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United States Senate

SPECIAL COMMITTEE ON AGING

WASHINGTON, DC 20510-6400

(202) 224-5364

October 26, 2006

Via Facsimile 202-690-6351

Honorable Michael O. Leavitt, Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Leavitt:

I am writing to express my concern about the failure of the Centers for Medicare and Medicaid Services (CMS) to implement the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by its failure to create a genetic testing specialty and establish standards for proficiency testing.

On May 4, 2000 the Department of Health and Human Services (HHS) published a Notice of Intent in the Federal Register announcing its intent to issue a proposed rule to create a genetic testing specialty under CLIA. In April 2006, HHS placed the issuance of a proposed rule on its Semiannual Regulatory Agenda, with a target release date for a notice of proposed rulemaking in November 2006. In June 2006 the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) received testimony that a proposed rule was in clearance at CMS. However, CMS officials have now stated their intent to abandon efforts to develop tailored standards for genetic testing laboratories. Based on recent testimony presented to the Senate Special Committee on Aging, I am convinced that CMS has reached the wrong conclusion and should rapidly reconsider.

On July 27, 2006 I convened a hearing of the Senate Special Committee on Aging to present the results of a year long investigation into the direct-to-consumer genetic testing industry. The findings from this hearing make clear that genetic testing in general, and direct-to-consumer genetic tests in particular, fall within a regulatory abyss of Federal Trade Commission, Food and Drug Administration and CMS jurisdiction. Lack of enforcement and unclear direction from the agencies about their jurisdiction, a six year delay by CMS in promulgating a genetics testing specialty under CLIA and regulatory loopholes have created an environment ripe for consumer fraud and abuse. That is why I urge you to ensure that a CLIA genetic testing specialty is swiftly issued.

There is ample evidence that standards for laboratories under a genetic testing specialty could substantially increase laboratory quality and test accuracy. More importantly, in the absence of such standards, I do not believe the American public can have the confidence in genetic tests that will be necessary to usher in the age of personalized genetic medicine.

As a nation, we have invested billions of dollars in genetics research based on the promise for improved public health. With the completion of the Human Genome Project and substantial progress in all areas of genetics research, we stand on the brink of a new era in medicine. However, we will not see a return on that investment and promised improvements in human health unless we can be assured that genetic tests are of high quality. The responsibility for ensuring the quality of genetic testing laboratories rests squarely with CMS.

I urge CMS to issue a genetic testing specialty so that doctors and patients can have confidence in the quality of the genetic tests they use to make critical health decisions. To ensure the industry does not continue to operate without adequate oversight, I call upon you to ensure that a notice of proposed rulemaking is issued by January 31, 2007, with a final rule to be issued after an adequate public comment period.

I look forward to hearing from you in writing by November 30, 2006 regarding whether HHS will move forward with issuance of a genetic testing specialty, and if not, the reasons for that decision. Should you have any questions regarding this correspondence, you may contact Chris Hinkle, Senior Investigative Counsel, from my staff at (202) 224-5364.

Warmest Regards,



Gordon H. Smith
Chairman

cc:

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