

STATEMENT OF CHAIRMAN GORDON H. SMITH

U.S. Senate Special Committee on Aging “At Home DNA Tests: Marketing Scam or Medical Breakthrough?” July 27, 2006

Good morning, and welcome. Thank you for attending today’s hearing, which will explore regulatory and scientific issues relating to direct-to-consumer genetic tests.

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

However, as reported just last month in the Washington Post, these home tests can shock and misinform consumers. The American College of Medical Genetics has advised the public to avoid home DNA tests, which it has called “potentially harmful,” citing the possibility of “inappropriate test utilization, misinterpretation of test results, [and] lack of necessary follow-up.” And just today, the Federal Trade Commission, in conjunction with the Food and Drug Administration and Centers for Disease Control, have released a consumer alert cautioning consumers that “some of these tests lack scientific validity, and others provide medical results that are meaningful only in the context of a full medical evaluation.”

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

I have numerous questions regarding the marketing practices of the companies selling these tests to consumers, as well as the clinical practices of the laboratories performing the tests. I also have serious concerns about the tests’ true predictive value, and what is in many instances, the lack of a health care professional’s involvement to help consumers determine the necessity of testing and the meaning of test results. I’d like some level of assurance that the tests are safe, accurate and useful, and that there are basic privacy protections in place.

The expansion of genetic testing services also raises important ethical and legal questions about how these tests should be administered and what level of protection is necessary for sensitive medical and personal information provided by consumers when

ordering these tests. I hope that through today's hearing, we find answers to these questions.

This morning we will hear from the Government Accountability Office about the results of their year long investigation into the direct-to-consumer genetic testing industry. We also will hear from industry stakeholders and the regulatory agencies charged with oversight of genetic testing.

I am deeply disturbed by GAO's finding that consumers are being misled and exploited. And I am shocked to learn how little the federal government is doing to help consumers make informed decisions about the legitimacy of these tests.

As we have several witnesses to hear from in a short timeframe, I will conclude my remarks and turn to my colleague Senator Kohl for his opening statement.