to do so.

23andMe may disclose Personal Information for the following reasons:

- **23andWe Research.** 23andMe may disclose Aggregated Genetic and Self-Reported Information intended to be published in a peer-reviewed scientific journal to research collaborators or as a result of publication. You may give/withhold consent for your data to be used in 23andWe Research when viewing the applicable Consent Document during the process of claiming your Genetic Information into your account. You may also give consent or change your global consent status through your Account Settings at any subsequent time; however, we cannot withdraw information that has previously been used for published research or shared with external collaborators prior to your request to withdraw consent
- **Contact Information.** 23andMe will ask for and require your explicit consent to allow partner organizations direct access to your Registration Information.
- **Commercial partnerships.** 23andMe may enter into commercial arrangements to enable partners to provide our Service to their customers and/or to provide you access to their products and services. We will not provide any individual-level Personal Information to these commercial partners without your explicit consent. 23andMe may include your Genetic and/or Self-Reported Information in Aggregated Genetic and Self-Reported Information disclosed to these commercial partners even if you have not given consent for your data to be used in 23andWe Research.

Information Disclosure Required By Law

Under certain circumstances Personal Information may be subject to disclosure pursuant to judicial or other government subpoenas, warrants, or orders. You acknowledge and agree that 23andMe is free to preserve and disclose any and all Personal Information to law enforcement agencies or others if required to do so by law or in the good faith belief that such preservation or disclosure is reasonably necessary to: (a) comply with legal process (such as a judicial proceeding, court order, or government inquiry) or obligations that 23andMe may owe pursuant to ethical and other professional rules, laws, and regulations; (b) enforce the 23andMe TOS; (c) respond to claims that any content violates the rights of third parties; or (d) protect the rights, property, or personal safety of 23andMe, its employees, its users, its clients, and the public. In such event we will notify you through the contact information you have provided to us in advance, unless doing so would violate the law or a court order.

Linked Websites

23andMe provides links to third-party websites operated by organizations not affiliated with 23andMe. 23andMe does not disclose your Personal Information to organizations operating linked third-party websites. 23andMe does not review or endorse, and is not responsible for, the privacy practices of these organizations. We encourage you to read the privacy statements of each and every website that you visit. This Privacy Statement applies solely to information collected by 23andMe

Account Closure and Correction of Personal Information

If you no longer wish to participate in our Services, you may close your account by sending a request to Customer Support at help@23andme.com. When closing an account, we remove all Genetic Information within your account (or profile) within thirty (30) days of our receipt of your request. As stated in the applicable Consent Document, however, Genetic Information and/or Self-Reported Information that you have previously provided and for which you have given consent to use in 23andWe Research will not be removed from ongoing or completed studies that use the information. Our contracted genotyping laboratory may also retain your Genetic Information as required by local law and we may retain backup copies for a limited period of time pursuant to our data protection policies. In addition, we retain limited Registration Information related to your order history (e.g., name, contact, and transaction data) for accounting and compliance purposes.

If your Personal Information changes, you may correct or update your Registration Information via your Account Settings page. You may also correct or reset Self-Reported Information entered into a survey, form, or feature indicated for 23andWe Research use by emailing a request to Customer Support at help@23andme.com and including the name of the specific survey, form, or feature.

Children's Privacy

23andMe is committed to protecting the privacy of children as well as adults. Neither 23andMe nor any of its Services are designed or intended to attract children under the age of 13. A parent or guardian, however, may collect a saliva sample from, create an account for, and provide Self-Reported Information on behalf of his or her child. The parent or guardian assumes full responsibility for ensuring that the information that he/she provides to 23andMe about his or her child is kept secure and that the information submitted is accurate

Security

23andMe takes seriously the trust you place in us. To prevent unauthorized access or disclosure, to maintain data accuracy, and to ensure the appropriate use of information, 23andMe uses a range of reasonable physical, technical, and administrative measures to safeguard your Personal Information, in accordance with current technological and industry standards. In particular, all connections to and from our website are encrypted using Secure Socket Layer (SSL) technology.

Please recognize that protecting your Personal Information is also your responsibility. We ask you to be responsible for safeguarding your password, secret questions and answers, and other authentication information you use to access our Services. You should not disclose your authentication information to any third party and should immediately notify 23andMe of any unauthorized use of your password. 23andMe cannot secure Personal Information that you release on your own or that you request us to release.

Business Transitions

In the event that 23andMe goes through a business transition such as a merger, acquisition by another company, or sale of all or a portion of its assets, your Personal Information will likely be among the assets transferred. In such a case, your information would remain subject to the promises made in any pre-existing Privacy Statement

Changes to This Privacy Statement

This Privacy Statement was last updated June 24, 2010. Whenever this Privacy Statement is changed in a material way, a notice will be posted as part of this Privacy Statement and on our customers' account login pages for 30 days. After 30 days the changes will become effective. In addition, all customers will receive an email with notification of the changes.

Contact Information

If you have questions about this statement, please email 23andMe's Privacy Administrator at privacy@23andme.com. You can also contact us at this address if you have a question about 23andMe's handling of your information.

Privacy Administrator
23andMe, Inc.
1390 Shorebird Way
Mountain View, CA 94043

Last updated June 24, 2010. Click here to see a summary of changes.

Read the previous version of the document.

Navigenics®

The Honorable Henry A. Waxman

Chairman, Committee on Energy and Commerce

U.S. House of Representatives

2125 Rayburn House Office Building

Washington, D.C. 20515-6115

November 8, 2010

Dear Chairman Waxman:

Thank you for your letter dated October 26, 2010, forwarding written questions for the record submitted by a Member of the Committee. Enclosed please find Navigenics' responses to those questions.

Navigenics has sought to cooperate fully with the Committee's investigation. It welcomes the opportunity to provide any further information should the Committee require it.

Very truly yours,

Vance K. Vanier, M.D.
Chief Executive Officer
Navigenics, Inc.
Phone: 650.585.7707
Email: vance.vanier@navigenics.com

Enclosure

1001 E Hillsdale Blvd, Suite 550, Foster City, CA 94404
www.navigenics.com / (866) 522-1585 / +1 (650) 585-7743

The Honorable Diana DeGette

1. What gaps do you believe exist in genetic privacy law? What recommendations do you have for addressing these gaps?

The Genetic Information Nondiscrimination Act of 2008 (GINA, Pub.L. 110-233), provides substantial protections for genetic information. For example, health insurers cannot use genetic test results to deny medical coverage or set the price for health insurance. Insurers also cannot ask or require employees to take a genetic test. These rules cover health insurance plans of all sizes and types, including group health insurance, employer-run and government-run plans, and individual policies.

GINA also prohibits employers from using genetic test results to make hiring and salary decisions or set other job-related policies. Moreover, employers cannot require employees to take a genetic test as part of starting or performing a job, except in very limited circumstances to protect worker safety.

Despite establishing these critical protections, GINA also has some noteworthy limitations. GINA's protections do not apply to other types of health-related insurance, such as life insurance or long-term care coverage. In addition, GINA only safeguards genetic testing and genetic information. GINA does not apply to a person who has been clinically diagnosed with a genetic disease. Other federal protections, however, may apply in that situation, including those lifting restrictions on health coverage for individuals with pre-existing conditions under the recently enacted Affordable Care Act (Pub. L. 111-148).

We encourage congressional leaders to extend GINA provisions to life insurance and long-term care insurance and to include those patients with a clinically diagnosed, or "manifested" disease.

2. Who should develop standards (*e.g.* biomarker standards, risk algorithm standards) or other relevant criteria for genetic tests and how should they be vetted?

We believe the National Institutes of Health (NIH) would be the best developer and overseer of genetic testing standards, in conjunction with ongoing Federal regulation of lab services under the Clinical Laboratory Improvement Amendments (CLIA) and the continued, active participation of professional specialty medical societies. We recommend that Congress encourage the NIH to establish a set of recognized scientific criteria and convene panels of external experts to review and validate markers based on such criteria. In addition, we believe NIH should establish a separate panel to address questions about related new technologies, potentially under a federal interagency mechanism as envisioned in legislation recently proposed by Congresswoman Eshoo and Congressman Kennedy and previously proposed by President Obama, the Genomics and Personalized Medicine Act of 2010.

3. Should a minimum scientific evidence requirement be met before a claim or risk assessment is made in a direct-to-consumer genetic test?

Yes, there should be minimum scientific criteria as well as testing standards that serve as the basis for any claim in genetic testing. There should also be a requirement that all testing markers and methodologies be transparent to physicians and patients. We believe it is important to note that all of Navigenics' testing is performed in our own CLIA-certified laboratory which has strict quality control procedures and lab methods to maintain the integrity of all of our samples. Our laboratory methods, as required by CLIA, undergo extensive laboratory validation to ensure that they are accurate and reproducible.

In furtherance of the goal of minimum testing standards, we have developed our own scientific and clinical criteria for validating markers, which includes the requirement that the association between the genetic marker and the condition must have been published in a top-tier, peer-reviewed journal and replicated at least once. It is then reviewed by our team of Ph.D. geneticists for accuracy and validity against a set of transparent criteria. Our clinical team then determines the "actionability" level for each condition or drug-gene interaction, since the goal of our service is to prevent or delay onset of conditions and to use medications more effectively.

4. Describe in detail what genetic counseling services are available to potential and current members of your company. Please include information regarding the type of counseling provided, the training and credentials of your genetic counselors, time of availability and duration of genetic counseling, and all costs associated with receiving genetic counseling, including one-time and ongoing counseling.

Navigenics is the only company that has a team of board-certified Genetic Counselors on staff who routinely counsel physicians and patients in order to ensure that they understand genetic information. Our Genetic Counselors are trained healthcare professionals who specialize in personal genomics, and their work has made them leaders in their field as they educate physicians and other providers to allow them to integrate personalized genetic analysis into healthcare programs. Our Genetic Counselors are also board-certified professionals, having completed two-year Masters Degree programs, and adhere to a code of ethics that includes maintaining the highest levels of privacy and confidentiality.

Currently, unlimited genetic counseling is included in the cost of the Navigenics Health compass. They offer counseling via telephone only.

5. Please describe in detail the process by which a client of your company receives a genetic evaluation. Include all steps that take place, from the point a client or physician solicits information about a genetic test to the point when a genetic report is received.

Following is a brief description of the process that a potential client undergoes to receive a report from Navigenics:

1) To request a Navigenics test, members must sign up through a physician or corporate wellness program. Members cannot visit the Navigenics website and order a test directly. Nor does Navigenics market its tests through a third-party retailer.

2) Once Navigenics has received a valid application to participate in its program, we send a saliva collection kit to the enrolled participant by mail. The kit includes detailed instructions, a saliva collection vial and materials for shipping the vial to our laboratory for testing. Members send their samples back to our CLIA-certified laboratory in the envelope provided.

3) Our CLIA-certified laboratory analyzes the saliva sample to identify risk markers. Navigenics then analyzes each individual's genetic risk for certain health conditions and medication reactions. This process typically takes approximately two to three weeks.

4) We notify members via email when the results of their genetic analyses are ready. In this email, members are provided with information on the availability of Genetic Counselors to clarify the test results and discuss any questions the member may have. Members can then log onto their secure online account and review a comprehensive report of results. If the customer has signed up through a physician, their results may be delivered directly to the physician, who will contact them to review the results.

5) As noted above, Navigentics' Genetic Counselors are available to explain genetic reports to each member and answer any ongoing questions. Our Genetic Counselors are also available to work with the member and his/her doctor to help them understand the member's genetic information as they develop personalized health strategies. Our Genetic Counselors are also available at any stage in the testing process—even before the member has decided to purchase Navigenics' services — to discuss any questions or concerns.

6) We continue to update risk reports as new markers are identified and validated, notifying members of new predispositions or drug-gene interactions, for as long as they subscribe to Navigenics' service.

6. Please describe all measures used by your company to protect client privacy and client identity. In your response, please discuss sample and data storage before and after samples are processed, and data transfer between all involved parties (*e.g.* between client and your

company, between your company and contractors, between your company and medical professionals).

Privacy has always been a hallmark of the Navigenics service. We have a very strong privacy policy that explains how we collect and use the information that our members provide to us. Set forth below are the key components of our privacy policy, including provisions addressing sample and data storage before and after samples are processed, and data transfer between all involved parties:

Collection and use of information

Navigenics collects a variety of information regarding use of our website and services, including personally identifiable information. The "personally identifiable information" addressed by this policy refers to the following:

- "Account Information" means the information that members or physicians provide to us when creating or updating Navigenics account, or purchasing our services, that can be used to uniquely identify each customer, such as name, telephone number, email address, billing/shipping address or credit card number.
- "Genetic Data" means the genotyping results that we generate for each customer or physician through our services (namely, the set of A's, G's, T's and C's at particular locations in the genome) but only to the extent such results, by themselves or when linked to other personally identifiable information, are sufficient to uniquely identify each customer.
- "Phenotype Information" means gender, birth date and, optionally, other personal information about each customer that he/she or a physician may voluntarily provide to Navigenics, which may include ethnicity/ancestry, the geographic regions where ancestors lived, any diseases or other health conditions that run in a customer's family, and personal traits such as height and weight.

We collect and use personally identifiable information to authenticate each customer's use of our website and services, to process purchase transactions, to provide the services our members or their physicians have requested, to communicate with members or their physicians, and to send customer or their physician's relevant information and materials. However, Navigenics will not, without the customer's consent, disclose or share personally identifiable information with third parties except as required to provide the services as requested by the customer, in the event Navigenics is acquired by or merges into another company, or as otherwise required by applicable law. We limit access to personally identifiable information to appropriate Navigenics personnel on a need-to-know basis.

Research

Navigenics believes in providing the highest quality service available and helping further scientific and medical research. To that end, we may analyze our members' genetic data and associated phenotype information on an aggregated basis and de-linked from any member account information, to:

- Improve the quality and features of our website and services
- Provide our members with new and more accurate analysis of genetic data
- Discover or validate associations between certain genetic variations and certain health conditions or traits, as well as other insights regarding human health
- Publish our findings and insights without disclosing Genetic Data in a quantity sufficient to uniquely identify the customer, and without otherwise disclosing the customer's identity

We may also give each member the opportunity to contribute his/her genetic information to science. If a member elects to contribute his/her genetic information to science through the Navigenics service, he/she allows us to share Genetic Data and Phenotype Information (de-linked from Account Information) with not-for-profit organizations who perform genetic or medical research, and he/she allows such not-for-profit organizations to separately or jointly publish study results that include Genetic Data and Phenotype Information (but not Account Information), in peer-reviewed scientific and medical journals and otherwise, and to deposit such data and information into public data repositories or otherwise make them publicly available to the extent required by such journals.

If a member elects not to contribute his/her genetic information to science through the Navigenics service, we will not share their Genetic Data or Phenotype Information with such organizations.

Finally, Navigenics will never sell a member's personal genetic information to any third parties.

November 15, 2010

Earley Green
Chief Clerk

Dear Mr. Green,

Below please see Pathway Genomics' responses to the questions submitted by Congresswoman Diana DeGette in a follow-up to our appearance before the Subcommittee on Oversight and Investigations on July 22, 2010 for the hearing on "Direct-to-Consumer Genetic Testing and the Consequences to the Public Health."

If there are any further questions, please do not hesitate to contact me (858-771-0523), or Ed MacBean (858-692-6242).

Sincerely,

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Q1. *What gaps do you believe exist in genetic privacy law? What recommendations do you have for addressing these gaps?*

A. As you know, the federal Genetic Information Nondiscrimination Act of 2008 (GINA) prevents health insurers from using genetic information to deny health coverage or establish the cost of health insurance. GINA also prohibits employers from using genetic information when making employment-related decisions. However currently only a minority of states prohibits genetic discrimination by either life, disability and/or long-term care insurers. Pathway describes this risk in "A Patient's Brochure on Comprehensive Genotype Testing," which is a supplement to our patient's Informed Consent.

Thirty-nine (39) states have genetic privacy laws that provide special legal protections for genetic information beyond the protections provided for other types of health information. As you know, state laws preempt the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act. The complexity of complying with varying state laws creates a burden on small- to medium-sized regional and national companies and introduces the risk of non-compliance when one or more states have requirements that may be different from the majority of states.

While it makes sense to regulate many things at the state level, genetic information should not be more, or less, sensitive depending upon the state. Regulating the privacy and security of genetic information at the federal level, with no state preemption, would provide a simpler regulatory scheme and better assure compliance. A single regulatory level playing field would also ultimately better serve all stakeholders, including consumers.

The National Conference of State Legislatures (NCSL) website demonstrates the gaps that exist in these laws.

- Genetic Privacy Laws - Updated January 2008: http://www.ncsl.org/default.aspx?tabid=14287
- Genetics and Life, Disability and Long-term Care Insurance - Updated January 2008: http://www.ncsl.org/default.aspx?tabid=14283

However, regardless of the regulatory structure that is in place, Pathway continues to remain committed to full compliance with all applicable laws and regulations at the local, state and federal levels.

Q2. *Who should develop standards (e.g. biomarker standards, risk algorithm standards) or other relevant criteria for genetic tests and how should they be vetted?*

A. Standards will need to be different for different types of genetic information. Each area of genetics, or intended use, poses specific challenges that require individualized approaches to ensure that safe and effective information is available to clinicians and to the public. Standards development should incorporate as many of the stakeholders as possible, including representatives of the public, patient

advocacy groups, personal genomics and diagnostics industry leaders, genetics experts and the regulatory agencies.

Such a group could be coordinated through the NIH, or other organizations, such as the Biotechnology Industry Organization (BIO) or the Personalized Medicine Coalition (PMC). The goal of the group should be to produce a balanced set of standards that provides for public safety and allows access to significant scientific findings through responsible reporting, innovative methods, the flexibility to adapt to rapidly evolving information and provide public education.

Q3. *Should a minimum scientific evidence requirement be met before a claim or risk assessment is made in a direct-to-consumer genetic test?*

A. The future of medicine is to empower patients with useful information that will improve personal engagement in health decisions. Emerging results suggest that personal genetic information can effect positive behavioral change that may lead to improved health. Further, providing personal genetic information is an opportunity to educate the public in the utility and limitations of this resource.

Standards should be established and should be specific to the type of genetic information and the risk of the intended use. Some genetic information is of low risk, for example ancestry and nutritional information such as the genetics of lactose intolerance. In this case, claims should be supported by sufficient evidence of replication from independent studies. Other genetic tests could present significant risk of false positive/negative results, such as the type of cancer treatment to employ, and as such, the claims of the genetic test would require regulatory review.

Regulators should be cautious to apply appropriate regulation that will protect the public, allow for innovation and adapt to the rapidly changing scientific environment. Simply producing a list of markers acceptable for personal genetic testing, although attractive in minimalism, may have far-reaching deleterious effects on innovation. If a genetic variation is to be used individually to imply risk, then the evidence supporting the intended use should be substantial, requiring that the findings be replicated by independent genetic studies. However, some biomarkers may have limited individual utility, yet could contribute significantly as part of a multiplexed test by capturing information about complex biological interactions. In such an instance, the test should be evaluated based on the risk to the patient and the claims about the overall results, not the individual markers per se.

A mandatory genetic test registry should be established, requiring genetic testing companies to provide enough information to evaluate the evidence supporting the claims being made about the genotype–phenotype correlation. The registry could provide regulators with information necessary to thoroughly evaluate all tests and determine if the test would require further regulatory review; at the same time the registry could allow non-proprietary information to be publicly available for comparison of providers. Genetic tests should be required to demonstrate acceptable levels of support based upon standards of evidence, along with the risk of the test results to the patient and the claims being made about the results. All genetic testing laboratories should be required to be certified or accredited through the Clinical Laboratory Improvement Amendment (CLIA) and/or the College of American Pathologists (CAP). In this fashion, regulatory inspections could ensure participation in the test registry, allowing proper assessment of all genetic testing

Q4. *Describe in detail what genetic counseling services are available to potential and current customers of your company. Please include information regarding the type of counseling provided, the training and credentials of your genetic counselors, time of availability and duration of genetic counseling, and all costs associated with receiving genetic counseling, including one-time and ongoing counseling.*

A. Pathway offers pre- and post-test genetic counseling to any individual who is interested in, or has taken, one of Pathway's genetic tests. All of Pathway's genetic counseling services are currently offered free of charge or obligation.

In pre-test genetic counseling, one of our counselors will typically explain the process for genetic testing and the type of information that an individual might learn from genetic testing, and the limits of genetic testing. The genetic counselors will also attempt to answer any specific questions raised by the individual, including consent-related questions.

The process for post-test genetic counseling has changed since we suspended consumer-initiated testing, but we will explain both methods here since they seem relevant to your line of questioning.

In the consumer-initiated model, post-test counseling was initiated in one of two ways. The first scenario would occur when a member of our clinical staff identified something in the report we believed to be important to discuss with the individual. The typical scenarios we identified for this action were the following:

- A pregnant woman, or an individual who reported their partner was pregnant
- An individual planning to have children and who was identified as a carrier of one, or more, recessive genetic diseases
- An individual who had reported a family history of a disease and the testing demonstrated an elevated genetic risk for that condition
- An individual who had reported they were using a medication and our test suggested a possibly atypical response, based on his or her genetic profile

Our overriding concern in all these cases was that an individual might misuse this information to make an uninformed decision about his or her health. Unless there was an indication of something severe or an extremely risky situation, we notified the individual that one of our genetic counselors was available to review the test results with but did not require it prior to releasing their results. Additionally, we always encourage individuals to share the results with a personal physician before making any changes to his or her medical treatment or initiating any lifestyle changes.

In our current medical model, the testing is requested by an individual's physician and the results, in the form of a detailed report, are returned to the physician. Our overriding concerns are the same; however, the process has been modified slightly. If there is information in our report that our clinical staff feels should be highlighted, we provide that information in a cover letter that is included with the paper copy of the report. Our genetic counselors are available to discuss the notations or any other aspect of the report with the ordering physician or, at the physician's request, directly with the patient.

All of Pathway's genetic counselors are Board-certified or -eligible by the American Board of Genetic Counseling. Our genetic counseling is regularly available Monday

through Friday from 8:00am to 5:00pm, Pacific Standard Time. It is important to note that we will make exceptions to be available during non-standard hours to accommodate an individual's needs. Typically, a call with a genetic counselor lasts between 10 and 20 minutes, though it can vary significantly based on customer needs. As our customer base grows, we anticipate that we may need to expand our operating hours to be available for customers in different time zones. Additionally, we currently record all calls with genetic counselors, after we receive from all participants consent to discuss genetic information and to record the call. If a person declines to have the call recorded, we will still speak with him or her, but only after documenting the request not to record the call.

Q5. *Please describe in detail the process by which a client of your company receives a genetic evaluation. Include all steps that take place, from the point a client or physician solicits information about a genetic test to the point when a genetic report is received.*

A. As with our response to the fourth question, we will discuss the process as it was when we offered consumer-initiated testing, as well as the process as it relates to our current medical model. The underlying tenets of accuracy and responsibility in testing are unchanged, but the processes are slightly different.

In the consumer-initiated model, an individual would come to our website (www.pathway.com) and choose which reporting services they wanted. They could select the health test (including risk for health conditions, presence of any recessive carrier mutations, and likely responses to certain drugs), the genetic ancestry test (an analysis of where their genetic ancestors originated and migrated from 10,000 to 150,000 years ago), or they could order both tests together. Once they had made their selection, they would provide payment information and complete the online checkout process. When we received their order, we would send them a collection kit, which includes a saliva collection vial and cap, a requisition form, instruction materials, a biohazard bag and prepaid shipping materials. The individual would typically receive the saliva collection kit within two to three days. The individual would provide his or her information on the requisition form, submit 2ml of saliva into the collection tube, screw on the cap to release the preservation fluid, place it in the bio-hazard bag and, using the pre-paid package, mail the sample back Pathway's CLIA-certified lab.

In our current medical model, the process has been modified to require an interested individual to contact his or her physician to order the desired test(s). Unfortunately, this can be a significant barrier as an individual may be required to schedule several appointments and take time off of from work to obtain the physician's order, have the physician collect the sample and review the results. In order to minimize any inconveniences, we have forms that can be downloaded from our website and allow the doctor to release the results directly to the patient. While we continue to make customer service and genetic counselors available for phone support, there is no question that the medical model creates some hurdles that can prevent many patients from accessing their genetic information.

In both models, the individual would go online to www.pathway.com/activate and create their secure online account before mailing the saliva back, though we do allow for a paper-based option to collect the same information in the medical model. During this process, individuals provide a username and password, provide personal information (contact information along with date of birth, ethnicity, and gender),

before reviewing and agreeing to the consent, terms of service, and privacy statement. At that point, the user can voluntarily complete a health survey, which captures information about their environment and lifestyle, current health, and family history.

For both models, we process the samples identically within the laboratory testing and review processes. When the sample is received in our lab, it first goes through an accessioning process where the sample is received and inspected. The accessioning team visually inspects the sample to make sure it contains a sufficient amount of specimen, that there are no signs of damage or other concerns, and that the personal data on the vial matches the personal data on the requisition form. Accessioning also checks the information on the requisition form to ensure that it matches the information provided during the activation process. If any of these steps fail, then the account is assigned to our customer service team to contact the customer to clarify information that does not match and, if necessary, request a new sample.

The DNA is processed in our on-site CLIA-certified laboratory, and the results are processed through the bioinformatics pipeline to analyze the genotypic information. This procedure includes several quality assurance checks to ensure that the sample has been properly processed. The bioinformatics analysis pipeline generates the results for the report by calculating the risk categories of complex health conditions, the presence or absence or recessive genetic mutations, and the expected drug response. The results, along with an individual's genotypic information, are loaded into our results delivery system and prepared for evaluation by our physicians and genetic counselors. This group reviews every test and looks for any items of concern as described above, and decides if the results can be published or if a communication is required prior to publishing.

In the consumer-driven model, the communications are accomplished directly with the individual being tested. In the medical model the communications are made only with the physician and, if specifically requested by the ordering physician, directly with the patient.

Q6. *Please describe all measures used by your company to protect client privacy and client identity. In your response, please discuss sample and data storage before and after samples are processed, and data transfer between all involved parties (e.g. between client and your company, between your company and contractors, between your company and medical professionals).*

A. Pathway takes its privacy and security responsibilities very seriously.

PRIVACY: We will use the FTC's Fair Information Practices as a framework for our response related to privacy.

Notice/Awareness: Pathway provides Summary and Full Privacy Statements (collectively the "Privacy Statement") that explain how information is collected, used, shared, and protected, and patient choices to limit sharing. The Privacy Statement is available via a prominent link in the footer of our website.
Choice/Consent: Prior to laboratory testing, either the ordering personal physician or Pathway obtains patient consent, as determined by the process. Pathway presents a two page Informed Consent and a more detailed Brochure (collectively "Informed Consent") that explain the purpose, benefits, risks and limitations for the genetic

report ordered, as well as how information is collected, used, shared, and protected, and patient choices to limit sharing. Pathway makes clear in its Informed Consent, Privacy Statement, and website that Pathway-authorized physicians and genetic counselors are available for pre-testing consent counseling, and provides a toll-free phone number to facilitate this.

Access/Participation: The Privacy Statement explains to individuals who have an account how they can update or correct account information (such as email address, street address, or phone number) to ensure accuracy and completeness. In cases where the physician establishes a patient record and there is no customer account, the physician is responsible for keeping appropriate record information current. The Privacy Statement and Informed Consent explain how patients can request earlier DNA extract destruction and/or account deactivation.

Integrity/Security: Pathway employs reasonable and appropriate administrative, physical, and technical security safeguards to protect patient personal information, which will be further explained below. The accuracy of information is explained in "A Patient's Brochure on Comprehensive Genotype Testing," as well as in all genetic results reports.

Enforcement/Redress: The Privacy Statement explains that privacy-related complaints can be brought to the attention of Pathway's Chief Privacy Officer whose contact information is provided in the document. It further explains that any unresolved privacy complaints can be filed with the Secretary of the U.S. Department of Health and Human Services and/or the California Department of Health Services.

IDENTITY: Pathway's customer service and genetic counseling personnel are privacy-trained and adhere to established procedures for verifying the identity of patients at the outset of a call.

SECURITY: As mentioned above, we employ a comprehensive system of industry-accepted administrative, physical and technical controls to safeguard the privacy of and protect the information that we collect, use and store.

All Pathway workforce members, including employees and independent contractors, who have access to personal information as a part of their regular responsibilities, are privacy and security-trained and sign a confidentiality agreement.

Pathway employs roles-based-access-controls (RBAC) to limit:

- Physical access to the building, laboratory and data room; and
- Systems access to personal information is provided to only personnel who reasonably have a need to know this information to provide our services

As an example, different roles, such as customer service representatives and physicians, have different and appropriate RBAC access levels to systems and information. We also maintain records of personnel logon access to systems and databases and we monitor and periodically review access to personal information.

Administrative Safeguards

- Chief Privacy and Security Officer with IAPP's CIPP certification
    - *IAPP = International Association of Privacy Professionals; CIPP =Certified Information Privacy Professional*

- Privacy and security-trained workforce members
- Criminal background checks of workforce members
- Confidentiality agreements for workforce members
- HIPAA Security Policy and Procedures
- Incident Response Policy and Procedures
- Implementing more comprehensive ISO 27002 system of controls
- Third party information security due diligence questionnaire
- Third party contracts include information security provisions as appropriate or Business Associate Agreement as addendum
- Roles-based-access-controls (RBAC) appropriately changed at termination or changes of status
- Periodic review of personnel roster of physical and systems RBAC rights for accuracy

Physical Safeguards - Pathway

- Card reader RBAC controls for our building, laboratory, and data room
- Motion-activated surveillance cameras
- Visitor sign-in log and escorting when in facility
- Locked paper shredding bin with scheduled pick-ups and shredding of paper documents containing personal information by a bonded NAID-certified company
- SAS 70 Type II information security audit certified colo hosting service provider's facility

Technical Safeguards - Pathway

- Separate development, testing, and production environments
- Data masked for engineers and QA testing personnel
- Encrypts system backup drives to safeguard personal information archived off the network
- Firewalls protect network; ports locked except those in active use
- Virus and intrusion detection software prohibit unauthorized access to our systems
- Secure Socket Layer ("SSL") encrypts personal data collected on web pages
- 256-bit SSL encrypted e-commerce website
- PCI approved payment processor platform
- All logs enabled and periodically monitored
- Periodic system vulnerability scans
- Systems access to personal data by others is limited to personnel on "need-to-know/use" basis using roles-based-access-controls

- Strong authentication/password controls to control personnel and customer access to personal information
- End-point security controls
- Laptops containing personal information have encrypted folders/drives
- Flash/USB and CD Writer devices locked out on company desktop/laptop computers for laboratory personnel
- Passwords stored in encrypted manner

Sample Processing and Data Storage
After a physician orders testing, either the physician or patient will submit the patient's saliva specimen to Pathway. Depending upon the process, patient consent to genetic testing is obtained by either the ordering physician or by Pathway. After consent and upon receipt of the sample, Pathway will extract DNA from the saliva and conduct comprehensive genotype testing to analyze unique DNA sequences.

Having our own on-site federal CLIA certified and California-licensed laboratory provides additional control over processing and security of saliva samples and DNA. Pathway employs a comprehensive system of laboratory controls that protects the security of samples and DNA. Our laboratory is secured by a card reader control system with motion-activated video surveillance cameras on all doors. Only authorized personnel are granted laboratory access privileges. Privacy-trained laboratory professionals process samples.

Saliva samples are destroyed about 60 days after the testing process is completed and the results are finalized. DNA extracts are placed in our secure freezer for safekeeping with only a limited number of authorized personnel having access rights. The DNA is destroyed no more than one year from the most recently ordered report sample receipt date. All genotype information derived from the process is retained in our laboratory information management system, member site information, and backup systems ("information system").

Either the physician will establish a patient record or the patient will establish an online account, providing requested information about age, gender, and ethnicity. This information is required as it provides the information necessary for Pathway, the physician and/or a genetic counselor to interpret the patient's report results. The record or account information is used to administer Pathway's services provided to the physician and patient. Depending upon the process, either the physicians can log in and change patient record information or the patient can log into their account and change the appropriate information to ensure its accuracy.

If a patient no longer desires to use our service, the patient can make a written request for Pathway to destroy his or her DNA extract at the next scheduled sample destruction date, which occurs about every sixty (60) days. In addition, or alternatively, an individual can deactivate his or her account from our systems within ten (10) business days by contacting Pathway's Chief Privacy Officer as identified in the Contact Us section of the Privacy Statement. Not all personal information can be removed from our systems. We are required by law and standards of medical practice to preserve medical records, some contact information, and disclosure records for specified time periods. Aggregate information and information in logs

cannot be deleted. Information archived on data backup media also cannot be deleted, however it is protected by encryption.

As disclosed in its Informed Consent and Privacy Statement, Pathway uses an internally assigned unique identification number, which will either not include patient name or contact information or will be encrypted for internal operations purposes to:

- Validate genetic information
- Improve the quality and accuracy of Pathway's genetic reports
- Develop new genetic reports and/or services, but not publish the results in scientific literature
- Promote the types of information that individuals may learn from our reports
- Improve the quality and features of our website and services
- Produce data for product approval or clearance by FDA or other regulatory authority or body

We analyze and use aggregate information and online profile information (computer IP address and non-personal information) to track and monitor aggregate usage of our website, as well as to improve the quality and features of our website and services. We explain how cookies can be deleted in the Privacy Statement.

Data Transfer between All Involved Parties
Pathway treats its independent contractors as workforce members as permitted by HIPAA, which means we conduct a screening of their backgrounds, and they each sign a confidentiality agreement, are privacy and security trained, and are assigned appropriate RBAC privileges.

Genetic testing results will be disclosed only to the ordering physician. Additionally, if the physician considers it appropriate and authorizes his or her patient to view the results, Pathway will release the report to the patient. It is important to note that Pathway **will not** release genetic report information to anyone else unless required by law.

We may contact and give individuals the opportunity to opt-in or refuse before any personal information is shared for any secondary purpose outside Pathway's immediate control, including published scientific research. No name or account information is shared with a research collaborator without express consent of the individual.

For individuals participating in an employee wellness program, Pathway provides the employer only aggregate information unlinked to name or account information. By contract, any reseller of our services must not collect personal information from patients without their consent.

Pathway also uses other third parties, companies and individuals, to perform other functions on our behalf. Examples include fulfilling and authorizing orders, delivering packages and testing results, sending postal mail and email, removing repetitive information from customer lists, analyzing data, providing marketing assistance, providing search results and links (including paid listings and links), processing card payments, systems development and managed technology services, and providing customer service. These third parties may have access to, and use, certain personal information to needed to perform their functions our behalf. However these third parties may not retain, share, store or use it for any other purposes and must maintain strict confidentiality of this information. They will have no access to genetic

information, other than the type of genetic report. All such third party service providers with access to personal information must agree to responsibly use such personal information in an authorized manner and to comply with all appropriate privacy laws and regulations.

For its service providers and partners with regular access to personal information needed to provide their services, Pathway requires an agreement specifying that they provide appropriate security for such personal information. In addition to implementing appropriate security measures, these service providers and partners must have either an independent audit certifying privacy and information security compliance, or they must attest to being compliant to Pathway's information security due diligence questionnaire, and they must agree to only the authorized use of any personal information. We believe these requirements provide practical assurance that our service providers and partners will exercise reasonable and appropriate protection of patient personal information.

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