United States Government Accountability Office

GAO

Testimony

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

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

DIRECT-TO-CONSUMER GENETIC TESTS

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

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

GAO-10-847T

July 22, 2010

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Highlights

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

Why GAO Did This Study

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

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

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

What GAO Found

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

Contradictory Risk Predictions for Prostate Cancer and Hypertension

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

Source: GAO.

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

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

Mr. Chairman and Members of the Subcommittee:

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

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

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

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

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

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

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

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

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

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

Table 1: Donor and Profile Information

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

Source: GAO

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

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

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

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

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

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

Test Results Are Misleading and of Little Use to Consumers

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

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

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

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

Figure 1: Selected Contradictory Risk Predictions for Donor 1

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

Source: GAO.

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

Figure 2: Selected Contradictory Risk Predictions for Donor 2

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

Source: GAO.

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

Figure 3: Selected Contradictory Risk Predictions for Donor 3

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

Source: GAO.

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

Figure 4: Selected Contradictory Risk Predictions for Donor 4

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

Source: GAO.

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

Figure 5: Selected Contradictory Risk Predictions for Donor 5

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

Source: GAO.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Donor 1 received a "clinical report" predicting that she had an average risk for developing atrial fibrillation and a "research report" stating that she was at below-average risk for the disease.

- Donor 2 received a "clinical report" stating that she was at below-average risk of developing celiac disease and a "research report" claiming that she was at above-average risk.

- Donor 4 received one "research report" claiming that was at above-average risk for obesity and another "research report" stated that he was at average risk.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Source: GAO.

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

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

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

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

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

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

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

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

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

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

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

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

Corrective Action Briefings

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

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

Contacts and Acknowledgments

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

Appendix 1: Test Results by Donor

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

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

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

Table 3: Comparison of Test Results for Donor 1

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

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

Source: GAO analysis of results from four companies.

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

Table 4: Comparison of Test Results for Donor 2

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

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

Source: GAO analysis of results from four companies.

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

Table 5: Comparison of Test Results for Donor 3

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

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

Source: GAO analysis of results from four companies.

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

Table 6: Comparison of Test Results for Donor 4

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

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

Source: GAO analysis of results from four companies.

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

Table 7: Comparison of Test Results for Donor 5

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

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

Source: GAO analysis of results from four companies.

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Ralph Dawn, Managing Director, dawnr@gao.gov, (202) 512-4400
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Washington, DC 20548

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