

GAO

Testimony

Before the Special Committee on Aging,
U.S. Senate

For Release on Delivery
Expected at 10:00 a.m. EST
Thursday, July 27, 2006

NUTRIGENETIC TESTING

Tests Purchased from Four Web Sites Mislead Consumers

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Highlights

Highlights of [GAO-06-977T](#), testimony before the Special Committee on Aging, U.S. Senate

Why GAO Did This Study

Scientists increasingly believe that most, if not all, diseases have a genetic component. Consequently, genetic testing is becoming an integral part of health care with great potential for future test development and use. Some genetic tests are sold directly to the consumer via the Internet or retail stores, and purport to use genetic information to deliver personalized nutrition and lifestyle guidance. These tests require consumers to self-collect a sample of genetic material, usually from a cheek swab, and then forward the sample to a laboratory for analysis. Companies that market this type of test claim to provide consumers with the information needed to tailor their diet and exercise programs to address their genetically determined health risks.

GAO was asked to investigate the “legitimacy” of these claims. This testimony reflects the findings of GAO’s investigation of a nonrepresentative selection of genetic tests. Specifically, GAO purchased tests from four Web sites and created “fictitious consumers” by submitting for analysis 12 DNA samples from a female and 2 samples from an unrelated male, and describing this DNA as coming from adults of various ages, weights, and lifestyle descriptions. GAO also consulted with experts in genetics and nutrition.

www.gao.gov/cgi-bin/getrpt?GAO-06-977T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Greg Kutz at 202-512-7455 or kutzg@gao.gov.

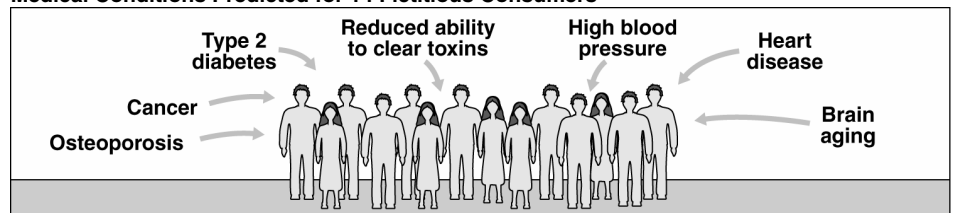
NUTRIGENETIC TESTING

Tests Purchased from Four Web Sites Mislead Consumers

What GAO Found

The results from all the tests GAO purchased mislead consumers by making predictions that are medically unproven and so ambiguous that they do not provide meaningful information to consumers. Although there are numerous disclaimers indicating that the tests are not intended to diagnose disease, all 14 results predict that the fictitious consumers are at risk for developing a range of conditions, as shown in the figure below. However, although some types of diseases, such as cystic fibrosis, can be definitively diagnosed by looking at certain genes, the experts GAO spoke with said that the medical predictions in the tests results can not be medically proven at this time.

Medical Conditions Predicted for 14 Fictitious Consumers



Source: GAO.

Even if the predictions could be medically proven, the way the results are presented renders them meaningless. For example, many people “may” be “at increased risk” for developing heart disease, so such an ambiguous statement could relate to any human that submitted DNA.

Results from the tests that GAO purchased from Web sites 1 and 4 further mislead the consumer by recommending costly dietary supplements. The results from the tests from Web site 1 suggested “personalized” supplements costing approximately \$1,200 per year. However, after examining the list of ingredients, GAO found that they were substantially the same as typical vitamins and antioxidants that can be found in any grocery store for about \$35 per year. Results from the tests from Web site 4 suggested expensive products that claimed to repair damaged DNA. However, the experts GAO spoke with stated that there is no “pill” currently available that has been proven to do so. The experts also told us that, in some circumstances, taking supplements such as those recommended may be harmful.

In addition, results from the tests that GAO purchased from Web sites 1, 2, and 3 do not provide recommendations based on a unique genetic profile as promised, but instead provide a number of common sense health recommendations. If the recommendations were truly based on genetic analysis, then the 9 fictitious consumers that GAO created for these sites using the female DNA should have received the same recommendations because their DNA came from the same source. Instead, they received a variety of different recommendations, depending on their fictitious lifestyles. For example, when GAO created lifestyle descriptions stating that the consumers smoked, they received recommendations to stop smoking. In contrast, if GAO said the consumers never smoked, they received recommendations to continue to avoid smoking.

Mr. Chairman and Members of the Committee:

Thank you for the opportunity to discuss our investigation of genetic tests that are sold directly to the consumer via the Internet, retail stores, or pharmacies. Recent advances in science have shown that the human genome is made up of about 20,000 to 25,000 genes, which are in turn made up of DNA.¹ These genes play a critical role in normal biological function, and scientists increasingly believe that most, if not all, diseases have a genetic component. Variants in these genes may increase an individual's risk for various common, complex medical disorders. Consequently, genetic testing is becoming an integral part of health care. There are now genetic tests available for close to 1,000 diseases or conditions, including hereditary breast cancer and cystic fibrosis, and there is great potential for future test development and use.

However, only about a dozen² genetic tests have been reviewed and approved by the Food and Drug Administration (FDA) to ensure their safety and effectiveness. A major reason is that the FDA regulates the safety and effectiveness of medical devices, meaning products intended to diagnose, treat, mitigate, or prevent disease.³ A genetic test is considered by the FDA to be a medical device only if it is manufactured as a freestanding "kit" and sold to a laboratory.⁴ Presently, though, most genetic tests are not sold as kits but are manufactured in-house by clinical laboratories.⁵ In these cases, the laboratory itself decides whether a test has sufficient "clinical validity" (i.e., is sufficiently effective at measuring what it purports to measure). Although all clinical laboratories must be approved under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meet general standards applicable to all laboratories, there is no genetic testing specialty under CLIA. This means that there are

¹DNA stands for deoxyribonucleic acid.

²These include tests for cystic fibrosis; factor II and factor V Leiden, which affect blood clotting; cytochrome P450 genotyping, which affects the rate at which drugs are metabolized and thus can help in determining dosage; and Her-2 neu, which is used to determine whether a woman will benefit from a breast cancer drug called Herceptin.

³See 21 U.S.C. §§ 360c(f)(1), 360e(c)(1) and 21 C.F.R. pt. 809.

⁴21 U.S.C. § 321(h).

⁵See 61 Fed. Reg. 10, 484.

no specific requirements or unique standards for laboratories that perform genetic tests.⁶

This minimal oversight makes it difficult for consumers to determine whether a genetic test provides meaningful, scientifically based information. In fact, some companies are directly marketing to consumers DNA tests that provide health-related information without the advice of a physician, including so-called “nutrigenetic” tests. Nutrigenetic tests purport to analyze a limited number of genes to provide personalized nutritional and lifestyle recommendations. These tests, which have not been approved by the FDA and are sometimes performed in laboratories that have not been approved under CLIA, range in cost from under \$100 to over \$1,000. The tests require consumers to self-collect a sample of genetic material, usually from a cheek swab, and then forward the sample to a laboratory for analysis. Demand for this type of service appears to be on the rise; one company estimates that it has sold over 35,000 nutrigenetic tests to consumers since it began selling the tests in the United States in 2003.

Although the companies that market nutrigenetic tests typically stress that the results and information they provide are not intended to diagnose or treat any disease or disorder, they do claim that their tests will provide consumers with the information needed to tailor their diet and exercise programs to address their genetically determined health risks. Because of your concerns that the companies marketing this type of test may be misleading consumers by providing inaccurate information, you requested that we investigate the “legitimacy” of these claims.

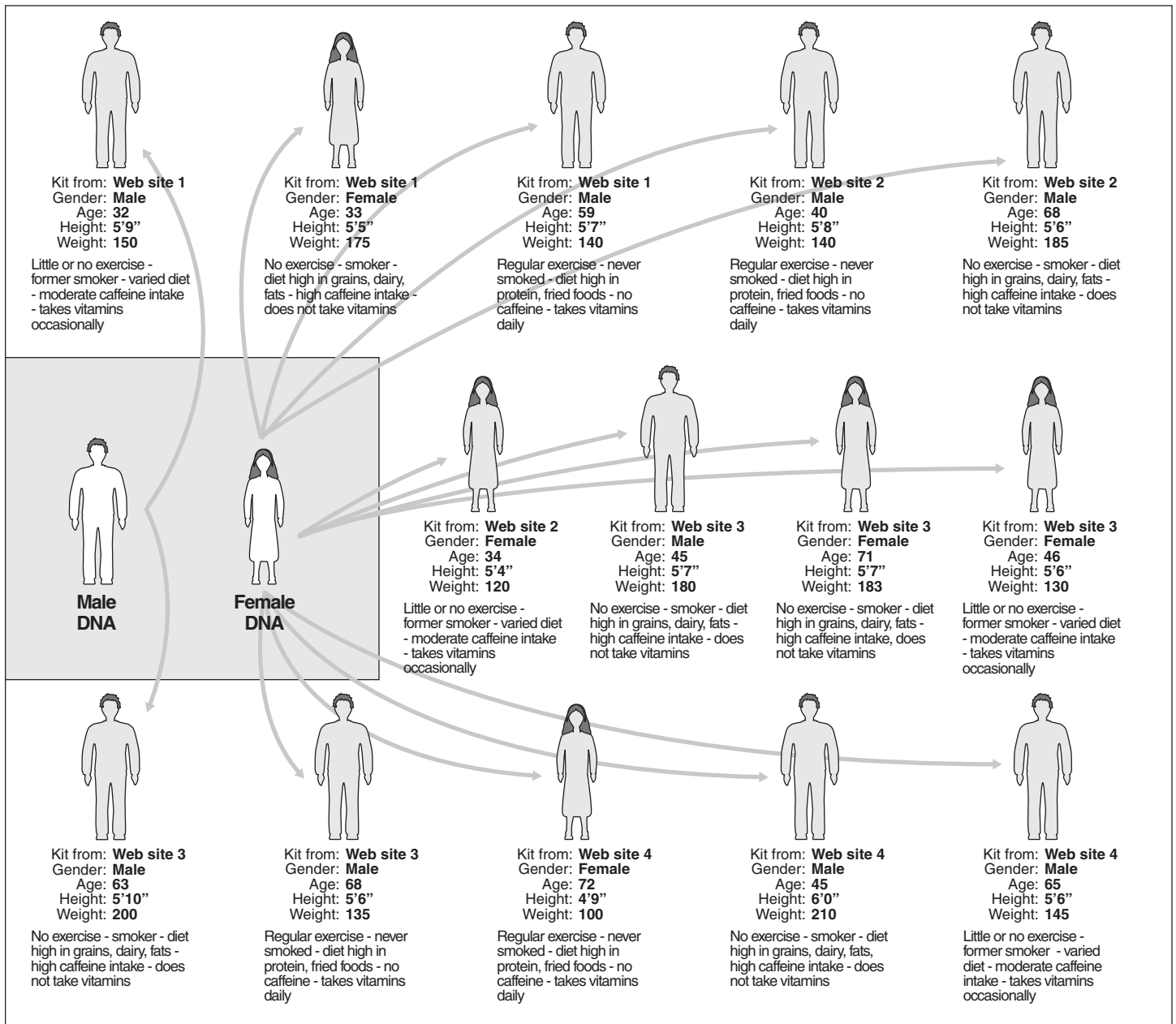
To complete our work, we investigated a nonrepresentative selection of four Web sites selling nutrigenetic tests. We chose these Web sites because they all claimed that their tests would analyze a limited number of genes, between 4 and 19, to create personalized dietary and other lifestyle-related recommendations; they also stated that their products would not test for disease or predisposition to disease. These tests ranged in price from \$89 to \$395. We purchased several similar types of tests from each site—14 in total—so that we could compare a variety of results. To create a testing scenario, we developed a series of “fictitious consumers.” To do this, we ultimately submitted 12 DNA samples taken by cheek swab from a 9-month-old female, with consent from her parents. For comparison

⁶See Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263(a).

purposes, we also submitted 2 DNA samples taken from an unrelated 48-year-old male. We had originally submitted DNA samples taken from a dog, a cat, and “blank” samples containing no DNA information, but these submissions were returned to us because they could not be processed by the laboratories.

On questionnaires that were included with each of the tests, we described the DNA from the female and the DNA from the male as coming from adult men and women of various ages, weights, and lifestyle descriptions. Each questionnaire asked for the same type of information about exercise, smoking, vitamin consumption, and intake of a variety of foods, but did not ask for information about current medical conditions or prescribed medications being taken. Figure 1 provides the basis for the 14 fictitious consumers we created.

Figure 1: DNA and Lifestyle Descriptions Used to Create 14 Fictitious Consumers



Source: GAO.

To assess whether the 14 results and related recommendations we eventually received provided any scientifically-based information, we consulted with outside experts in the fields of genetics and nutrition.

These experts have background in a variety of areas related to both fields, including genetic technology, genetic discrimination, legal and public policy issues pertaining to genetics and human research, pediatrics, prevention of communicable diseases and diseases associated with poor nutrition, and defining global nutrient requirements. We also reviewed recent studies on genetic links to specific diseases and on the efficacy of nutritional supplements. In addition, we interviewed representatives from the Web sites marketing the tests and the laboratories processing the results. We conducted our investigation from August 2005 through June 2006 in accordance with quality standards for investigations as set forth by the President's Council on Integrity and Efficiency.

Summary

The results we received from all the tests we purchased mislead the consumer by making health-related predictions that are medically unproven and so ambiguous that they do not provide meaningful information to consumers. Although the results contain statements indicating that the information provided is not intended to diagnose disease or predisposition to disease, all of the 14 results we received do contain predictions that a consumer may interpret as diagnoses. For example, the 14 results indicate that our fictitious consumers are at risk for developing a range of conditions, including osteoporosis, high blood pressure, type 2 diabetes, heart disease, a reduced ability to clear toxins, brain aging, and cancer. The 3 results we received from the tests we purchased from Web site 4 also stated that our fictitious consumers were at *below average* risk for developing certain medical conditions. Experts informed us that although some types of diseases, such as cystic fibrosis, can be definitively diagnosed by looking at specific genes, the kinds of predictions we received cannot be proven given the level of scientific evidence available today. Even if the predictions could be medically proven, the way the results are presented renders them meaningless. For example, many people "may" be "at increased risk" for developing heart disease because of a variety of factors, so such an ambiguous statement could apply to any human that submitted DNA.

Results from the tests that we purchased from Web sites 1 and 4 further mislead the consumer by recommending costly supplements that they claim are developed according to an individual's unique DNA. In reality, the pills are not unique in any way, make unproven medical claims, and are potentially harmful. For example, the 3 results we received from the tests from Web site 1 encourage the purchase of "personalized" dietary supplements, supposedly formulated based on our fictitious consumers' DNA and lifestyle profiles, and costing approximately \$1,200 per year.

However, when we examined the lists of ingredients, we found that the pills do not appear to be customized because the 3 fictitious consumers we created for this Web site received recommendations to purchase the same product, despite the fact that there were 2 different DNA donors and each had a different lifestyle profile. Moreover, experts confirmed that these supplements are substantially the same as typical multivitamins that can be found in any grocery store for about \$35 per year. In addition, the 3 results we received from the tests we purchased from Web site 4 claimed that for over \$1,880 per year, its “unique” and “personalized” products could repair damaged DNA. The experts we spoke with stated that there is no “pill” currently available that has been proven to do so. Again, these supplements do not appear to be personalized because the 3 fictitious consumers we created for this site received the same recommendation. Finally, the experts we spoke with told us that in some circumstances, taking supplements such as those that were recommended to us can be harmful. For example, taking levels of some vitamins and nutrients that exceed the recommended daily allowance may promote cancers and chronic diseases.

Furthermore, results from the tests that we purchased from Web sites 1, 2, and 3 do not provide dietary and lifestyle recommendations based on a unique genetic profile as promised. Instead, the recommendations we received simply provide generally accepted health advice directly linked to information we submitted via the questionnaires included with the tests. If the recommendations were truly based on a consumer’s unique genetic profile, then the 9 fictitious consumers that we created for Web sites 1, 2, and 3 using the female DNA should have received the same recommendations. Instead, these 9 consumers received a variety of different recommendations, depending on the fictitious lifestyles we provided for them. For example, if we said the consumers smoked, we received recommendations to stop smoking. In contrast, if we said that the consumers never smoked, we received recommendations to continue to avoid smoking. These results lead us to conclude that we could have invented any type of lifestyle description for the DNA we submitted and the recommendations would simply echo this information. Although these recommendations may be beneficial to consumers in that they constitute common sense health and dietary guidance, DNA analysis is not needed to generate this advice.

During the course of our investigation, we found other information that raises concerns for consumers purchasing these tests. For example, we discovered that Web sites 1, 2, and 3 were in fact selling the same genetic test developed by the same company, and that this company was

pressured by consumer groups in the United Kingdom to stop selling the test in that country. The company now sells the same type of test in the United States. In addition, we found evidence suggesting a lack of quality control by the laboratory actually conducting the DNA analysis for Web sites 1, 2, and 3. For example, even though all of the genetic information contained in the test results based on a single source should be identical, we received disparate results for a sample from the same source from the tests we purchased from Web site 1. We also found that a laboratory used by Web site 4 is not approved under CLIA.

Results Contain Health-related Predictions That Are Both Medically Unproven and Meaningless

Although there are numerous disclaimers indicating that the tests we purchased do not diagnose disease, the 14 results we received predicted that our fictitious consumers were at risk of developing a myriad of medical conditions. These predictions were similar for all of our fictitious consumers, no matter which DNA or lifestyle description we used. Results from the tests we purchased from Web site 4 also stated that our fictitious consumers were at *below average* risk for developing certain diseases. However, after consulting with outside experts, we determined that these predictions cannot be medically proven at this time. Even if the predictions could be medically proven, the results use ambiguous language to describe the supposed health risks, rendering them meaningless.

Claims That Test Results Will Not Diagnose Disease

As shown in table 1, the results we received from the tests we purchased from all four Web sites contain statements indicating that the information they provide is not intended to diagnose disease or predisposition to disease. The results also contain language stressing that the tests do not screen for genetic disorders and advising consumers to consult with a physician if they feel that they might be ill.

Table 1: Claims That Test Results Are Not Intended to Diagnose Disease

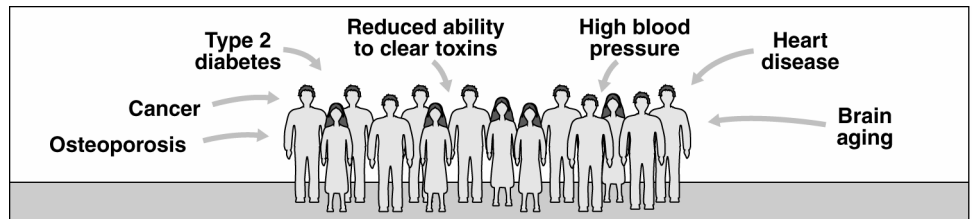
Tests purchased from	Selected disclaimers
Web site 1	[This is] not a genetic test for disease or predisposition to disease, nor does it determine a medical condition. If you think you may be ill, consult your doctor.
Web site 2	Please note that this screening is not a test for inherited disorders.
Web site 3	[This is] not a genetic test for disease or predisposition to disease, nor does it determine a medical condition. If you think you may be ill, consult your doctor.
Web site 4	[Our] products are not intended to diagnose or treat any disease or disorder; only your doctor can do so.

Source: GAO.

Predictions of Medical Conditions Received

Despite these statements, the results we received from the tests we purchased from all four Web sites do contain medical predictions that a consumer may interpret as diagnoses. The overriding impression from all the results is that the 14 fictitious consumers we created are at risk for developing a variety of medical conditions, as shown in figure 2.

Figure 2: Medical Conditions Predicted for 14 Fictitious Consumers



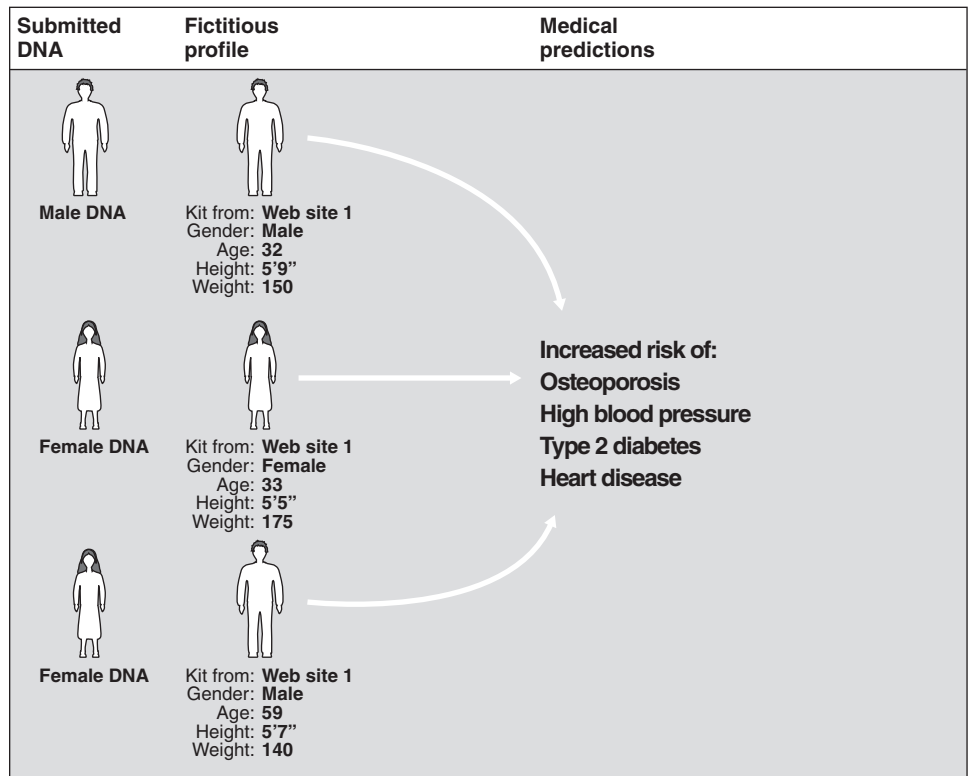
Source: GAO.

Furthermore, the results from the tests we purchased from Web site 4 even suggested that our fictitious consumers with the female DNA were at *below average* risk for developing certain conditions. As comparison, the 2 results we received from Web sites 1 and 3 for the fictitious consumers with the male DNA contained similar predictions, despite having different DNA variants from the female sample. Specific predictions from each test are discussed in further detail below.

With regard to the tests we purchased from Web site 1, the 3 results we received stated that the DNA sample from the female displayed an “increased risk of reduced calcium and Vitamin D absorption,” meaning

that she “may be at increased risk of developing osteoporosis.” Results from the same tests contained similar predictions with regard to risks for developing high blood pressure, type 2 diabetes, and heart disease. The DNA sample from the male that we submitted for this test showed the exact same risks, despite having different DNA variants from the female, as shown in figure 3.

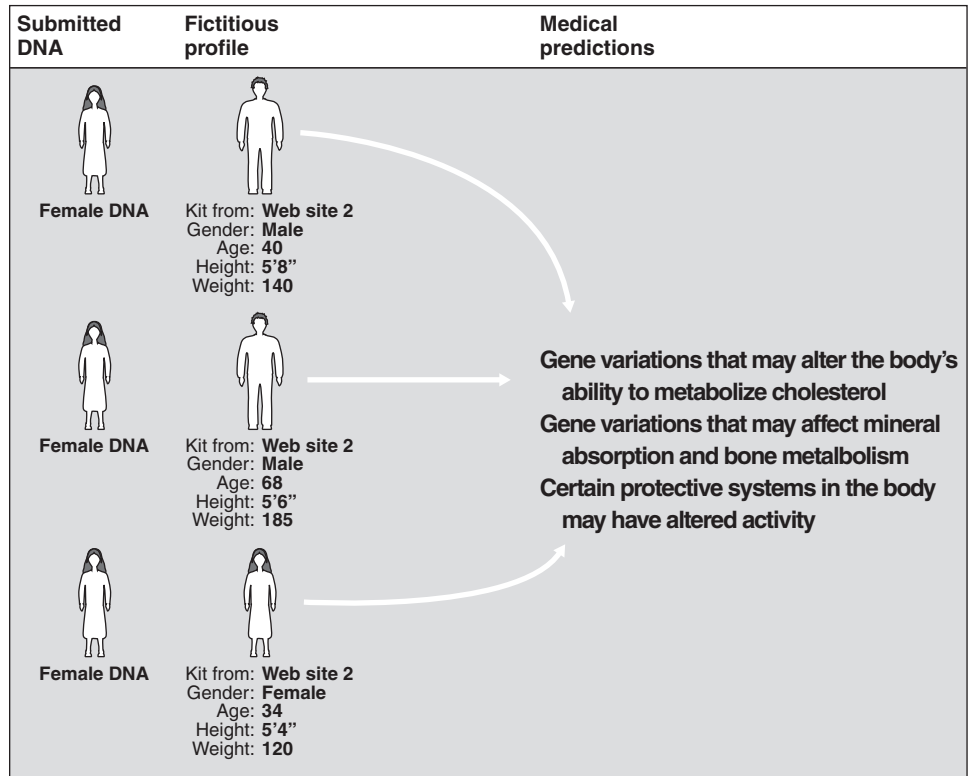
Figure 3: Predictions Received from the Tests Purchased from Web Site 1



Source: GAO.

As shown in figure 4, the 3 results from the tests we purchased from Web site 2 stated that the DNA sample from the female showed “gene variations that may alter the body’s ability to metabolize cholesterol” and variations that may affect “mineral absorption and bone metabolism.” These results also suggested that “certain protective systems” in the body “may have altered activity.”

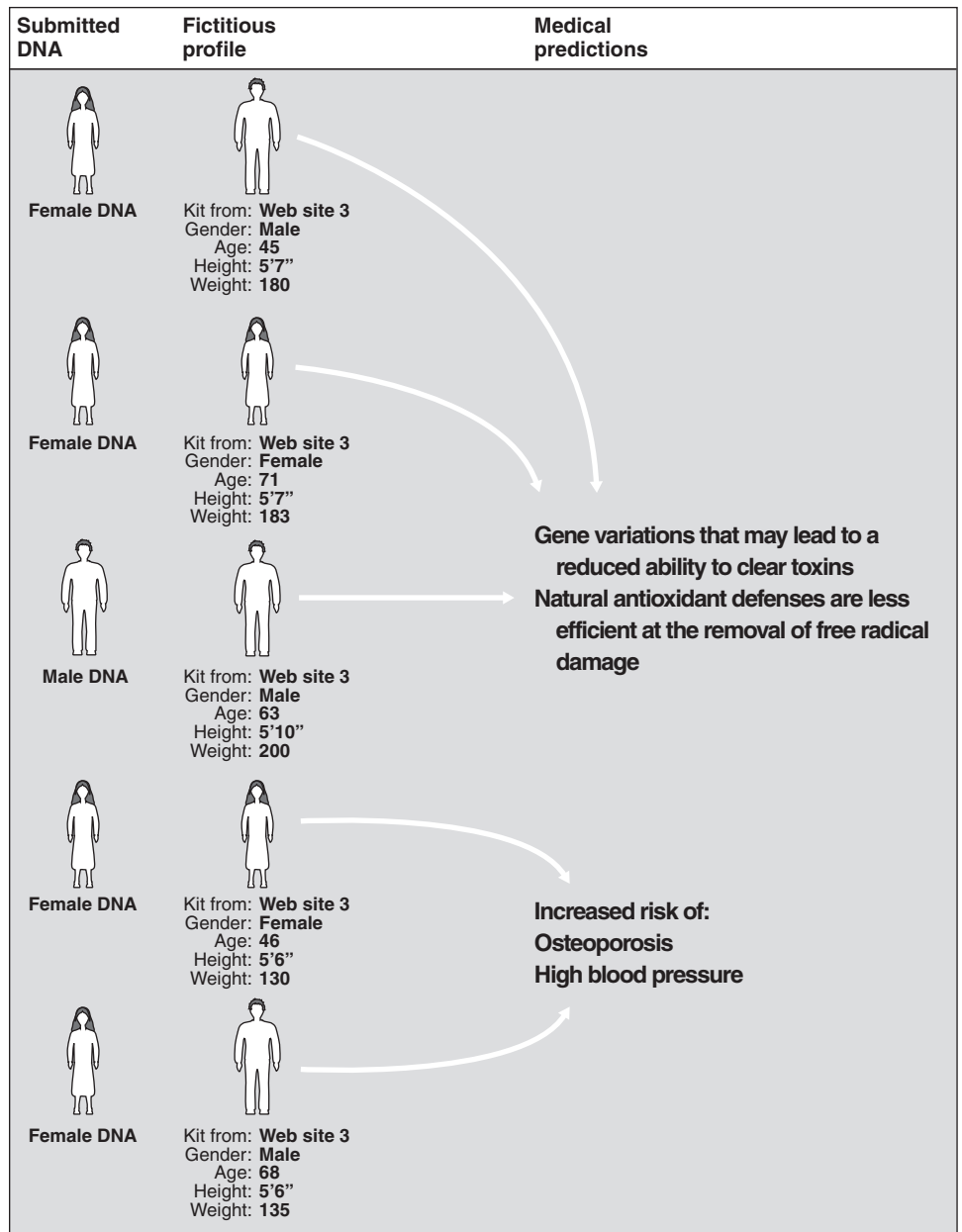
Figure 4: Predictions Received from the Tests Purchased from Web Site 2



Source: GAO.

Of the 5 tests we purchased from Web site 3, 3 focused on detoxification, 1 focused on heart health, and 1 focused on bone health. The 5 results thus showed a range of predictions, including that the DNA from the female contained gene variations that “may lead to a reduced ability to clear toxins” and that her “natural antioxidant defenses are less efficient at the removal of free radical damage.” The results also showed increased risk of high blood pressure and osteoporosis. The DNA we submitted from the male showed similar risks with regard to toxins and removal of free radicals, despite having different DNA variants from the female sample. See figure 5.

Figure 5: Predictions Received from the Tests Purchased from Web Site 3

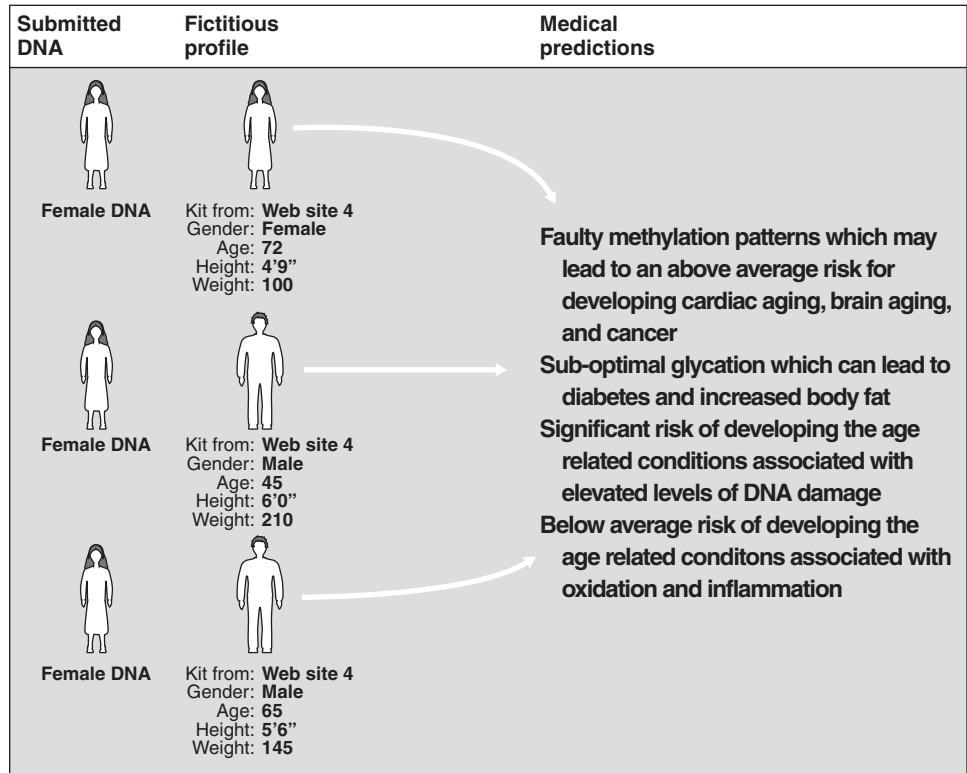


Source: GAO.

Note: Of the five tests we purchased from Web site 3, three focused on detoxification, one focused on heart health, and one focused on bone health.

As shown in figure 6, the 3 results from the tests we purchased from Web site 4 showed that the DNA sample from the female revealed “faulty methylation patterns” which may lead to “an above average risk for developing cardiac aging, brain aging, and cancer” and “sub-optimal glycation,” which can lead to diabetes and increased body fat. These same results also stated that the DNA displayed a “significant risk of developing the age related conditions associated with elevated levels of DNA damage.” Results from the tests we purchased from Web site 4 also contain predictions that the DNA sample from the female shows relatively low risk for developing some diseases. For example, all the results from these tests note that the DNA displayed a “below average risk” of developing “the age related” conditions associated with “oxidation” and “inflammation.” According to the results, oxidation can lead to diabetes, heart disorders, and Alzheimer’s disease and inflammation can lead to diabetes, heart failure, and fragile bones.

Figure 6: Predictions Received from the Tests Purchased from Web Site 4



Source: GAO.

Predictions of Medical Conditions Cannot Be Medically Proven

Despite the implication that these predictions are based on the DNA submitted, none of the results we received contained scientific support to assist the consumer in evaluating their credibility, and there is no evidence to suggest that the tests have been evaluated by independent experts. Furthermore, the genetic experts we spoke with informed us that even though it is possible to make a definitive diagnosis of disease by looking at certain genes, none of the predictions contained in any of the results we received can be medically proven at this time. According to the experts, cystic fibrosis and Huntington's disease are examples of illnesses that can be diagnosed based on an analysis of only one gene.⁷ In contrast, the diseases and conditions identified in the test results we received involve complex bodily processes. According to the experts we spoke with, although genes are known to be associated with these processes, scientists have very limited understanding about the functional significance of any particular gene, how it interacts with other genes, and the role of environmental factors in causing disease.

With regard to the specific predictions of heart disease, diabetes, osteoporosis, cancer, altered ability to metabolize cholesterol, and reduced ability to clear toxins, the experts informed us that research proving a genetic connection to the development of these conditions is at a very early stage and there are many issues yet to be resolved.

In addition, the experts we spoke with also stated that the types of tests we purchased cannot be used to confirm that an individual has a reduced risk of developing these types of diseases. Therefore, the claims that a person may be at "below average risk" of developing certain "age related conditions" based on the analysis of a few genetic variants is misleading. There could be other genetic variants not tested for that confer risk or other environmental factors not assessed.

Medical Predictions Are Also Meaningless

Even if the predictions could be medically proven, the way the results are presented—using ambiguous language—renders them meaningless. For example, it is unclear what is meant by a "damaged" gene. According to the experts we spoke with, although a specific gene can be "damaged" in that it contains a variation that causes a loss of function or impaired

⁷Cystic fibrosis is an incurable disease that causes mucus to build up in the body. People who have cystic fibrosis can have serious breathing problems and lung disease. Huntington's disease is a rare condition that causes parts of the brain to break down, or degenerate, causing rapid, jerky movements and dementia.

function, the results do not clearly explain what this means. The experts also told us that informing someone that they may be at increased risk for heart disease or that they have “high levels of DNA damage,” “faulty methylation patterns,” or “altered activity” in certain genes are all statements that are so ambiguous as to be meaningless. In fact, these types of predictions could apply to any human that submitted DNA. For example, according to the experts, many people “may” be “at increased risk” for developing heart disease because of known and unknown genetic risk factors; environmental and behavioral risk factors such as obesity, smoking, and high cholesterol; and the interaction between these genetic, environmental, and behavioral factors.

Results Encourage the Purchase of Supplements That Are Overpriced, Make Unproven Medical Claims, and May Even Be Harmful

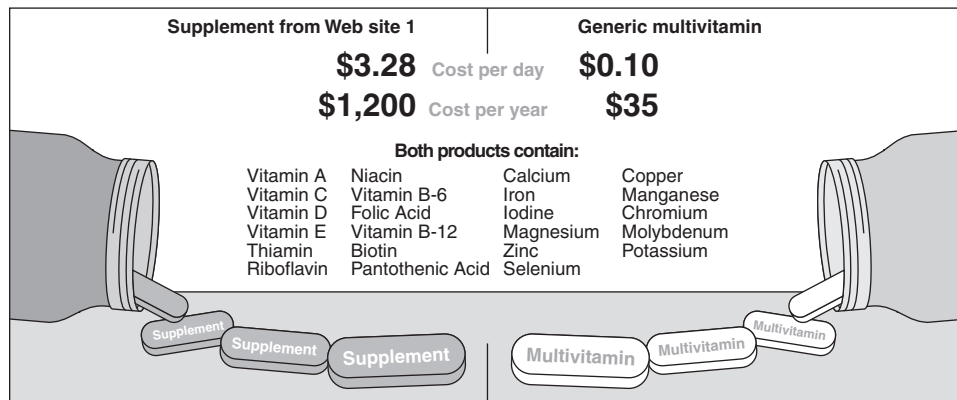
Results from the tests that we purchased from Web sites 1 and 4 further mislead the consumer by recommending expensive supplements. The 3 results we received from the tests we purchased from Web site 1 recommend a supplement that is supposedly based on an individual’s unique DNA; in reality, the supplements are not unique and are simply a grossly overpriced version of a typical multivitamin. The 3 results we received from the tests we purchased from Web site 4 similarly recommend expensive supplements that are supposedly unique to the consumer; these results also contain medical claims about the supplements that cannot be proven at this time. Finally, the experts we consulted informed us that, in some instances, taking certain supplements may be harmful.

Supplements Recommended by the Tests Purchased from Web Site 1

The results from the tests we purchased from Web site 1 recommended a 90-day supply of a “personalized, custom” nutritional formula for \$295, or approximately \$1,200 per year. According to the product information, this formula is based on “what your genetic profile reveals as areas in your body that may need special support.” Despite this claim, when we examined the listed ingredients, we found that we were recommended the same product for all 3 of the fictitious consumers we created for this test—2 of these consumers actually had the DNA from the female, 1 had the DNA from the male, and all 3 had different lifestyle descriptions, as previously shown in figure 1. However, when we compared the contents of the supplements recommended for the 2 fictitious consumers with DNA from the female with the supplement recommended for the fictitious consumer with DNA from the male, we found that the ingredients were the same.

Moreover, the experts we spoke with confirmed that the supplements themselves are not unique; they contain vitamins that can be found in any pharmacy or grocery store. To find a comparable product, we went to a local drug store and found a generic multivitamin with the same ingredients, though with different amounts, as those in the recommended supplement. In contrast to the exorbitant price requested for the supplement, we paid just under \$10 for a 100-day supply of this multivitamin—or about \$35 per year, as shown below.

Figure 7: Comparison of Recommended Supplement from Web Site 1 with Generic Multivitamin



Source: GAO.

Although these products are not identical, the experts we spoke with said that both the supplement and the generic vitamin would probably provide the same nutritional benefits for most people. However, they also cautioned that the elevated amounts of certain vitamins in the supplement may be harmful, as discussed later in this testimony.

Supplements Recommended by the Tests Purchased from Web Site 4

The results from the tests we purchased from Web site 4 recommended a “personalized” supplement “regimen” costing over \$1,880 per year. According to the results, these supplements are personalized based on the DNA submitted and lifestyle descriptions provided on the questionnaires, and they are supposed to help “compensate” for “genetic deficiencies.” Specifically, the product information accompanying the test results claims that the regimen will repair damaged DNA through the consumption of 7 pills per day, including

-
- 4 tablets per day of a supplement containing over “70 vitamins, minerals, and enzymes combined with “CAEs”, a proprietary extract from the Tropical Rainforest botanical *Uncaria tomentosa*, known as Cat’s Claw, which has been clinically shown to promote DNA repair in the body.” A 60-day supply costs \$160.
 - 1 tablet per day of a supplement designed to “enhance the body’s ability to repair damaged DNA.” A 60-day supply costs \$50.
 - 1 tablet per day of a supplement to control blood sugar and body fat. A 60-day supply costs \$50.
 - 1 tablet per day of a supplement designed to manage the process “whereby certain genes are activated and deactivated.” A 60-day supply costs \$50.

As with the other products we were recommended, these supplements are not unique to the consumer. Although the 3 fictitious consumers we created for this site in reality all had the female DNA, they all had varying lifestyle descriptions, as previously shown in figure 1. However, we received the same product recommendation for all 3 consumers. For example, our fictitious 72-year-old female nonsmoker with a diet high in protein was recommended the same supplement regimen as our fictitious 45-year-old male smoker with a diet high in fats, which seems illogical given that the supplements are supposedly developed based in part on the submitted lifestyle information.

Furthermore, although the regimen touts “Cat’s Claw” as being the ingredient primarily responsible for DNA repair, the experts we spoke with told us that these claims are not medically proven at this time. According to the experts, Cat’s Claw is a plant whose pharmacological properties are being studied for a wide variety of biological effects, but the experts were aware of no reports in peer-reviewed scientific literature that have demonstrated the ability of Cat’s Claw to repair DNA. Furthermore, although there is some research indicating that taking antioxidants may help with DNA repair, no pill has yet been proven to repair damaged DNA. In fact, manufacturers of supplements are prohibited from claiming that their products can treat, cure, or prevent disease; products that make these claims are considered drugs and must be approved by the FDA before they can be sold. The FDA has already sent Warning Letters to several dietary supplement manufacturers who explicitly claimed that Cat’s Claw could help treat cancer and arthritis. However, we do not know whether the FDA would consider a claim of “DNA repair” to render Cat’s Claw an unapproved drug.

Nutritional Supplements May Also Be Harmful

Regarding safety, the nutritionists we spoke with said that it is possible that improper use of dietary supplements can be harmful. For example, the nutritionists said that taking levels of some vitamins and nutrients that far exceed the recommended daily allowance⁸ may promote cancers and chronic diseases. A recent statement issued by the National Institutes of Health⁹ also notes that taking more than the recommended daily intake of certain vitamins and minerals may cause adverse health effects. For example, smokers who consume excessive amounts of beta-carotene may be at increased risk for developing lung cancer, while consumption of excessive amounts of vitamin D and calcium may increase the risk of kidney stones. Furthermore, we were told that all nutrients or “food components” can be toxic if provided in sufficient quantities, but the susceptibility to toxicity varies among the population. For example, there is evidence that some people may be at risk because of excessive intakes of vitamin E, folic acid, calcium, or selenium.

When we asked the nutritionists about the safety of specific ingredients in the supplements recommended for our fictitious consumers, they generally believed that the supplements were comparable to typical multivitamins, as previously stated. However, they also expressed a variety of concerns. For example, one of the nutritionists we consulted characterized the levels of vitamin B-6 in both products as “disturbing.” Another felt that the levels of Vitamin A in both were “high,” and that the supplements from Web site 1 contained excessive amounts of iron, because iron stays in the blood and could become toxic. Other experts told us that the supplements could be harmful if taken in combination with certain medications. For example, Cat’s Claw may have an adverse interaction with a medication prescribed for people who are at increased risk for forming blood clots, and individuals taking this medication are advised to avoid all supplements unless a physician approves.

⁸See <http://dietary-supplements.info.nih.gov> for detailed information on recommended daily allowances.

⁹National Institutes of Health, *State-of-the-science Conference Statement: Multivitamin/Mineral Supplements and Chronic Disease Prevention*, May 15–17, 2006.

Results Do Not Provide Recommendations Based on a Unique Genetic Profile

Results from the tests that we purchased from Web sites 1, 2, and 3 promise recommendations based on the consumer's unique genetic profile. However, the 11 results we received from these three sites suggest that the DNA submitted was not a factor in determining the recommendations. Rather, the results simply provide a number of common sense health recommendations based on information we submitted on the lifestyle questionnaires.

Tests Promise Unique Recommendations

Although Web sites 1, 2, and 3 acknowledge that information submitted on the questionnaires is taken into consideration when determining diet and lifestyle recommendations, the overall implication to the consumer is that the information derived from the DNA analysis is the most important factor, as shown in table 2.

Table 2: Statements Promising Recommendations Based on Consumers' Unique Genetic Information

Tests purchased from	Product Claims
Web site 1	<ul style="list-style-type: none">• "Recommendations are based on your own DNA."• By "adjusting your diet and lifestyle to your genetic profile, you can make sure that your body functions at an optimum level."
Web site 2	<ul style="list-style-type: none">• "Recommendations are based on the unique combination of your genetic makeup" because it is important to "make lifestyle choices" that match your genes.
Web site 3	<ul style="list-style-type: none">• "Recommendations are based on your own DNA."• Recommendations will "focus on gene variations, the potential of which may be offset by eating certain foods, increasing the intake of specific micronutrients, or making lifestyle changes."

Source: GAO.







Results Instead Provide Recommendations Based on Information Submitted on Questionnaires

Despite these claims, the recommendations we received are simply common sense regimens directly linked to the information we submitted on the questionnaires included with each test. For example, 9 of the 11 consumers we created for Web sites 1, 2, and 3 had the female DNA. If the recommendations were truly based on the consumer's unique genetic profile, then these 9 consumers should have received the same recommendations because their DNA came from the same source. Instead, they received a variety of different recommendations, depending on the fictitious lifestyles we provided for them. For example, when we said that

a fictitious consumer with the female DNA smoked and ate a lot of fatty foods, we received recommendations to stop smoking and eat fewer fatty foods. In contrast, when we said that another fictitious consumer with the female DNA never smoked and did not eat a lot of fatty foods, we received recommendations to continue to avoid both smoking and eating foods high in fat. Similarly, when we said that fictitious consumers with the female DNA did not eat a lot of fruits and vegetables, we received recommendations to eat more of these foods. However, if we said that the consumer had a diet rich in fruits and vegetables, we were told to continue this high level of consumption.

We received similar recommendations with regard to the 2 remaining consumers we created using the male DNA. For example, for one of the fictitious consumers with this DNA, we provided a lifestyle description stating that the consumer ate only moderate levels of leafy green vegetables, cantaloupe, and eggs—foods that are rich in antioxidants. In this case, the consumer was told to eat more foods rich in antioxidants. In contrast, we said that the other consumer with the male DNA ate a lot of antioxidant-rich foods. This time, we received recommendations to continue high consumption of these foods. Figure 8 provides further examples of the relationship between the lifestyle information we submitted on the questionnaires and the recommendations we received.

Figure 8: Lifestyle Descriptions Directly Linked to Diet and Health Recommendations

Submitted DNA	Fictitious profile	Submitted lifestyle information	Lifestyle recommendations
 Male DNA	 Kit from: Web site 1 Gender: Male Age: 32 Height: 5'9" Weight: 150	Little or no exercise Former smoker Diet low in food containing Omega-3 fatty acids and calcium Moderate caffeine intake	Increase exercise Continue to avoid smoking Increase intake of Omega-3 fatty acids Increase calcium intake Decrease caffeine consumption
 Female DNA	 Kit from: Web site 2 Gender: Male Age: 40 Height: 5'8" Weight: 140	Regular exercise Never smoked Diet high in cruciferous vegetables (broccoli, cauliflower, turnips) Diet high in fried foods	Continue to exercise Continue to avoid smoking Continue consumption of cruciferous vegetables Decrease total fat intake
 Female DNA	 Kit from: Web site 3 Gender: Female Age: 71 Height: 5'7" Weight: 183	No exercise Smoker Diet high in carbohydrates Diet high in fats	Increase exercise Stop smoking Reduce intake of refined carbohydrates Reduce saturated fats

Source: GAO.

These results lead us to conclude that we could have invented any type of lifestyle description for the DNA we submitted and the recommendations would simply echo this information. Although these recommendations may be beneficial to consumers in that they constitute common sense health and dietary guidance, DNA analysis is not needed to generate this advice.

Other Investigative Findings Raise Concerns

During the course of our investigation, we found other information that raises concerns for consumers purchasing these tests. For example, we discovered that Web sites 1, 2, and 3 were in fact selling the same genetic test developed by the same company and that this company was pressured by consumer groups in the United Kingdom to stop selling the test in that country. The company now sells the same type of test in the United States. In addition, we found evidence suggesting a lack of quality control by the

laboratory actually conducting the DNA analysis for Web sites 1, 2, and 3. For example, even though all of the genetic information contained in the test results based on a single source should be identical, we received disparate results from the tests we purchased from Web site 1. We also found that the laboratory used by Web site 4 is not approved under CLIA.

Nutrigentic Testing in the United Kingdom: The company that manufactures the tests used by Web sites 1, 2, and 3 used to sell the same type of test in the United Kingdom—consumers provided DNA samples and filled out a lifestyle questionnaire, and the company provided advice on what consumers should do to improve their health with diet and lifestyle changes. The Human Genetics Commission, the U.K.’s strategic advisory body on developments in human genetics, and GeneWatch UK, a consumer protection group, alleged that the company’s tests were misleading because no scientific evidence validated their clinical claims. Other scientists and consumer protection groups also cited numerous problems with the tests, including that the claims were exaggerated, the service should not be offered without adequate counseling, and that they provided advice which differed little from standard guidance on diet and exercise.

Eventually, the tests were subjected to assessment by a team of three experts—a clinical geneticist, a scientist leading a program of research in nutritional genomics, and the chief dietitian of a leading teaching hospital. They published the findings in a detailed report that concluded that there was no value in the genetic tests being offered. Subsequently, GeneWatch U.K. raised these concerns with major retail chains and pharmacies carrying the tests and urged them to stop selling the tests. By July 2002, the company was no longer attempting to sell their test directly to the consumer in the United Kingdom, either over the Internet or through retailers. In 2003, the company moved its operations from the United Kingdom to the United States. Despite the findings of the British experts, the company now sells the same type of test to American consumers.

Contradictory DNA Analysis: The results we received from the tests we purchased from Web site 1 appear to be contradictory and reflect inaccurate lab results. Specifically, the results we received from these tests contained a listing of the genes being analyzed and any “variations” found in those genes. When we compared the two results we received based on the DNA from the female, we found that the gene variations listed were not exactly the same: one result said that the DNA showed a variation in the “eNOS” gene, but the other result said that there was no variation in this gene. According to the experts we spoke with, because

the DNA sample was taken from the same individual, any gene variations should be identical. The experts also stated that a competent laboratory should reliably be able to detect the presence or absence of a particular gene variant. Consequently, concerns exist about whether this laboratory has basic quality control procedures in place to identify and prevent mistakes.

Lack of CLIA Approval: As noted in the introduction to our testimony, laboratories performing genetic tests for medical purposes must be approved under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). In general, CLIA regulations address personnel qualifications, quality control and assurance, recordkeeping requirements, and also require laboratories to conduct proficiency testing. All laboratory tests performed to provide information about an individual's health must be conducted by law in approved laboratories. During the course of our work, when we interviewed a representative from a laboratory conducting tests for Web site 4, we were told that this lab is not approved under CLIA.

Conclusion

The current regulatory environment provides only limited oversight to those developing and marketing new types of genetic tests. Consequently, companies that sell nutrigenetic tests like the ones we purchased may mislead consumers by promising results they cannot deliver. Further, the unproven medical predictions these companies can include in their test results may needlessly alarm consumers into thinking that they have an illness or that they need to buy a costly supplement in order to prevent an illness. Perhaps even more troubling, the test results may falsely assure consumers that they are healthy when this may not be the case.

With further advances in science, nutrigenetic tests like those we purchased may in the future be valid, allowing consumers to use DNA-based analysis to make diet and lifestyle changes that will actually prevent the development of disease. However, as demand for these new tests continues to rise, it will become increasingly important for consumers to have reliable information in order to determine which tests are accurate and useful.

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

Contact

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