

Genetics and Public Policy Center

Berman Bioethics Institute
1717 Massachusetts Ave., N.W., Suite 530
Washington D.C. 20036
202-663-5971 / Fax 202-663-5992

November 18, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore MD 21244

Dear Dr. McClellan:

On behalf of the Genetics & Public Policy Center, we are writing to share with you a White Paper addressing the need for the Centers for Medicare and Medicaid Services (CMS) to create a genetic testing specialty pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). We are concerned that the science of genetic testing has outpaced the regulations in place to ensure the quality of genetic testing laboratories. We plan to release this White Paper, along with a press statement, on Monday, November 28th.

For more than ten years, federal advisory committees have been calling upon the government to provide more oversight for genetic tests. Central to such oversight is the development of a genetic testing specialty to govern clinical laboratories that perform molecular and biochemical genetic tests. The development of such a specialty is an important part of ensuring the safety and accuracy of genetic testing by clinical laboratories and therefore is clearly mandated under CLIA.

In 2000, the Centers for Disease Control (CDC) issued a Notice of Intent containing the recommendations of a federal advisory committee regarding the development of a genetic testing specialty. In issuing the Notice of Intent, the CDC noted that, along with its potential for improving health and preventing disease, genetic testing “can also do great harm if errors occur” in test selection, test performance, test interpretation, and clinical application of test results. The Notice further noted that false positive and false negative results “can be especially troublesome when the test is being used to predict future risk of disease in an individual without any current symptoms of disease.” The Notice cited reports documenting problems in the pre-analytic, analytic, and post-analytic phases of clinical testing.

The Notice indicated that CMS would be issuing a proposed rule based on the comments received. Yet, more than five years later, nothing has been issued by the agency. During this same time period, genetic testing has grown dramatically; today, there are more than 800 genetic tests clinically available, and many more are on the horizon. Genetic tests may be the basis for profound life decisions, such as whether to undergo prophylactic mastectomy, terminate a pregnancy, or take a certain drug or certain dosage of a drug.

The absence of a specialty area for genetic testing with specifically tailored requirements for the now burgeoning genetic testing industry hampers CLIA's ability to oversee the quality of genetic testing and adequately to ensure its safety.

In the enclosed White Paper, we review the comments submitted in response to the NOI. While some within the government viewed the comments as negative, and may have therefore been reluctant to proceed, we find that there was widespread support for the creation of a genetic testing specialty, but specific concerns with regard to a few of the proposed requirements that could, in our view, be addressed in a relatively straightforward manner. Our review indicates that the creation of a genetic testing specialty is achievable if the requirements focus on key components needed to ensure quality, such as analytic and clinical validity and proficiency testing.

We urge CMS to take immediate steps to issue proposed regulations for a genetic testing specialty. We would welcome the opportunity to meet with you and to discuss this matter further in the near future.

Sincerely,



Gail Javitt, JD, MPH
Policy Analyst



Kathy Hudson, Ph.D.
Director