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LOUISE M. SLAUGHTER  
CONGRESS OF THE UNITED STATES  
28TH DISTRICT, NEW YORK

May 24, 2010

The Honorable Kathleen Sebelius  
Secretary of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Charlene Frizzera  
Acting Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Avenue, SW  
Washington, DC 20201

The Honorable Margaret Hamburg  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Secretary Sebelius, Acting Administrator Frizzera, and Commissioner Hamburg:

I appreciate your commitment to fully realize the promise of genetic testing and personalized medicine.

While the expansion of personalized medicine holds the potential to improve patient outcomes, the expansion of genetic testing will require support and oversight in order to achieve this potential. These concerns were highlighted by the news that Walgreens was planning to sell a non-Food and Drug Administration (FDA) approved genetic test in its stores. I commend the FDA for its prompt action that resulted in the removal of these potentially misleading tests. This incident, however, reminds us that enhanced oversight of genetic testing is necessary. Government oversight has not kept pace with science, and two reports by a Health and Human Services (HHS) federal advisory committee have called for more consistent genetic testing oversight.

There are currently almost 1,700 genetic tests available, and new genetic tests are being developed at a rapid pace. As genetic technologies proliferate, they are increasingly available to guide clinical treatment, and being marketed directly to consumers.

The effectiveness of genetic tests depends on their analytical validity, clinical validity, and clinical utility. Analytical validity provides information about the ability of the test to perform reliably in the laboratory. Clinical validity is a measure of how strong the association is between the genotype and the phenotype. Clinical utility measures the impact of test results on clinical care and health outcomes.

Genetic testing oversight is currently divided between several federal agencies, with the FDA and Centers for Medicare and Medicaid Services (CMS) assuming major roles. FDA regulates genetic test kits that are manufactured and sold for clinical diagnostic use. As part of its review, FDA requires manufacturers of the kits to

submit documentation supporting the clinical validity of the test to ensure it detects what it asserts it will detect in the intended patient population. However, the overwhelming majority of genetic tests are offered as laboratory developed tests over which the FDA has chosen not to exercise its authority. Consequently, while the analytical validity of genetic tests is regulated by the CMS through the Clinical Laboratory Improvement Amendments (CLIA), the clinical validity of the majority of genetic tests is not regulated. The lack of external review of the clinical validity of genetic tests has left a serious gap in oversight. This is especially troublesome with the direct-to-consumer marketing of genetic tests where a health care provider is not available to ensure the appropriate test is ordered and interpreted in the context of the consumer's complete medical and family history. Some tests may mislead consumers into believing that the results of such tests could improve their health status when in fact there is no scientific basis underlying such an assertion.

The Secretary's Advisory Committee on Genetics, Health, and Society raised similar concerns about the current oversight system of genetic testing through two reports. In January of 2009, the Secretary's Advisory Committee on Genetics, Health, and Society at HHS issued a report entitled *The Integration of Genetic Technologies Into Health Care and Public Health*. This report outlines recommendations to strengthen oversight of genetic tests including creating a national registry of genetic tests and testing facilities, as well as enhancing the oversight of genetic tests, especially those marketed directly to consumers. The report recommended "that CLIA regulations and, if necessary, CLIA's statutory authority, along with the FDA's risk-based regulatory authority and regulatory processes, should be expanded to encompass the full range of health-related genetic tests, including those offered directly to consumers. Relevant federal agencies should collaborate to develop an appropriate definition of health-related tests that the FDA and CMS could use as a basis for expanding their scope." We share the Secretary's Advisory Committee's concerns, and recommend additional and comprehensive review of the oversight system to ensure the analytical validity and clinical validity of genetic testing.

I recognize and appreciate that progress has been made in this arena since the January, 2009 report from the Secretary's Advisory Committee. In particular, we appreciate the National Institutes of Health's (NIH) creation of a voluntary national registry of genetics tests. While this is a good first step, we must go further. Given the importance of this issue as well as the increased availability of genetic testing, I encourage HHS to enhance the oversight of genetic tests through enhanced regulations and guidance documents. The Walgreens' marketing of un-reviewed genetic tests provides an example of the concerning implications of waiting to increase oversight of genetic testing.

I recommend that genetic testing oversight be enhanced by:

- Establishing a transparent and consistent approach for reviewing the analytical and clinical validity of all emerging genetic testing technologies.
- Adopting proficiency testing and quality assurance for quality management and the maintenance of process standards for laboratories performing genetic testing.
- Supporting research to determine clinical utility and to show how genetic testing affects health outcomes, whether this is overseen by NIH or the Patient-Centered Outcomes Research Institute.
- Educating and providing guidance to clinicians, laboratory personnel, and other health care professionals to ensure accurate use and interpretation of genetic tests.
- Maintaining ongoing public health surveillance to monitor the uptake and use of genetic tests and the determinants of care. We recommend establishing a mandatory registry of genetic tests that would provide important health information to the medical and consumer community about the availability of tests, their intended audience, and the evidence to support the use of their test.

- Coordinating public and private sector activities to strengthen oversight of genetic testing, including the adoption of complementary and consistent requirements for establishing analytical validity, quality assurance, clinical validity, and clinical utility.

These recommendations draw on the careful and thorough recommendations from the two reports by the Secretary's Advisory Committee on Genetics, Health, and Society. Thank you for your review and consideration of these recommendations, and I look forward to working with you on this important issue.

Sincerely yours,



Louise M. Slaughter  
MEMBER OF CONGRESS