

STATEMENT OF RANKING MEMBER GORDON H. SMITH

U.S. Senate Special Committee on Aging
Roundtable Discussion
Genetic Testing Oversight
June 12, 2008

Good afternoon, and welcome. Thank you for attending today's roundtable, which will explore scientific, ethical and regulatory issues relating to genetic tests, with particular focus on direct-to-consumer, or DTC, tests.

Two years ago I presented to the Aging Committee findings from an investigation showing that consumers were being exploited and misled by purveyors of direct to consumer nutri-genetic tests. My investigation also revealed questionable clinical practices of the laboratories performing these tests – despite the fact that these labs purportedly were CLIA certified.

While that hearing focused on a particular subset of DTC tests, the concerns raised at that hearing apply across the board to genetic testing, chiefly:

- Do consumers have adequate assurances of the safety, accuracy and usefulness of genetic testing, be it DTC or physician-ordered tests;
- What protections exist for consumers' DNA, genetic test results and other sensitive information provided in the course of genetic testing, particularly in the DTC arena; and
- Does CLIA provide adequate oversight standards for genetic testing laboratories?

I have invited our panelists here today because from what I have seen, there remains much work for regulators and Congress to do to protect consumers and ensure the privacy and confidentiality of personal genetic information. CMS has abandoned plans for a CLIA genetic testing specialty. To my knowledge, the FTC has done little to pursue enforcement actions, despite clear evidence of fraud in the marketplace. And confusion abounds regarding the roles of CMS and FDA in regulating certain aspects of genetic tests, especially DTC tests.

For two years I have been sounding the alarm calling for more stringent oversight – a call that is echoed in the recent report from the Secretary's Advisory Committee on Genetics, Health and Society. And in the two years since this Committee's 2006 hearing, genetic tests have continued to proliferate. According to genetests.org, there now are available genetic tests for over 1,500 diseases. This proliferation continues to fuel concerns about the oversight of genetic testing and the protection of consumers' health data.

I am hopeful that today's panelists will address these and other issues relating to genetic testing. And since we have a lot of ground to cover in a short period of time, let's get the conversation started.