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AT HOME DNA TESTS: MARKETING SCAM OR MEDICAL BREAKTHROUGH

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HEARING

before the

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

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C O N T E N T S

AT-HOME DNA TESTS: MARKETING SCAM OR MEDICAL BREAKTHROUGH?

THURSDAY, JULY 27, 2006

U.S. Senate,
Special Committee on Aging,
Washington, DC.

The Committee met, pursuant to notice, at 10:03 a.m., in room SD-106, Dirksen Senate Office Building, Hon. Gordon H. Smith (chairman of the committee) presiding.

Present: Senators Smith and Talent.

OPENING STATEMENT OF SENATOR GORDON H. SMITH, CHAIRMAN

The Chairman. Good morning, ladies and gentlemen. We welcome you to this hearing of the U.S. Senate Special Committee on Aging. This morning's topic is ``At Home DNA Tests: Marketing Scam or Medical Breakthrough.''

We will be exploring the regulatory and scientific issues relating to direct-to-consumer genetic tests. Genetic science holds great promise, and with that promise a hope for a better understanding of human health and disease. Recent advances in genetic science have fueled the growth of a direct-to-consumer genetic testing industry. With a few clicks on the Internet, consumers can now purchase at-home tests that claim to predict propensities for a myriad of health conditions, including Alzheimer's, cancer, diabetes and arthritis.

However, as reported just last month in the Washington Post, these home tests can shock and misinform consumers. The American College of Medical Genetics has advised the public to avoid home DNA tests, which it has called, quote, ``potentially harmful,'' citing the possibility of inappropriate test utilization and misinterpretation of test results and a lack of follow-up.

Just today, the Federal Trade Commission, in conjunction with the Food and Drug Administration and the Centers for Disease Control, have released a consumer alert cautioning consumers that, quote, ``Some of these tests lack scientific validity and others provide medical results that are meaningful only in the context of a full medical evaluation,'' end of quote.

These concerns give rise to questions about the oversight of the tests and the science behind them. The sales companies and testing laboratories currently operate apparently, unfortunately, in a regulatory abyss between jurisdictions of the FTC, the FDA and the CMS. Further, unclear direction from the agencies about their jurisdiction, a 6-year delay by the administration in promulgating a genetics testing specialty rule under the Clinical Laboratory Improvement Amendments and regulatory loopholes have created an environment ripe for consumer fraud and abuse.

It is my concern about that environment that is ripe for consumer fraud and abuse which has necessitated this hearing today. This Committee has had a long history of trying to especially protect the senior citizens of this country against those who would perpetrate on them things which have less than value.

I have numerous questions regarding the marketing practices of the companies selling these tests to consumers, as well as the clinical practices of the laboratories performing the tests. I also have serious concerns about the tests' true

predictive value and what is in many instances the lack of a health care professional's involvement to help consumers determine the necessity of testing and the meaning of the test results. I would like some level of assurance that the tests are safe, accurate and useful, and that there are basic privacy protections in place.

The expansion of genetic testing services also raises important ethical and legal questions about how these tests should be administered and what level of protection is necessary for sensitive medical and personal information provided by consumers when ordering these tests. It is my hope that through today's hearing, we will find answers to these questions.

This morning, we will hear from the Government Accountability Office about the results of their year-long investigation into the direct-to-consumer genetic testing industry. We also will hear from industry stakeholders and regulatory agencies charged with oversight of genetic testing. I am deeply disturbed by GAO's finding that consumers are being misled and exploited, and I am shocked to learn how little the Federal Government is doing to help consumers make informed decisions about the legitimacy of these tests.

Because of the nature of today's hearing, the Committee will be receiving all testimony under oath. I will administer the oath to each panel as a group and ask all of our witnesses to please be sworn in and to promise to tell the truth. After I administer the oath, I would ask that the panel witnesses each, in turn, one after another, individually acknowledge their affirmation to the oath by stating ``I do.'' With that, I would ask the first panel of witnesses to stand and raise your right hands.

Do you promise to tell the truth, the whole truth, so help you God?

Mr. Kutz. I do.

Dr. Hudson. I do.

The Chairman. Our first panel includes Mr. Greg Kutz, who is the managing director of Forensic Audits and Special Investigations at the Government Accountability Office. Mr. Kutz and his team have spent the past year canvassing the direct-to-consumer genetic testing industry, purchasing test kits, obtaining test results, and consulting with experts and conducting site visits at the companies and laboratories involved in the industry. I commend Mr. Kutz and his team for their fine work, and we very much look forward to hearing your investigative results.

He will be followed by Kathy Hudson, who is the director of the Genetics and Public Policy Center at Johns Hopkins University. She will provide her expert opinion regarding various ethical, legal and social concerns relating to direct-to-consumer genetic testing.

I appreciate both of you being with us. Greg, why don't we start with you?

STATEMENT OF GREGORY KUTZ, MANAGING DIRECTOR, FORENSIC AUDITS AND SPECIAL INVESTIGATIONS, U.S. GOVERNMENT ACCOUNTABILITY OFFICE, WASHINGTON, DC

Mr. Kutz. Mr. Chairman, thank you for the opportunity to discuss genetic testing. Our investigation relates specifically to certain genetic test kits sold directly to consumers on the Internet. The companies marketing these kits claim to provide consumers with lifestyle programs based on their genetically determined health risks. You asked us to investigate the legitimacy of these claims.

My testimony has two parts: first, how we conducted our investigation, and, second, our key findings. First, we investigated four websites selling what are referred to as nutrigenetic tests. These sites claimed that their tests would analyze between 4 and 19 genes, and provide personalized lifestyle recommendations. The cost of the kits that we purchased ranged from $89 to $395. We purchased several of the same kits from each website so that we would have a variety of results to analyze.

To test the legitimacy of these products, we created 14 fictitious consumers. As shown on the poster board, we used DNA from a female for 12 of these consumers and DNA from a male for 2 of the consumers. For all 14 kits, we submitted cheek swabs, 12 from a 9-month-old female and 2 from a 48-year-old male. In addition to the cheek swab, one company required us to submit a urine sample. We also sent in cheek swabs from a dog, a cat and several blanks, which were all returned to us because they could not be processed.

For each fictitious consumer, we filled out a questionnaire, pretending to be adult men and women of various ages, weights and different lifestyles. The questionnaires asked us about exercise, smoking, diet and vitamins taken, but did not ask us about any medical conditions we had or medications that we were taking. In assessing the results of the 14 fictitious consumers, we consulted with experts primarily in the areas of genetics and nutrition. We also interviewed representatives from the four websites and two labs processing the results.

Now that I have set up what we did, let me go on to my second point, our key findings. The poster board shows the medical conditions predicted for the 14 fictitious consumers based on the DNA that we submitted. As you can see, our consumers are at risk of developing osteoporosis, cancer, type 2 diabetes, heart disease and brain aging. Although all four websites said the kits were not intended to diagnose a disease, all 14 consumers were told they were at risk of developing these very serious medical conditions.

The primary problem here is that according to the experts, none of these predictions can be medically proven at this time. Research related to the genetic connection to the development of these conditions is at a very early stage, with many issues to be resolved.

The secondary problem is that the predictions use ambiguous language that renders them meaningless. For example, several results said the consumer may be at increased risk of developing heart disease. In other words, you might have an increased chance of developing heart disease. These predictions could apply to any human submitting DNA.

Websites 1 and 4 also recommended supplements, supposedly based on a consumer's unique DNA. However, our testing showed

that these supplements are, in fact, not unique. For example, for website 1, two of our fictitious consumers were recommended the very same unique supplement. However, one of the consumers was actually the female and the other was actually the male.

Further, the next poster board shows that the supplement from website 1 contained the same ingredients, although in different amounts, as a multivitamin that we purchased at Rite-Aid. Look at the cost comparison: $1,200 per year for the supplement compared to $35 a year for the Rite-Aid multivitamin.

Although not identical, the expert nutritionists that we spoke to said that the costly supplement and the Rite-Aid vitamin would likely provide the same nutritional benefits for most people. Also, they expressed concern about the amount of vitamin A, B-6 and iron in the supplements that could be harmful.

Finally, the results from websites 1, 2 and 3 promise recommendations based on a consumer's unique genetic profile. However, our test shows that we could have created any lifestyle description and the results would simply echo the data submitted. For example, we submitted the same DNA for nine fictitious consumers and received advice that varied, clearly showing that the results are based on the questionnaire and not the DNA.

In conclusion, in a best-case scenario the test kits and supplements that we investigated provide little or no value to consumers. In a worst-case scenario, the test results could frighten a consumer into thinking that they will develop cancer, osteoporosis, heart disease, or brain aging. The fear could also cause them to purchase supplements at outrageous prices.

I understand that there is great potential for genetic testing and I don't want the results of our investigation to cast any shadows on the progress made to date. However, for the products that we tested, I want to send a message to consumers across the country: buyer beware. Before buying any of these products, consumers should not only think twice, but should consult with their doctor.

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

[The prepared statement of Mr. Kutz follows:]

[GRAPHICS NOT AVAILABLE IN TIFF FORMAT]

The Chairman. Thank you very much, Greg.

Kathy Hudson.

STATEMENT OF KATHY HUDSON, DIRECTOR, GENETICS AND PUBLIC POLICY CENTER, AND ASSOCIATE PROFESSOR, BERMAN BIOETHICS INSTITUTE, INSTITUTE OF GENETIC MEDICINE AND DEPARTMENT OF PEDIATRICS, JOHNS HOPKINS UNIVERSITY, WASHINGTON, DC

Dr. Hudson. Thank you, Mr. Chairman, and thank you for inviting me to testify today and for focusing your attention on this important topic that has consequences for people of all ages.

I would like to begin by saying unequivocally that genetic

testing today is having a documented beneficial impact on clinical care and holds enormous promise for future improvements. Today, there are genetic tests clinically available for nearly 1,000 different diseases and hundreds more in development.

Genetic tests provide information, information that can be used to diagnose disease, to predict risk of future disease, and to guide decisions about whether to undergo a medical procedure or to take a particular dose of drug or a particular drug. Genetic tests lead to critical health and life decisions, and therefore it is imperative that this information be accurate and reliable and relevant to an individual's health.

While many genetic tests available today are of extraordinary quality, inadequacies in the current oversight of genetic testing identified by the GAO and studies by my Center threaten more than the public's pocketbook; they threaten the public's health. For a genetic test to be of high quality, it must be analytically valid as well as clinically valid. Analytic validity refers to a laboratory's ability to get the right answer reliably over time, to detect a genetic variation when it is present, and, importantly, not to detect it when it is not present. Clinical validity refers to the relationship of a genetic mutation to a specific health outcome.

Current regulations fail to ensure either analytic or clinical validity of genetic tests. The responsibility for ensuring the analytic validity of genetic tests lies with the Centers for Medicare and Medicaid Services, CMS, as you mentioned, which is responsible for implementing the Clinical Laboratory Improvement Amendments of 1988.

In enacting CLIA, Congress believed that proficiency testing, or external validation of a laboratory's performance, was, and I quote, ``testing should be the central element in determining a laboratory's competence, since it purports to measure actual test outcomes rather than merely gauging the potential for accurate outcomes.'' Unfortunately, 18 years after enacting the laboratory amendments, problems persist and are particularly acute in the genetic testing arena.

Despite the recommendations of government advisory committees, CMS has failed to create specific proficiency testing standards for genetic tests. While some laboratories maintain accuracy of their testing procedures by voluntarily enrolling in programs for proficiency testing, others do not. Immediate action by CMS is urgently needed to create proficiency testing standards for genetics under CLIA. In November of last year, my center called on CMS to issue these regulations expeditiously, and subsequently nearly a hundred groups, including patients, health care providers, industry and women's health advocates, have added their voices and called on CMS to act.

The GAO reports real errors occurring in genetic testing laboratories. The GAO submitted a DNA sample from a single individual for testing under different assumed identities. Even though the DNA was identical, the test results were not. This should disturb us all.

Testing errors have real consequences for real people, and enhancements in CLIA could make a real difference. A recent survey by my center showed that higher levels of participation

in a proficiency testing program is correlated with a reduction in errors. So we need to increase proficiency testing and we need to enhance CLIA.

Even if CLIA were to operate perfectly, there would still be problems, and that is because CLIA is focused on analytic validity and laboratory quality and not on the clinical validity. What is the relationship between the DNA mutation and health? Does it cause cancer, does it cause diabetes, et cetera?

Currently, there is no government agency with clear responsibility to ensure clinical validity of most tests. Therefore, each laboratory director makes an independent decision regarding whether tests have sufficient validity to be offered to the public. As I said, many laboratories are of extraordinarily high quality and offer only tests for which there is broad scientific agreement regarding the clinical validity. But several reports, notably the GAO report, indicate that laboratories are offering tests to the public in the absence of sufficient evidence of their clinical validity. Moreover, because there is no requirement that laboratories disclose the scientific basis for their test, it is not possible for consumers to determine whether a test is bogus or based in real science.

Some have recommended that the Food and Drug Administration step in here and ensure the clinical validity of some or all genetic tests. Currently, FDA regulates only a small handful of these tests, those that are marketed as test kits. FDA has sent very mixed signals over the years regarding its jurisdiction and willingness to regulate home brews.

As a result, we have a two-path system for regulation of genetic tests. Those companies that have invested time, money and effort to develop test kits face competition from clinical laboratories using home brews. This uneven regulatory playing field provides a disincentive for the development of test kits with clear clinical validity.

In conclusion, quality genetic testing requires good tests and competent laboratories. Current oversight assures neither. I want to applaud you, Mr. Chairman and the Committee, for taking the first steps in investigating questionable oversight and questionable genetic tests, and I urge you to continue to provide leadership in this area.

Thank you.

[The prepared statement of Ms. Hudson follows:]

[GRAPHICS NOT AVAILABLE IN TIFF FORMAT]

The Chairman. Thank you, Kathy.

It seems to me that the whole thing speaks for itself when GAO submits four samples from one person and gets back four different results. Is that what happened?

Mr. Kutz. Yes.

The Chairman. I think the point you are making is between actual and clinical validity. In order to really be valuable, genetic testing has to include environmental understanding of a person's--you know, how they are living, where they are living, what their habits are, all of the factors that go into making up a diagnosis of any kind of genetic impact to a person's

health and their propensity to a disease.

Is that basically what you are saying?

Dr. Hudson. Yes, and in order to document the correlation between a specific genetic mutation or variant and a specific health outcome, it really requires rigorous studies following many people who have the mutation and don't have the mutation, and making a direct correlation between their genes and their health outcomes.

The Chairman. The clinics have to have valid procedures that are scientifically verifiable, and then it has to be followed up with physicians to take a holistic approach to it or else it really isn't very valid.

Dr. Hudson. That is right, and there is enormous promise. In the wake of the Human Genome Project, we are trying to unravel the genetic contributions and environmental contributions to common, complex diseases that affect many, many Americans--heart disease, diabetes, and many, many forms of cancer. One of my concerns is that the effort to move genetics into clinical practice and to improve human health is going to be tainted by the ability of bad actors to operate in this area.

The Chairman. Home kits just are not going to do it. It sounds to me from your opinion, they are simply going to erode credibility in the promise of the genome project and genetics as a part of understanding fully health care and disease.

Dr. Hudson. If sufficient regulations were in place to assure the analytic validity of tests and the clinical validity of tests, I think then we could really have a conversation about whether it is appropriate for consumers to access some tests directly without a health care provider's intervention.

For example, if there was a test that would tell me which over-the-counter pain medication would be most effective for me, do I really need to go to a physician to get that information? All genetic tests are not created equal, and so we need to have a nuanced approach to whether a health care provider's intervention is required always, sometimes or never.

The Chairman. We don't have that regulatory structure now?

Dr. Hudson. We don't have that regulatory structure as a baseline to assure quality today.

The Chairman. Greg, I wonder if for the record you can identify the companies referred to as websites 1 through 4.

Mr. Kutz. Sure. Website 1 was Market America and they were marketing via Internet distributor Martin Marketing. Website 2 was Genelex, website 3 was Sciona, and website 4 was Suracell.

The Chairman. The laboratories?

Mr. Kutz. The laboratory was Genaissance that processed most of the kits, but also there was SeraCare Laboratories that website number 4 used, we believe, for some of our later tests. Then Genox Corp. processed our urine sample, we believe.

The Chairman. How about the DNA donors?

Mr. Kutz. One was a 48-year-old male. He is one of our special agents. The 9-month-old female was my daughter, Katie.

The Chairman. I understand your investigations also uncovered some difficulties that Sciona encountered when trying to sell these genetic tests in the United Kingdom. Can you share with us what you found?

Mr. Kutz. Yes. There were consumer groups in the United

Kingdom that raised concerns about the validity and the usefulness of similar products being marketed over there. Also they put together a panel of experts similar to the people we consulted with in looking at our 14 fictitious consumers and they concluded that the kits being marketed there were of no value to consumers. The company stopped selling them over there and has come to the United States and is marketing them here.

The Chairman. So if there are of no value to the British, are they of any value to Americans?

Mr. Kutz. Well, as I mentioned in my closing, I mean our view is certainly that in a best-case scenario they are of little or no value. Worst-case scenario--and I will use the supplements; $1,200 per year for supplements that you could buy at a grocery store for $35 a year is less than no value. It is a rip-off.

The Chairman. Did you send your samples directly to labs?

Mr. Kutz. Some of them were sent directly to labs. Some were sent to the websites who forward them to the labs. So the return envelopes in the kits varied as to where they went.

The Chairman. I understand that the urine sample that was submitted was a synthetic sample. Did the lab identify it as synthetic?

Mr. Kutz. It was synthetic urine. It was something called Quick Fix, which is used to beat drug tests, and there is no evidence that the lab identified it as fake urine, basically.

The Chairman. So they made no conclusion as to it?

Mr. Kutz. They did make--I mean, it was part of the kit. They tested the cheek swab and the urine.

The Chairman. So they tested it as urine?

Mr. Kutz. They tested two, yes. They tested urine and a cheek swab, and then we got the results back. There were no indications that came back to us----

The Chairman. They did not discern that it was synthetic?

Mr. Kutz. Not that we can tell, no.

The Chairman. Are any of the DNA donors--obviously, your daughter is pretty young and I don't know that she would be worried. But the 48-year-old man--is he worried at all about conditions for which they were diagnosed in these tests?

Mr. Kutz. We are worried about him for other reasons, Senator. [Laughter.]

But for purposes of the tests that were actually made of him, no, I think he knows and we know based on the experts that we have spoken to that I am not worried about my daughter and I don't think he is worried about the results there.

The Chairman. It is my understanding that in the course of the investigation the GAO was contacted by a nutritionist after these tests and they tried to sell you the products of this company.

Mr. Kutz. They tried to sell us on a diet, a nutritional diet that would supposedly help us with the problems that were identified. Within that diet, it was another way to market the supplements. If you actually read through the diet, it looked like some very good dietary suggestions, quite honestly, but within those were also some marketing of specific supplements that, you know, if you take these, according to this, it would help you with whatever gene problems that they identified for you.

The Chairman. It is my understanding that Sciona has a disclaimer on its website asserting, quote, ``its unlimited rights to consumers' information.'' That, for me, raises a real privacy issue about sensitive data, even if it may be inaccurate data, that is out there in cyberspace.

So I am wondering based on your investigations, what do consumers need to do know about companies' privacy policies and the potential of sending out this kind of information about themselves.

Mr. Kutz. Well, let's use the example--you just asked me the question about the dietitian who somehow got our results. We don't believe she worked for the company. Somehow, she got the results from one of our fictitious consumers and made a call to us. So it is unclear. I mean, they all made representations, all four websites, that our DNA would be destroyed actually after the results were sent to us and that they would protect all of our other information.

The Chairman. How would the dietitian have known it?

Mr. Kutz. Well, we don't know. There is no way to tell exactly whether it was a subcontractor or what other relationship she had to that company.

The Chairman. But it raises the question that information is out there for anybody to see?

Mr. Kutz. Yes, that would raise a question.

The Chairman. In your opinion, what is the most pressing public health threat posed by inadequacies in current oversight in genetic testing?

Mr. Kutz. Well, I think again there are two parts to this. There is the actual part of the kits and whether or not people should take them, whether they provide value. Certainly, telling someone to stop smoking, to reduce caffeine intake are all great ideas, but you don't really need to buy a kit to actually come up with those.

So I think more significant is the $1,200 and $1,800-a-year supplements that were marketed to us that were linked directly to the results of our genetic tests which said we were at risk of having these very serious medical conditions sometime in the future, and at least implying that if you took these supplements, which again are very, very expensive, this somehow could help you so you would be able to prevent getting these medical conditions.

The Chairman. So at the end of the day, your ultimate conclusion is that these companies are, in fact, misleading consumers?

Mr. Kutz. Absolutely, yes.

The Chairman. No question about it?

Mr. Kutz. No.

The Chairman. Senator Talent.

Senator Talent. Mr. Chairman, I want to thank you for holding this hearing. I am not going to keep this panel too long because I know we have two more coming.

Let me just ask a question that came to mind as soon as the Chairman scheduled this hearing. Why hasn't this industry been better regulated and why has this been allowed to happen? I think Congress passed the underlying legislation in the late 1980's.

Dr. Hudson. For the regulations of the clinical

laboratories and whether or not they can get the right answer reliably over time, the Clinical Laboratory Improvement Amendments are the relevant statute.

Senator Talent. My understanding is that they give the administrative agencies adequate authority to regulate. Is there a statutory gap here that you see?

Dr. Hudson. I don't believe that there is necessarily a statutory gap. There is a regulatory gap. Over the years, CMS has created a number of specialty areas for different types of tests--microbiology, toxicology, immunology, et cetera, et cetera, et cetera. When you create those specialty areas, then that comes with certain standards that people who are testing in that area have to meet.

Despite the fact that genetics is arguably one the most rapidly growing areas of diagnostics and has such great promise and is complicated, CMS has failed to create a specialty area for genetics. In 2000, they said they were thinking seriously about it, and now here we are 6 years later and we still don't have a proposed regulation. It is inertia.

Senator Talent. Does it really make sense to run these tests through mail order? To me, this seems to be a pretty serious area. If properly regulated, do you think this industry serves an important purpose and we can allow this to continue? Or is it just too complicated to do this way?

Dr. Hudson. I think that there are some genetic tests for complicated, serious medical conditions where a health care provider's intervention is certainly beneficial, if not required. But the notion that all genetic tests are equally complicated and equally serious is probably not the case, and so we need to be a little nuanced about whether or not this is an all-or-none proposition.

We also have a problem with whether or not health care providers are adequately trained and prepared to be able to interpret this information for consumers. Ironically, in regard to the question about privacy, a number of these companies advertise privacy as a selling point. You can do your genetic testing in the privacy of your own home and you don't have to share that information.

But the bottom line is if somebody actually has a mutation that increases their risk for disease or they actually have a disease today, what do we want them to do? We want them to walk directly into their health care provider's office and get medical attention. So the whole notion that this is private is sort of a thin veneer because ultimately that information will be in the medical record and protected by HIPAA and other laws.

Senator Talent. If adults are aware of what they are receiving and still decide they would like to purchase for whatever reason. I will not prevent anyone from doing so. But it seems to me that to the extent this has real medical value in identifying people who are at high risk, you would think that the profession would have begun to incorporate it into some regular testing or they would recommend it for certain people who have other characteristics that might make them high-risk.

Do you understand what I am saying?

Dr. Hudson. Yes, yes, absolutely.

Senator Talent. Well, much of this refers to what the other

two panels are going to testify to, Mr. Chairman. I appreciate your holding this hearing. Thank you.

The Chairman. Thank you, Senator Talent.

A couple of follow-ups. Mr. Kutz, one of the companies in your report, Suracell, has represented to this Committee that they do not conduct direct sales to consumers. When pressed on the point about sales from Suracell's website, they modified their response and indicated that when consumers purchase test kits from Suracell's website, they are assigned a physician in their area based on their zip code. When asked point-blank if a consumer can purchase a test kit without the involvement of a physician, Suracell's response was no. I note in their written statement to the Committee, Suracell has further modified its response and acknowledged that 28 percent of its sales are direct to consumers.

Mr. Kutz, my question to you is with respect to the tests that GAO purchased from Suracell, how many kits did you purchase and for how many of those tests did you have to go through a doctor's office to obtain either the test kits or test results?

Mr. Kutz. We purchased three and there were no doctors involved in consulting with us at any stage that we were aware of, at least. If they were assigned to our three cases, they never contacted us.

The Chairman. You weren't aware of it?

Mr. Kutz. No.

The Chairman. Until this morning--and I say this morning because Sciona has just changed its website--Sciona advertised that its lab, which we know to be Genaissance, is CLA-certified. I presume that to mean CLIA, or C-L-I-A. Your investigation reveals some interesting facts about Genaissance CLIA certification as it pertains to nutrigenetic tests.

Could you please tell the Committee what your investigation revealed?

Mr. Kutz. I am not sure we know exactly what their CLIA certification is. We did not challenge that they were CLIA-certified. The actual lab that did the urine tests had represented to us that they were not CLIA-certified. So I don't believe that Sciona had represented that they were not CLIA-certified. They may not be CLIA-certified for the specific tests that we did and that may be the issue you are talking about.

The Chairman. Are you aware that Genaissance refused CLIA recertification inspection for these very tests?

Mr. Kutz. I was aware of that, yes.

The Chairman. It probably indicates they are not certified.

Thank you both very much. We appreciate your work and your expertise in helping this Committee to understand this very real issue of consumer, buyer beware.

We will now call up our second panel. On our second panel, we have representatives from several of the companies referenced in today's GAO testimony. Ms. Rosalynn Gill-Garrison is the chief science officer for Sciona. Dr. Carol Reed is senior vice president and chief medical officer for Genaissance Pharmaceuticals. Mr. Kristopher King is the CEO of Suracell. Dr. Ramarathnam is president of Genex Corporation. Mr. Howard Coleman is CEO of Genelex Corporation.

If you will each stand and raise your right hand, do you promise that the testimony you are about to give will be the truth, the whole truth and nothing but the truth, so help you God?

Individually. Rosalynn?

Ms. Gill-Garrison. I do.

Dr. Reed. I do.

Mr. King. I do.

Mr. Ramarathnam. I do.

Mr. Coleman. I do.

The Chairman. Thank you very much.

Rosalynn Gill-Garrison, we will start with you.

STATEMENT OF ROSALYNN GILL-GARRISON, CHIEF SCIENCE OFFICER, SCIONA, BOULDER, CO

Ms. Gill-Garrison. Thank you. I would like to thank the Committee and Senator Smith for the opportunity to appear before you today. My name is Rosalynn Gill-Garrison and I am the chief science officer for Sciona, Inc. Sciona was formed with the goal of bringing the benefits of the Human Genome Project directly to the consumer. The initial meeting that led to the formation of our company was actually held on the day that President Bill Clinton and British Prime Minister Tony Blair announced that the first draft of the Human Genome Project was now complete.

At this initial meeting, the cornerstones of the philosophy of Sciona were laid down that the knowledge resulting from this enormous public and private investment should be used to benefit the average person on the street and that each member of the public should be able to learn directly about his or her own genetic information. The goal of our company is to use this information to provide health care information which is focused on health and wellness rather than the treatment of illness, and it is the duty of our company to deliver this information in an ethical and responsible manner.

Sciona decided to focus on the growing body of knowledge of the impact of genetic variation on response to dietary and environmental factors. This was a deliberate decision to focus on health- and wellness-based applications and to focus in an area in which there was a significant body of research that substantiated the links between dietary and environmental factors and genetics.

Sciona's nutritional advisory report which we have actually provided for participants in this conference includes information on 19 genes, 24 variations in these genes, and 18 particular nutritional and lifestyle factors. The report has been written in language that is intended to be easily understood by the consumer. However, technical information such as the exact genetic variation has been included so that individuals or health care practitioners can refer directly to this genetic information, if required.

The report describes how the interaction of these genes and nutritional factors can play a role in different areas of health. Sciona does not sell any products in conjunction with this report. These reports do not diagnose any disease, but are focused on nutritional and lifestyle status to promote general

health and wellness.

The Sciona nutritional lifestyle information service has been developed through an extensive survey of peer-reviewed literature from the fields of nutrition research, biochemistry, epidemiology and molecular biology. In order to build further upon the knowledge available in the public domain, Sciona has actually invested in collaborative research with academic groups interested in exploring gene-diet and gene-environmental relationships.

The laboratory work for Sciona is outsourced and the company maintains close scrutiny on the results and performance of the laboratory testing supplier, which is Clinical Data, Inc. Each batch of samples which are run by the supplier includes a set of blinded controls supplied by Sciona for processing. The laboratory is not aware of the nature of the blinded samples, and so when the results are supplied back to Sciona, these blinded controls are used as a measure of reproducability and reliability of the laboratory results. Pass/fail criteria have been set in which both Clinical Data internal controls and Sciona blinded controls must be in concordance before any set of results is released for report production.

So in conclusion, Sciona is safely, effectively and ethically providing important genetic information to consumers concerning their nutritional well-being, contributing to their health and wellness. Sciona is not involved in diagnostic or disease-related services or information. Sciona believes that the nutritional genetic information provided can best assist consumers if it is available to the consumer through direct access to the service, and we look forward to the development of a regulatory environment and we intend to fully comply and cooperate with the regulatory authorities.

Thank you.

[The prepared statement of Ms. Gill-Garrison follows:]

[GRAPHICS NOT AVAILABLE IN TIFF FORMAT]

The Chairman. Thank you, Rosalynn.

Dr. Reed.

STATEMENT OF CAROL R. REED, M.D., SENIOR VICE PRESIDENT AND CHIEF MEDICAL OFFICER, CLINICAL DATA, INC

Dr. Reed. First of all, thank you very much, Senator Smith, for the opportunity to appear here today. As you know, my name is Carol Reed. I am chief medical officer of Clinical Data, Inc. We are a company that has been in the forefront of the development of pharmacogenetics research and testing for many years. We provide pharmacogenomic and molecular services to the research industry, including clinical trial aspects of drug development, but key to our business is our ability to discover, develop and commercialize genetic tests to guide drug development and utilization.

As the Committee is well aware, drug spend is one of the largest components driving the total cost of health care, despite many efforts to contain it. Health care providers and

payers face the difficult task of deciding which drugs to be prescribed to specific patients and are suitable for reimbursement. These decisions are based on medical outcome studies and economic benefit factors, but with little knowledge of which individual patients are most likely to benefit from a specific drug.

In fact, managed care plans employed by payers and prescription benefit managers have a significant impact on providers' decisions as to which drugs should be prescribed. All participants in the decision to prescribe would benefit from the ability to more clearly identify drugs that are most efficacious and safest for a specific individual or patient population.

The medical community generally acknowledges that most drugs work more effectively for some patients than for others. The genomic blueprint each person inherits from his or her biological parents is contained within a person's DNA and determines not only the obvious physical characteristics that differentiate us, such as height, hair color and eye color, but also has a large impact on how we respond to medications. By understanding genetic variation and its relationship to drug response, it is possible to determine which individuals are most likely to benefit from a given drug even before the drug is prescribed.

Clinical Data's main focus is the development and delivery of genetic tests that may be used to more confidently predict an individual's response to an intervention. As an example, our FAMILION test is used to identify mutations in ion channel genes that are associated with Familial Long QT Syndrome. This test has had a very direct and positive impact on patients' lives, helping physicians determine the right intervention for each patient, as well as assisting the family in ascertaining the status of their relatives, as these syndromes may be asymptomatic until presenting suddenly with syncope, seizures or death.

This test requires a provider's order, is performed in our CLIA-certified and compliant laboratory in New Haven, and test results are reported directly to the provider for use in decisionmaking as clinically indicated. Despite the absence of an approved proficiency testing program for this high-complexity test, we conduct proficiency testing with the assistance of academic experts. This is the model that Clinical Data intends to follow as we develop and deliver pharmacogenetic tests to payers and providers.

Regarding nutrigenomic testing, in 2002 Genaissance Pharmaceuticals entered into an agreement with Sciona, a nutrigenomics testing company. In the good-faith opinion of the company at that time, this testing did not fall under CLIA oversight. The Genaissance laboratory accepts de-identified samples from Sciona customers, extracts DNA and performs genotyping. We have a quality control process in place that meets CLIA standards for proficiency testing and our accuracy in genotypes calls is over 99 percent. The genotying results are sent to Sciona, who provides interpretation and a report to their customers.

Genaissance Pharmaceuticals was acquired by Clinical Data in October 2005. Clinical Data is supportive of the interest on

the part of CMS and CLIA and the Federal Government to consider increasing regulatory oversight of this testing, and the Committee may well be aware that we have now undergone CLIA auditing of our nutrigenomics testing and we are now awaiting the results of that audit.

The Chairman. But did you actually refuse their reauthorization?

Dr. Reed. At the time when we were conducting the test earlier and felt that it was not under CLIA regulation, yes, we did refuse that inspection, but we have since permitted that inspection.

The Chairman. You refused it, but you have since allowed it?

Dr. Reed. Correct.

The Chairman. You are awaiting the results for that?

Dr. Reed. Correct.

The Chairman. I guess my problem was just that that fact, coupled with GAO's finding of inconsistent test results, have clearly led to some concern on the part of the Committee.

Dr. Reed. Understandable.

The Chairman. You understand, OK. Thank you very much, Carol.

Dr. Reed. You are welcome.

[The prepared statement of Dr. Reed follows:]

[GRAPHICS NOT AVAILABLE IN TIFF FORMAT]

The Chairman. Kristopher King.

STATEMENT OF KRISTOPHER KING, CHIEF EXECUTIVE OFFICER, SURACELL, INC., MONTCLAIR, NJ

Mr. King. Mr. Chairman and members of the Committee, my name is Kristopher King and I am the chief executive officer of Suracell, Inc. We are sorry that our chief science officer, Dr. Vincent Giampapa, was unavailable to testify today.

I would like to begin by stating some key points about Suracell. Suracell is not a laboratory and does not perform genetic testing, but recommends it as one component of the program we offer to our clients. Suracell offers nutritional advice and supplements to our clients. Suracell does not make any diagnosis in relation to disease, medical conditions or prescription drugs. Suracell has a robust privacy policy and Suracell has a comprehensive informed consent process. Suracell's program is based on sound and accepted scientific research, and Suracell is committed to the ongoing education of an informed client base.

Suracell was incorporated in 2004 with the mission of providing consumers with state-of-the-art, personalized nutritional information and products that can help optimize wellness. Suracell's chief science officer is Vincent Giampapa, and based on his 10 years of practicing age management medicine, Dr. Giampapa observed that within specific types of DNA and biomarker testing and focused nutritional advice, his patients' overall health status in several areas greatly improved in a relatively short period of time. This research

was published. Suracell is guided by an advisory board comprised of specialists in genetics, microbiology, gerontology and several M.D.s.

One of the three components of Suracell's personalized nutritional program is an analysis based on information obtained from the results of a buccal cell-based gene variant test that identifies 26 gene variants that are associated with the efficiency of five metabolic processes--glycation, inflammation, methylation, oxidative stress and DNA repair. One example would be for a consumer whose profile reveals a deficient value for the SNP MTHFR which relates to homocysteine levels. This consumer would benefit from increasing their intake of folic acid.

The correlation between particular genetic variations and optimal nutritional support are based on peer-reviewed scientific literature. Suracell offers a DNA test and the laboratory that processes this test is SeraCare BioServices, based in Maryland. SeraCare uses a home brew method for processing DNA samples submitted as part of Suracell's nutritional program. Suracell understands from SeraCare that its lab has CLIA certification. SeraCare destroys specimens upon completion, so those samples cannot be used for any other purpose.

Suracell provides clients and their health care professionals with the results of the analysis provided by our program and recommends nutritional supplements based on those results. The Suracell program is designed for informed clients between the ages of 40 to 60 because the processes affecting glycation, inflammation, methylation, oxidative stress and DNA repair are typically less efficient at this age due to genetic inheritance, environmental exposures and lifestyle. But research indicates that improvements can still be made within this age range to enhance overall wellness.

The vast majority, approximately 85 percent, of Suracell's customers are in the 40 to 55 age range. Suracell does not sell to anyone under the age of 18 and requires each customer to provide informed consent. Suracell's consent process requires that customers actively consent to the testing of the samples they provide in advance of any testing procedures and, separately, that they consent to have their physician or health care practitioner receive the results of the analysis of such tests.

Suracell has a detailed published privacy policy available on our website. Suracell adheres to FTC standards for privacy and protection of consumer information. In addition, Suracell maintains compliance with the privacy and information provisions of HIPAA.

You asked us to address direct-to-consumer genetic testing. The most important aspect of this is the accuracy of the testing and the results provided. In some cases, consumers may be making life-altering decisions based on the results of these tests, particularly in the area of paternity, disease screening and prenatal screening. An expansion of the CLIA standard to include the sub-specialty of genetic testing would be a useful step in this process.

You asked us for our views on the article ``Federal Neglect: Regulation of Genetic Testing,'' in ``Issues in

Science and Technology,'' Spring 2006. Suracell agrees with the following points raised by the article. There should be a specific CLIA standard for the sub-specialty of genetic testing. There needs to be government oversight of the accuracy of tests. Suracell agrees with FTC oversight of advertising claims made by companies offering direct-to-consumer DNA testing.

Suracell strongly believes that consumers who choose to do so can benefit from knowing their genetic variance as it relates to the aforementioned metabolic processes because such knowledge enables them to make dietary and behavioral changes to improve their overall wellness. In addition, Suracell believes that in order for the benefits of new genetic knowledge and technology to be realized, the public must be assured that genetic testing is accurate.

Suracell again recommends that establishing genetic testing specialty certification within CLIA may be an effective strategy to achieving oversight of genetic testing and is supportive of this action.

Thank you.

The Chairman. Mr. King, you are testifying on behalf of Dr. Giampapa?

Mr. King. I am testifying on behalf of Suracell.

The Chairman. Suracell.

Mr. King. Dr. Giampapa, our chief science officer, would be better at explaining the science behind the program.

The Chairman. Well, he is your chief science officer?

Mr. King. Yes, sir.

The Chairman. It is my understanding he is a plastic surgeon.

Mr. King. Yes, sir.

The Chairman. How does that qualify him to do genetic testing?

Mr. King. Well, over a 10-year period, Dr. Giampapa has believed that plastic surgery focusing on the outside of the body is really deficient and doesn't focus on the total body. For over 10 years, he has worked on looking at inside-out approaches to improve wellness.

The Chairman. But my point is just simply that if he is your chief science officer and he is a plastic surgeon working in the very technical field of genetics, I guess it raises a question.

Mr. King. Well, we do have an advisory board. We have several geneticists, molecular biologists that work on a full-time or a part-time basis advising the company.

The Chairman. You would admit, though, genetics is a much more complicated field than plastic surgery?

Mr. King. Yes.

The Chairman. You have indicated that SeraCare is CLIA-certified, but you also use Genox as a laboratory and have represented to the Committee staff that you verified Genox' CLIA certification. We know that Genox is not CLIA-certified. Can you address the misrepresentation?

Mr. King. Well, there are three components to our program. We have the genetic test which is done by SeraCare. We have the assessment which is done by Genox, and we have the lifestyle questionnaire. I was unaware of the lack of CLIA certification

in the Genox laboratory.

The Chairman. So it was ignorance on your part?

Mr. King. Yes, sir.

The Chairman. You didn't know they weren't certified?

Mr. King. Yes, sir.

The Chairman. But it was represented to us by you that they were.

Mr. King. I honestly don't recall when I spoke with the GAO if I had made that claim. If you say I have, then I, you know----

The Chairman. Well, it simply goes to this whole credibility issue which leads to this hearing today. I am not trying to cast aspersions on you personally, or any of you.

Mr. King. I understand.

The Chairman. But we have a responsibility to consumers and this is just so loosy-goosy here that I am really concerned about what you are selling, what it means, the doom and gloom, the validity, the premium price that is being charged, the peddling of health advice, frankly, when there isn't the basis for it.

I am worried that we are exploiting and misleading people--this industry. I am very alarmed that consumers are being preyed upon, that this great promise of the Genome Project is being exploited in a way that is victimizing people who have no assurance of the accuracy, validity or utility of these tests.

I want to emphasize, too--and we are going to get to this--privacy and confidentiality. Who do you share it with? Why does a nutritionist follow up with the GAO investigating, wanting to sell them something based on something from a genetic home brew kit?

[The prepared statement of Mr. King follows:]

[GRAPHICS NOT AVAILABLE IN TIFF FORMAT]

Mr. Ramarathnam.

STATEMENT OF NARASIMHAN RAMARATHNAM, PRESIDENT, GENOX CORPORATION, BALTIMORE, MD

Mr. Ramarathnam. Thank you, Mr. Chairman. My name is Narasimhan Ramarathnam. I know it is pretty complicated and for the sake of convenience, people know me as Rama.

The Chairman. Dr. Rama?

Mr. Ramarathnam. Dr. Rama. That is right.

The Chairman. OK.

Mr. Ramarathnam. I am the president of Genox Corporation, a position that I have held since November 1998. I understand that you have been provided with a copy of my written testimony and attachments that are to be made part of the record.

I would like to take this opportunity to describe briefly the history and mission of Genox. Genox is a small biotechnology company located in Baltimore, MD. The company was organized in October 1991 by a small group of U.S. investors, along with Dr. Richard Cutler and his son, Roy Cutler. Dr. Cutler is a well-known scientist in the field of aging. Prior to founding Genox, Dr. Cutler spent 18 years as a research

chemist at the National Institute on Aging, which is a division of NIH.

The late Dr. Hirotomo Ochi, the founder of Nikken Foods and Nikken groups of companies in Japan, was asked to invest in Genox shortly after the laboratory was established. Prior to investing in Genox, Dr. Ochi had already established the Japan Institute for the Control of Aging. We call it JaICA. Dr. Cutler served as the president of Genox from January 1995 until he resigned in November 1998.

During the past decade, Genox has served the scientific community by providing to researchers products and services for the measurement of biomarkers that would indicate oxidative stress levels. In layman's terms, oxidative stress is like a see-saw. We have damage on one side and the anti-oxidative defense forces on the other side. The moment a tilt takes place toward the damaged side, the aging process sets in, leading to the gradual loss of physiological functions normally later in life.

Genox sells this patented kit which is made by JaICA. This kit is normally sold to scientists and researchers for them to use in their laboratories. Using this kit, the researchers can measure the DNA damage biomarker 8-OHdG, 8-hydroxy deoxyguanosine. Please note that this test kit is not the so-called home test DNA kit. It should not be used by anyone at their homes. It does not measure DNA directly. One has to have special skills, and also will need special equipment to use this kit. Once again, this is not a home test kit.

Among the many institutions using this kit are OXIS Health Products, located until last year in Portland, OR; the Medical College of Wisconsin; NYU; the University of North Carolina; University of Pennsylvania; Yale; Harvard; Johns Hopkins University; VA Hospital; and U.S. EPA. We have submitted to this Special Committee a list of 28 publications by scientists who have used this product that will demonstrate the importance and utility of this kit.

Genox also offers analytic services to scientists who are involved in basic and applied research. These research scientists lack either the necessary equipment or expertise needed to measure 8-OHdG in their research samples. Through the provision of its analytic service, Genox enables more extensive research on aging than would otherwise be possible.

The major institutions whose researchers use Genox analytic services are the University of Pittsburgh, Johns Hopkins University, Colorado State University, Harvard School of Public Health, VA Hospital, and the National Institute on Aging. I have attached to my testimony copies of seven publications by scientists who have used Genox services.

Take, for example, the interesting studies of oxidative stress in individuals trained at moderate and high altitudes. The work was done by Professor Eldon Askew, of the University of Utah. This research is of great significance for our armed forces. Every time scientists like Dr. Askew call us and request our service, it makes Genox and me personally grow younger and not older.

In closing, again I want to thank the Committee for inviting me to testify and commend you, Mr. Chairman, for holding this hearing. I will be happy to answer any questions

you may have for me.
Thank you.
[The prepared statement of Mr. Ramarathnam follows:]

[GRAPHICS NOT AVAILABLE IN TIFF FORMAT]

The Chairman. Mr. Rama, your kit may be entirely valid when used by medical institutions and physicians, but what I am concerned about is your lab. It is not CLIA-certified. Is that correct?
Mr. Ramarathnam. That is correct, sir. Our mission is to be of service to the scientific community who are involved in basic and applied research related to oxidative stress and aging.
The Chairman. Why would your lab not be able to pick up synthetic urine?
Mr. Ramarathnam. We treat all samples as samples. We do not classify whether it is natural urine, whether it is synthetic urine. When we are able to report or detect the levels of 8-OHdG, we will give the value. If it is not detectable--we will report it as not detectable. We cannot identify that it is artificial or natural urine.
The Chairman. Are you aware your customers, some of whom are selling their kits and using your lab, are making representations that you have these abilities?
Mr. Ramarathnam. Our research report clearly says it should be used as a research tool in the study of oxidative stress related to aging and disease--oxidative stress related disease and aging. Genox Corporation assumes no responsibility for the use of this report for diagnosis, treatment, cure, or prevention of any health-related condition.
The Chairman. Well, you disclaim using genetic tests, but your company's website clearly markets in-house tests for assessing DNA damage.
Mr. Ramarathnam. That is correct, sir. We measure the end product of oxidative DNA damage. We do not measure DNA by itself.
The Chairman. So you are saying that assessing DNA damage is something different than performing--is no part of a genetic test?
Mr. Ramarathnam. It is not related to genetic testing.
The Chairman. Now, I understand your lab is not just dealing with research because it is running tests on samples received straight from consumers from Suracell. Is that correct?
Mr. Ramarathnam. Our understanding was we were--I mean, Suracell would use this report only for their product development. It should not be used for treatment of any disease or curing any illness. So all these subjects or volunteers who would send their samples to us--we will test them and report back to Suracell as a research tool to help them in their product development.
The Chairman. You are receiving their samples directly from Suracell's customers? They come right to you?
Mr. Ramarathnam. Yes, sir.
The Chairman. Are you aware how they are representing your

results from those tests?
Mr. Ramarathnam. No, we are not aware of that.
The Chairman. Do you have any concern with that?
Mr. Ramarathnam. Yes, we do.
The Chairman. I think you should. That is why you are here today.
Mr. Ramarathnam. Thank you, sir.
The Chairman. We thank you for being here today.
Howard Coleman.

STATEMENT OF HOWARD COLEMAN, FOUNDER AND CHIEF EXECUTIVE OFFICER, GENELEX CORPORATION, SEATTLE, WA

Mr. Coleman. Thank you, Senator. Thank you very much for inviting me here today. I share your concerns about the quality of the results that are produced by this industry as it very rapidly grows. I very much support the regulatory process.

Genelex is a DNA testing company that I founded with our laboratory director in 1987. We have been providing direct-to-consumer DNA testing for more than a decade, beginning with paternity testing in the mid-1990's. In 2000, we began to do pharmacogenetic DNA drug reaction testing, and then in 2002 the nutritional genetic testing.

We are a CLIA lab, and we are also accredited by the American Association of Blood Banks Parentage Testing Committee. For 5 years, we were accredited by the American Society of Crime Laboratory Directors' Laboratory Accreditation Board. I bring those accreditations up because they represent the best in quality assurance programs in the DNA field at this time.

One of the reasons that those programs were so successful and continue to be successful is because they were peer-initiated and done in a cooperative fashion. Federal, State and local government worked together with industry. The College of American Pathologists was involved, the National Institute of Standards and Technology was involved, and as a result we came out with excellent programs that are ongoing today.

I am disappointed in the GAO report based on what I heard today. I regret that we did not have the opportunity to see this report beforehand. There are a lot of points in this that could be clarified had the GAO come to us and said, ``here is what we found out and here are the conclusions that we are making'' and given us the opportunity to comment.

One of the things that I am familiar with is the dietitian they are speaking of, I am guessing, is a dietitian that we work with. She is adamantly opposed to selling supplements, and we don't sell supplements either because it is an intrinsic conflict of interest for us as the DNA tester. She certainly would not contact someone if they weren't seeking, or based on telephone calls to us and questions to us, had not expressed a need for further information. This perhaps addresses the statement that the reporting is ambiguous. We provide this extra level of support in order to help people interpret the test results and put them into action.

In general, these tests--and I want to include the pharmacogenetic testing we do are the wave of the future in terms of gaining benefit from the Human Genome Project. These

tests are in various ways on the cutting edge of science, and while some of them may not be proved to the standards required to prescribe a dangerous drug to someone, for altering your lifestyle in terms of your diet and other factors, they can be very useful.

I make that statement based on the fact that we have done this testing for hundreds of people and the feedback we get from people is that these tests help them make the behavioral and lifestyle changes they need to do to control risk factors that over a period of decades lead to major diseases.

The Chairman. Do those people take those tests from your lab at the direction of a physician?

Mr. Coleman. The nutritional genetic testing, generally not.

The Chairman. Do you think they should?

Mr. Coleman. Yes, very much so, if----

The Chairman. But they don't necessarily?

Mr. Coleman. No, sir, they do not.

The Chairman. They are being, frankly, sold these tests without the context of how to really take advantage of what you call the fruits of genetics?

Mr. Coleman. I don't think that is true, sir. That is why we work with a certified nutritional specialist. That is why the reports provide a level of detail around these individual factors.

The Chairman. So you just simply have a difference of opinion with the earlier witnesses from Johns Hopkins that, to be meaningful, genetic testing needs to be done in a more comprehensive fashion?

Mr. Coleman. I wouldn't describe that as the nature of the disagreement I have. The disagreement I have is with the conclusions that the GAO reached, and from listening to that testimony I regret that we did not have an opportunity to see this report so that we could address the specific items in this report.

The Chairman. Well, that is fair enough. I mean, you can have a difference of opinion. That is allowed in America.

Mr. Coleman. Sure.

The Chairman. As a CLIA-certified lab, do you have concern with what you have heard this morning about how loosely this enterprise is being engaged with?

Mr. Coleman. Yes, sir, I do. I support your efforts here and I think we need to have more regulation. I think that, in general, now most of the testing is done in CLIA labs and in a quality fashion. The people that I know in the industry are very conscious and aware of this, but I think that we are going to see an explosion of people coming into this field in the fairly near future and I think it is very important that there are some regulations in place to see that that is done in an orderly fashion so that people can gain the benefits of this testing, as they do now, in the most efficient and beneficial fashion.

The Chairman. Howard, you have one position and you are entitled to a difference of opinion. My struggle here is just simply that your genetic tests--if they are accurate, how do you explain the results from 14 profiles based on only two DNA samples?

Mr. Coleman. Senator Smith, I would like to see those reports and be able to go over that and understand it.

The Chairman. Well, I hope you will. I mean, this Committee is following congressional protocol. GAO is following their protocol. You ought to get into this because, frankly, if you are coming up with results from 14 profiles based on two DNA samples that are all varied, I think you ought to have some very real concern about that.

Mr. Coleman. I want to know why, exactly. I want to know why that is.

The Chairman. So you can understand why the GAO would come to their conclusion?

Mr. Coleman. Yes, I can, and I think that they should have come to us to say, here are our conclusions, what is going on here, because there may be explanations for this.

The Chairman. Well, I encourage you to stay in contact with this Committee. We would like an answer, too. I mean, to me, it is per se a problem if you have got only two DNA samples and 14 profiles that are different.

Mr. Coleman. It could be based on differences in the lifestyle questionnaire. Until I would have an opportunity to review those reports--and I would like to involve Dr. Gill-Garrison in that process--it is impossible to say.

The Chairman. Well, I think we have demonstrated why we need to get into this as a Government to provide some standards so that the public is protected and you can pursue a credible enterprise, but we don't have that right now.

Mr. Coleman. I very much welcome those efforts. If I could continue?

The Chairman. Please.

Mr. Coleman. In the more medicalized arena of the drug reaction testing, the pharmacogenetic testing that we have been doing direct to the public since 2000, this is the single greatest opportunity to improve the health care of the aging because of the huge, as the FDA describes it, adverse drug reaction problem. They describe it as a major solvable public health problem, and that is because half of the people that we test have a variation in their genetics that alter how they are able to process about half of the most commonly prescribed meds.

We are talking about several classes of heart medicines, anti-depressants, anti-psychotics, pain meds, anti-diabetics, and the list goes on. Those DNA test, particularly when combined with drug interaction software that can help interpret those results, is a very powerful solution to the adverse drug reaction problem. There is an embarrassing gap between our knowledge in that area and its application in medicine, and that is one of the reasons that we sell those tests direct to the public.

We warn people, we tell people on everything, don't change your meds without going to your doctor. But many of our people come to us who have had a history, a very long history of problems with meds, and these problems have not been addressed by their physicians or their other health care providers. We do the genetic test and this shows why they have had these problems all these years and leads them to work out a solution with their physician.

The Chairman. Should I be worried, Howard, about the privacy of your customers?

Mr. Coleman. Well, I would say that coming to a company like ours is a way for you to protect your privacy. If you go to your doctor and order one of these tests, then you don't have control of that information. That has gone into the health care records system, and HIPAA notwithstanding, I think people have concerns about the security of that information. If you come to a company such as ours, then that information will remain secure. It is your property and short of a court order, we under no circumstances would release that information to anyone.

The Chairman. But I understand in reviewing your company that your questionnaire doesn't even ask if they have medications or existing diseases to warn consumers about risk. Am I wrong on that?

Mr. Coleman. The questionnaire for the nutritional genetic test you are asking about?

The Chairman. Yes. You don't even ask if they are on medications for existing diseases.

Mr. Coleman. I look forward to the day when we have a more comprehensive program and we combine the medical aspects with the more nutritional aspects. But I think that in designing this test, Sciona has wanted to draw a very sharp line between what is medical and what is not, and I think they have been very careful not to stray into the medical arena with their test.

The Chairman. Well, I think you have just made the point that Dr. Hudson was making from Johns Hopkins. You have got to have actual and you have got to have legitimate clinical studies.

Mr. Coleman. Well, you have to have clinical studies. You can prove this stuff to death, though, and it will never get out to the public. The use of it will never be made. The fact is people find this information useful now and it does help people.

The Chairman. But it can't be very useful if you don't even ask them if they are on medication, if you don't know anything about their environment, their medical history.

Mr. Coleman. When we do the pharmacogenetic testing, we have a questionnaire that we send to people asking all the meds that they are on. We have a software that they can access in a password-protected fashion. They can put all their meds in that program and get a report that they can take to their doctor.

The Chairman. But you are going to beef up your questionnaire, though.

Mr. Coleman. Pardon?

The Chairman. You are going to beef up that questionnaire to get a more comprehensive background on somebody?

Mr. Coleman. The nutritional genetic----

The Chairman. Yes.

Mr. Coleman. I don't have control over that questionnaire, sir.

The Chairman. Who has control of that?

Mr. Coleman. Sciona does.

[The prepared statement of Mr. Coleman follows:]

[GRAPHICS NOT AVAILABLE IN TIFF FORMAT]

The Chairman. OK, back to Sciona. Ms. Gill-Garrison, your company was shut down in the United Kingdom.

Ms. Gill-Garrison. It was not shut down. We made a commercial decision to move the company to the United States in response to consumer demand. We found that people in the United States, in North America in general, were much more interested in taking a proactive role in their own health and well-being.

The Chairman. So you are still doing business with the British?

Ms. Gill-Garrison. It is still possible to obtain our test in the UK, that is correct.

The Chairman. Have your sales declined with them?

Ms. Gill-Garrison. Excuse me?

The Chairman. Have your sales in Britain declined as a result of your moving?

Ms. Gill-Garrison. Have they declined----

The Chairman. I mean, the consumer complaints and the investigation of the British government.

Ms. Gill-Garrison. We did not have consumer complaints. We were part of a campaign by an anti-genetic campaign organization, but we did not actually have consumer complaints. We have a data base of all of the actual inquiries, comments that we did obtain from consumers at that time. We are not actively marketing in the UK, so the most accurate answer to your question is, yes, sales have declined. We do not have an active marketing presence in the United Kingdom.

The Chairman. You disclaim testing for predisposition for disease, is that correct?

Ms. Gill-Garrison. That is correct.

The Chairman. But the test results tell consumers that they have an increased risk of developing type 2 diabetes, high blood pressure and heart disease.

Ms. Gill-Garrison. We actually have supplied a copy of the test to the group assembled here so that you can see the language that we do produce. We stop where the science stops. So there are very clear gene-diet interactions that focus on particular variations that are related to elevated homocysteine levels, for instance, elevated cholesterol levels. That is where our information particularly related to the genetic variations and the dietary interventions that we recommend is focused.

The Chairman. I hope you can understand why I am having a problem because I understand you disclaim testing for predisposition for disease. I have got somebody's report right here from your company and you are saying right here, ``You may be at an increased risk of developing type 2 diabetes, high blood pressure and heart disease.'' That tells me that it is a pretty scary diagnosis.

Ms. Gill-Garrison. Indeed. I would like to see the actual part of the report that that came from and I would also like to have an opportunity to address the finding of the GAO so that we can clarify that. The 14 different results that were found are not surprising to me because there were 14 different lifestyle questionnaires.

If you look through the report example that you have there, you will see that we provide personalized information to the individual based on their questionnaire results, and this is a way of telling people how they are doing in particular nutrition areas. There is quite a lot of research that has been done that demonstrates that consumers really don't have a good feeling for their actual nutrient intake, and so our lifestyle questionnaire is designed to give them feedback on what their vitamin B intake is, for instance, and then we set goals which are based on the genetics. Also, as you go through the report, you will find sections that describe the activity of the different genes, the biomarkers such as cholesterol levels, homocysteine levels that can be affected by these variations.

The Chairman. Well, now Mr. Coleman is saying that your questionnaire doesn't even ask if your people are on medication.

Ms. Gill-Garrison. We do on the report recommend that anyone that is on the medication or under the care of a physician seek out the advice of that physician before taking on any of the information that we provide in these reports.

The Chairman. But you don't ask them what their medications are?

Ms. Gill-Garrison. Not at this time.

The Chairman. Would it be a good idea?

Ms. Gill-Garrison. That is an interesting question. It is something that we are exploring with our ethics advisers at this point.

The Chairman. Just last week, the NIH issued a statement about genetic testing for type 2 diabetes and they say, ``While the genetic variant does predict a greater risk of developing type 2 diabetes, the researchers are not recommending routine genetic testing for it. We don't currently have evidence that such a test would mean better outcomes for patients or that it would be cost-effective.''

I guess in light of that, I wonder, is your company going to discontinue offering type 2 diabetes testing.

Ms. Gill-Garrison. We don't offer type 2 diabetes testing. We look at particular genetic variants that are related to insulin sensitivity, and I think that what you can find in the scientific literature is some discordance in what is an agreeable end point for a person's health care. Do we think that monitoring cholesterol levels, keeping cholesterol levels low, is an adequate end point, or do we have to wait to see whether or not they go on to develop full-blown heart disease, full-blown cancer, before we can intervene with nutritional advice and information?

The Chairman. Thank you all for coming. This may not have been pleasant, but I think it is very, very important that we not exploit and mislead people. There is a lot of doom and gloom that comes with the findings that come out of your companies and your labs. I don't want consumers preyed upon in such a manner. I don't want costly, potentially harmful supplements to be sold to people without a full medical involvement as it relates to genetic testing and I think we have to do a better job of protecting privacy. So we are going to lean on the Government with the next panel.

We cast no personal aspersions on you. We have great

concern about this industry. We want to see the promise of the Genome Project fully realized, but this industry, I fear, is getting ahead of that and may be doing damage to customers in a way that will set us back. I don't think you want that, I don't want that, and the American people deserve better than that. So with that, we will thank you and dismiss this panel and call up our third.

On our final panel, we will hear from Thomas Hamilton, who is the director of the Survey and Certification Group at the Centers for Medicare and Medicaid Services, and Dr. Steve Gutman, director of the Office of In Vitro Diagnostic Devices at the Food and Drug Administration.

Gentlemen, to be consistent with the other panels, would you stand and be sworn?

Do you promise that the testimony you are about to give will be the truth, the whole truth and nothing but the truth, so help you God?

Dr. Gutman. I do.

Mr. Hamilton. I do.

The Chairman. Thank you.

Steve, why don't we start with you?

STATEMENT OF STEVEN R. GUTMAN, M.D., DIRECTOR, OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ROCKVILLE, MD

Dr. Gutman. Good morning, Mr. Chairman and members of the Committee. I am Steve Gutman, director of the Office of In Vitro Diagnostic Device Evaluation and Safety within the Center for Devices and Radiological Health at the FDA.

The safety and quality of in vitro diagnostics, or IVDs, is of utmost importance to the agency and I appreciate the opportunity to discuss these devices and the findings of the GAO investigation. I have submitted testimony for the record. For my opening statement, I will provide a brief overview of our regulatory authority regarding IVDs.

The regulation of IVDs by FDA, like the regulation of all medical devices, is risk-based, with devices classified into different categories--class I, II or III. The FDA regulatory program is comprehensive and includes requirements for registration and listing of products for high-quality production using good manufacturing practices and for post-market reporting of adverse events. For some class I, most class II and all class III devices, FDA review is required before a new medical device can enter the marketplace.

FDA applauds the GAO for its work in investigating the important issue of genetic tests sold directly to the consumer. In the early stages of GAO's investigation, we briefed staff on the existing regulatory framework for devices generally and IVD products, in particular. As defined by law, a product is a medical device if it is intended for diagnosis of disease or other conditions, or for use in the cure, mitigation, treatment or prevention of disease. To the extent the tests GAO investigated make such claims, they are devices subject to FDA jurisdiction.

The next question we ask is what type of devices these are.

If they are test kits or systems that are intended to be used at multiple laboratories, they are subject to FDA pre-market review. If the laboratories develop the tests themselves using commercially available active ingredients, then FDA regulations require that the tests be ordered by a physician or other person authorized under State law to order such tests.

The Chairman. Dr. Gutman, after having heard today what you did, shouldn't they all be under that basis?

Dr. Gutman. Well, it would depend on the State law, actually, so I can't actually----

The Chairman. But you don't have the jurisdiction to do that?

Dr. Gutman. Not to trump State law.

The Chairman. OK.

Dr. Gutman. These tests must be performed in laboratories that are certified by CMS as high-complexity under CLIA 1988.

At this point, Mr. Chairman, we are working to determine if some tests investigated were subject or are subject to pre-market review or other regulatory requirements. We have contacted the companies involved to gather information about the tests and will consider appropriate enforcement actions.

Having reviewed the information gathered by GAO, FDA experts have a number of scientific concerns, concerns you have clearly put on the table this morning, with these testing services and the diagnostic claims that they make. FDA believes that the tests being offered are not grounded in valid scientific evidence, and we agree with GAO that they largely appear both medically unproven and meaningless.

The agency looks forward to working with Federal partners to address concerns about Internet sale of genetic tests direct to consumers. We are active participants in the evaluation of genomic applications and practice and prevention program, which is spearheaded by CDC to perform technology assessment on specific tests, including direct-to-consumer testing. We have participated broadly in outreach programs with work groups at the NIH, and most recently we have participated in two working groups recommended by the Secretary's Advisory Committee on Genetics, Health and Society to address the specific issues on the table today of direct-to-consumer sale of genetic tests.

An important work item, as you have already noticed from one of these, is a collaborative development with FTC and CDC of an advisory alerting consumers to the hazard of direct-to-consumer genetic tests. This advisory cautions consumers on the importance of using trained health care professionals or genetic counselors before obtaining or acting on these tests.

We appreciate the efforts by the Committee and the GAO to examine the tests under discussion. We are committed to working with other Federal regulatory and non-regulatory partners to address the problems identified. Thank you for this time and I am happy to answer any questions you may have.

The Chairman. Doctor, do you think that the FDA should have jurisdiction to regulate home-brew tests? I just heard you, I think, agree with the GAO that these tests are not scientifically sound. Do you think you ought to have the congressional authority, the statutory authority?

Dr. Gutman. Yes, sir, I do believe we should. I actually believe we do.

[The prepared statement of Dr. Gutman follows:]

[GRAPHICS NOT AVAILABLE IN TIFF FORMAT]

The Chairman. Mr. Hamilton.

STATEMENT OF THOMAS HAMILTON, DIRECTOR, SURVEY AND CERTIFICATION GROUP, CENTER FOR MEDICAID AND STATE OPERATIONS, CENTERS FOR MEDICARE AND MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Mr. Hamilton. Good morning, Chairman Smith. Thank you for the opportunity to come here today and discuss the manner in which CMS implements the Clinical Laboratory Improvement Amendments of 1988, otherwise known as CLIA.

CLIA established nationally uniform quality standards for all clinical laboratories and all their testing to ensure the accuracy, reliability and timeliness of patient test results, regardless of the setting in which the test was performed. Those requirements apply across the full spectrum of lab tests, including genetic tests.

Under CLIA, as Dr. Gutman explained, three categories of laboratory tests have been established--waived tests; tests of moderate complexity, including the sub-category of provider-performed microscopy; and tests of high complexity. CLIA specifies detailed quality standards for the latter two categories and most genetic tests fall into the high-complexity category.

To enroll in the CLIA program, laboratories must register by completing an application, pay fees, be surveyed if they perform tests of moderate or high complexity, and receive a CLIA certificate. Laboratories that perform moderate and/or high-complexity tests must be surveyed onsite biennially in order to maintain certification, and may choose whether they wish to be surveyed by CMS or CMS's agent or by a private CMS-approved accrediting organization. Laboratories that conduct only waived or provider-performed microscopy tests are subject to surveys only if a complaint is alleged.

The CMS survey process focuses on outcomes; that is, we focus on the test results and the actual or potential harm that may be caused to patients due to inaccurate testing. Education and enforcement are both used. An educational approach permits a surveyor to provide resources and an explanation of the applicable requirements to the laboratory. This facilitates the laboratory's ability to correct deficiencies prior to imposition of enforcement actions.

However, if the laboratory cannot or will not correct the problems within a reasonable and specified amount of time, sanctions are imposed that are commensurate with the history, seriousness and pervasiveness of the deficiencies. Fulfillment and enforcement of CLIA standards is CMS' primary focus.

When CMS finds problems during a survey, the laboratory is generally provided an opportunity to correct those problems prior to enforcement actions, unless there is actual or potential harm to patient safety or there are recurring deficiencies. Over the past 5 years, CMS has initiated

enforcement action in more than 5,000 cases. These proposed sanctions carry a clear communication: problems must be fixed promptly and effectively. I am pleased to say that in less than 8 percent of the time that we proposed such sanctions have we actually needed to implement the sanctions because of laboratory failure to take effective and timely remedial action.

I wish to emphasize that the Clinical Laboratory Improvement Amendments enacted by Congress and faithfully implemented by CMS have substantially improved the reliability and accuracy of laboratory testing in this country. The first onsite surveys of laboratories conducted right after CLIA implementation in 1992, for example, revealed that up to 35 percent of laboratories had significant quality control and quality assurance problems. Currently, less than 7 percent of the labs surveyed by CMS each year have such quality control or quality assurance problems.

More recently, the percentage of laboratories that meet our proficiency testing standards has increased from about 88 percent in 1988 to about 93 percent in 2003. We place high importance on strengthening the application of CLIA requirements for genetics testing and for all laboratory testing. To such an end, for example, in 2003 we strengthened quality control standards. In 2004, we established performance standards for State agencies. Also, in 2004 we initiated national meetings with all accrediting organizations to strengthen the national system and enter into better information-sharing agreements.

In 2005, we implemented national cytology proficiency testing for all people who examine pap smears. For the first time, more than 12,000 people took individual exams to test their individual ability to make accurate readings of pap smears. In 2006, we implemented a national electronic tracking system for all complaints and all complaint investigations received by CMS and State survey agencies.

It is important to note that the laboratories conducting genetic tests are already subject to existing CLIA regulations. Tests for genetic markers are dispersed throughout the various specialties identified in the regulations, and requirements for those tests are encompassed by the current quality standards.

In addition, we strengthened the CLIA regulations in 2003 and incorporated certain recommendations related to genetic testing that came from the Secretary's Clinical Laboratory Improvement Advisory Committee, otherwise known as CLIAC. Examples include additional confidentiality requirements, facility work flow requirements to minimize contamination, and quality control requirements for the genetic test method of polymerase chain reaction.

When problems are identified with any laboratory, including laboratories that conduct genetic tests, we take action. For example, earlier this month we issued a notice of potential revocation of the CLIA certificate for one laboratory conducting genetic tests and we are currently in the process of conducting a complaint investigation for a number of other laboratories that reportedly conduct genetic testing.

Our reconnaissance periodically identifies a few laboratories that we believe should have registered under CLIA,

but which have not done so, or laboratories that have a CLIA certificate, but have expanded their testing beyond the areas for which they are certified. In such cases, we communicate with the laboratory and subsequently take enforcement action if we do not receive a favorable and timely reply. Such enforcement action may include revocation of the laboratory's CLIA certificate, if it already has a certificate, or an injunction to cease testing if the laboratory does not have a CLIA certificate.

In conclusion, we in CMS are dedicated to ensuring the accuracy of test results from our Nation's laboratories, including those conducting genetic tests. There is no substitute for objective, trained personnel examining the quality of health care onsite. That is the purpose of the survey and certification system.

I thank the Committee and you personally, Chairman Smith, for your interest in improving clinical laboratory testing in the United States and I look forward to answering any questions you may have about our efforts.

[The prepared statement of Mr. Hamilton follows:]

[GRAPHICS NOT AVAILABLE IN TIFF FORMAT]

The Chairman. Thank you, gentlemen. No doubt, you individually and your agencies are doing much good work, but we have got a problem. I think this hearing has made that abundantly clear to me; I hope it has to you. Here we sit, 6 years after discussions about genetic testing under CLIA, but we don't have a rule in place. So I am wondering why, over the last 6 years, we don't have a stronger regulatory process for them.

Mr. Hamilton. We did promulgate additional rules in 2003 that strengthened the quality control processes and we drew upon the CLIAC committee recommendations quite heavily in doing so. We continue to evaluate the need for additional rules, but we do believe at this point that the greatest gain can be made in strengthening our application of existing rules and adopting as comprehensive an approach as possible.

Let me try to put the situation into context. It may be useful to think about this entire situation in terms of five different activities: the advertising of genetic tests, the sale of genetic tests, the testing itself, the interpretation of results, and the communication of those results to consumers. Of those five, CLIA focuses on the testing itself, and within testing, CLIA focuses not on clinical validity, not on the question of whether the test is of value to the consumer and measures the right things, but rather the analytical validity. Does the measurement process measure what it is supposed to be measuring.

The Chairman. So you don't speak at all as CMS, anyway, to ensure the accuracy, utility and safety and validity of the home genetic tests themselves?

Mr. Hamilton. CLIA speaks to the analytical validity. Are the tests done accurately and reliably? But that additional regulation for CLIA itself----

The Chairman. You evaluate the process, but their

conclusions, you don't evaluate their legitimacy?

Mr. Hamilton. There would be nothing to prevent a company from taking these and over-claiming through hyperbolic claims about effectiveness or extending the results in a consumer sales process. I think it was Dr. Hudson who emphasized the need for a fairly comprehensive approach, and that is why we are engaged with CDC and the FTC in looking at all of this because it all has to work together. Our particular job in CLIA is really to make sure that the testing itself is accurate and reliable.

The Chairman. Have you looked at any of their websites and found hyperbolic claims?

Mr. Hamilton. Indeed, and we are very concerned about that. I found hyperbolic claims. I found the kinds of statements that are so vague and apply to so many people that it might amount to no more than a genetic horoscope.

The Chairman. Do you think they have any liability for such a thing?

Mr. Hamilton. I think that is a consumer sales and protection realm of activity and I can speak only to the question of CLIA itself.

The Chairman. If they do have erroneous results, if you were in their place, you would be concerned about liability.

Mr. Hamilton. To the extent that a laboratory is performing genetic tests that are subject to CLIA and does note have a CLIA certificate, they have a liability. To the extent that they are performing tests inaccurately, then we not only have a concern, but the laboratory ought to have a real concern about those results.

The Chairman. Do you have any concerns about privacy of the people, of their customers?

Mr. Hamilton. Protecting privacy is an important part of the CLIA regulations, as well as the Privacy Act on Health Insurance Portability and Accountability Act (HIPAA). Both of those are invoked under the CLIA regulation. We have heard a number of instances in which laboratories seem to be doing testing, but do not have a CLIA certificate and have not registered for one. In our reconnaissance of those, we are following up with such laboratories and informing them of the need to make such application, and to the extent that they refuse to do so, then we follow up either by removal of any existing CLIA certificate or by an injunction to cease testing.

The Chairman. Dr. Gutman, am I accurate that the evaluation of the clinical validity of the tests is the responsibility of your agency, of the FDA?

Dr. Gutman. Well, that certainly is one of the charges in the products that we review, yes.

The Chairman. What are you doing to protect consumers from fraudulent tests?

Dr. Gutman. Well, in general, for tests that we are reviewing, we, in fact, on a test-by-test basis look at the claim and do establish both analytical and clinical validity. As you probably know, sir, for many of these tests we have currently been applying enforcement discretion and approaching these on a risk-based basis. So we have taken some action.

We are assessing what our role might be. As Dr. Hudson suggested, this is a very complex and nuanced area and as we

assess this, we would like to see regulatory controls put into place. We are very concerned that we not chill this technology, so we actively are addressing how to approach this.

The Chairman. Well, I just want to encourage stepping on the accelerator.

Dr. Gutman. OK. I appreciate that comment.

The Chairman. I think you see the promise in genetic testing. I hope you come away from this hearing with a suspicion that some damage is being done to that promise, and there may be marketing going on right now that is simply today's snake oil and we owe the American people better than that.

Thomas, specifically, are nutrigenomic tests subject to CLIA regulation?

Mr. Hamilton. It depends on exactly what they are testing and the purpose of those. I think the kinds of examples that you have brought out in today's hearing--we would say they are subject to CLIA. We look first to ask whether or not they are using specimens from the human body. Yes. Are they providing information? Yes. Are they providing information for the purpose of diagnosing or treating or preventing disease or impairment, or for the assessment of a person's health? If yes, if all those things pertain, they are subject to CLIA.

The Chairman. My understanding is all those are answered yes in the cases we have looked at.

Mr. Hamilton. That is my interpretation, yes.

The Chairman. So I would certainly encourage a biomarker assessment or a regulation such as performed by Genox be subject to CLIA regulation. If it isn't now, I really do encourage that it be included.

How can a doctor or a patient find out whether a lab or CLIA-certified?

Mr. Hamilton. They can go to our website and get information about the laboratories. I appreciate that sometimes navigating through our website is a difficult process, particularly since we just reorganized it. So that is an area that we are looking at in terms of how we can make information about laboratory status more effective.

The Chairman. Is it a concern to CMS if a lab represented itself as CLIA-certified but is not?

Mr. Hamilton. It is of great concern to us if a lab represents itself as certified.

The Chairman. Well, I would strongly encourage that the website be made easier, user-friendly, and that these kinds of representations be pursued by CMS.

Mr. Hamilton. I think one of the things that is coming out from the GAO report that we have a deeper appreciation for is some of the claims made by companies and some of the confusion that may be out there as to whether or not some of these laboratories do fall under CLIA. That is something that we can remedy, and we will be issuing additional communications to the field making it very clear that these laboratories are subject to CLIA.

The Chairman. Gentlemen, thank you for being here. Again, we appreciate your work. I did not know where this hearing was going to go when a year ago--or if we would even have a hearing--when I asked for this review. But looking at the

review, I am alarmed, and the stewardship falls to your agencies to provide a framework that keeps the Genome Project promise, protects consumers and, frankly, stops perhaps industry practices which amount to fraud.

I am not concluding that, but I am suspicious of it, and this Committee is going to continue to encourage you. After 6 years, let's get the regulatory structures in place so that the American people are protected and the promise of genetic testing is not damaged by some who may take advantage of unsuspecting American consumers.

So thank you all, and we are adjourned.

[Whereupon, at 11:54 a.m., the Committee was adjourned.]

A P P E N D I X

Prepared Statement of Senator Ken Salazar

Thank you Chairman Smith and Ranking Member Kohl for holding today's hearing.

Throughout its history, the Aging Committee has led the way in calling attention to important public policy issues impacting older Americans and has not been afraid to take on industries that prey on vulnerable seniors.

As Colorado's Attorney General, I spent considerable amount of time and energy protecting the elderly in my state from fraud and abuse. I consider the creation of the Medicaid Fraud Unit one of my proudest accomplishments.

I welcome the witnesses testifying here today. It is my hope that they can shed light on an industry that I have only recently learned existed: the Direct-to-Consumer Genetic Testing Industry. In particular, I thank Ms. Rosalynn Gill-Garrison, who is here representing Sciona Inc., headquartered in Boulder, Colorado.

Sciona has been bery cooperative throughout Aging Committee's investigation on the practices of companies currently engaged in Direct-to-Consumer Genetic Testing. I appreciate their cooperation.

While advances in the field of genetic science continue to open doors in the field of healthcare and improving the quality of life for many people, many questions about on this emerging science remain open for discussion and debate.

I know I have many questions.

For example, how are these companies marketing their products and services? What are the effects of their products on Americans who receive their ``genetic health forecasts''? And finally, how reliable is the science these companies employ?

There are certainly ground-breaking possibilities that genetic testing and diagnosis could bring to the field of healthcare, but I believe the impact on those using these products must always be of paramount concern.

Today, someone sitting at home on their couch can go to the drug store or log onto the internet and purchase a mail-in genetic test that purports to tell them whether they are genetically prone to any number of medical conditions,

including heart disease, breast cancer, and Alzheimer's.

When that person receives the results from these tests in the mail, without the counseling and interpretation of a specialized medical professional, the results of these genetic tests can be confusing, alarming, and easily misinterpreted.

I am very interested in learning more about the GAO's recent investigation on these genetic and am pleased to see that GAO representatives are on hand to answer questions about their study.

At first glance, I find GAO's conclusions very troubling. GAO claims that tests sold by the companies here today frequently mislead individuals by making claims that they are unable to substantiate.

By submitting volunteer samples to genetic testing companies, they established a disturbing scheme. After being informed that they are susceptible to a number of serious and possibly chronic diseases, companies market and sell costly supplements, medical supplies, and further tests, which are either unnecessary or based on questionable science, to vulnerable Americans.

We have provided the companies named in this study an opportunity to defend their company practices. I fully anticipate they will detail the practices they are taking to ensure that their services and the representations they make to their customers are honest and accurate.

If America's seniors are indeed being sold a bag of goods, I believe it is the responsibility of our government to regulate this industry and to protect consumers.

I look forward to hearing the testimony of today's experts from CMS and the FDA to explain what regulations and oversight are these Direct-to-Consumer genetic testing firms currently fall under. In particular, I am interested learning whether CMS and FDA believe they have the authority to regulate these firms under current law. If the answer is no, it may be the case that the members of this Committee need to work together to rectify this.

Again, I thank the Committee for holding today's hearing.

[GRAPHICS NOT AVAILABLE IN TIFF FORMAT]