DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

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INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Steve Gutman, Director, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). I am a board certified pathologist. Before joining FDA, I had 15 years of practice experience running clinical laboratories of all sizes. For the past 14 years I have worked as an FDA regulator in the area of laboratory tests (referred to by FDA as in vitro diagnostic devices [IVDs]). As the Director of the Office of In Vitro Device Evaluation and Safety, I consider the safety and quality of IVDs to be of utmost importance and appreciate your invitation and the opportunity to discuss the findings of the General Accountability Office's (GAO) investigation of certain direct-to-consumer IVD tests.

REGULATORY OVERVIEW

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

GAO'S INVESTIGATION

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

The next question is what type of devices these are. If they are test kits or systems that are intended to be used at multiple laboratories, they are subject to FDA pre-market review. If the laboratories develop the tests themselves using commercially available active ingredients, then FDA regulations require that the tests be ordered by a physician or other person authorized under state law to order such tests, and that they be conducted in laboratories certified by the Centers for Medicare and Medicaid Services as high complexity under the Clinical Laboratory Improvement Amendments of 1988. If the test is not ordered by a physician or authorized person or the laboratories that conduct the tests are not certified as high complexity, then the tests would violate these restrictions.

MOVING FORWARD

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

appropriate enforcement actions. Having reviewed the information gathered by GAO, FDA experts have a number of scientific concerns with these testing services and the diagnostic claims that they make. FDA believes that the tests being offered are not grounded in valid scientific evidence. We agree with GAO that they largely appear both medically unproven and meaningless.

FDA looks forward to working with GAO and other federal partners to address concerns about internet sale of genetic tests directly to consumers. We are active participants in the Evaluation of Genomic Applications in Practice and Prevention program spear-headed by the Centers for Disease Control and Prevention (CDC) to perform technology assessment on specific tests, including direct-to-consumer testing. We have participated broadly in outreach programs with work groups at the National Institutes of Heath.

Most recently, we have participated in two working groups recommended by the Secretary' s Advisory Group on Genetics, Health, and Society to address the specific issues of direct–to-consumer sales of genetic tests. An important work item from one of the working groups has been the collaborative development with the Federal Trade Commission and CDC of an advisory alerting consumers to the hazards of direct–to-consumer genetic tests. This advisory cautions consumers on the importance of using trained health care professionals or genetic counselors before obtaining or acting on genetic test information.

CONCLUSION

FDA appreciates the Committee's and the GAO's efforts to examine the tests under discussion today. We are committed to working with other federal regulatory and non-regulatory partners to address the problems identified. Thank you again for the opportunity to testify today. I am happy to answer any questions you may have.