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**OVERHAUL OF GENETIC AND OTHER ADVANCED DIAGNOSTIC TESTING
REGULATIONS NECESSARY FOR
PERSONALIZED MEDICINE, HHS SECRETARY TOLD**

A joint announcement of the Genetics & Public Policy Center and the Coalition for 21st Century Medicine

(Washington, May 5, 2009) -- To “get personalized medicine right,” Health and Human Services (HHS) Secretary Sebelius will need to “create and implement a reasonable and responsible regulatory framework” for genetic tests and other advanced medical diagnostics, a diverse coalition of more than a hundred organizations representing genetic testing laboratories, patient advocates, investors, and health policy researchers said today.

In a letter to the newly confirmed Secretary, the group noted that while accurate, reliable, and timely genetic testing offers enormous promise to help shape our healthcare system to meet the challenges of the 21st century, “poor quality testing can harm patients and waste scarce resources.” Physicians already are using genetic tests – currently available clinically for some 1,500 diseases or conditions – to diagnose disease, to predict an individual patient’s risk of future disease, and to guide decision making about further diagnostic procedures and choices among therapeutic options. “Advanced diagnostic testing is becoming the standard of care for many diseases,” the group told Sebelius.

Regulatory oversight of genetic testing needs to “strike the right balance between assuring patient safety and embracing policies that encourage the incorporation of rapidly advancing scientific methods and knowledge,” the group wrote. Moreover, “it is essential that new regulatory oversight policies be clearly stated and publicly vetted before they are implemented,” they said.

The new regulatory framework should “put patients first, be grounded in science, appropriately incentivize innovation, and be fully consistent with established statutes,”

the group counseled. Its letter outlines three goals Secretary Sebelius should adopt in crafting a framework of genetic testing oversight:

- All advanced diagnostic tests – including both test kits and genetic tests developed in-house by the laboratory, which currently are subject to different levels of regulatory scrutiny under Food and Drug Administration (FDA) policies – should be regulated using consistent risk-based standards recognizing the unique aspects of each. Scientific capabilities at HHS and FDA may need to be enhanced and strengthened to accomplish this, the group notes.
- Sebelius should establish a publicly accessible registry that includes the name of laboratory performing a specific test, the name of the laboratory or company that developed the test, and information to support claims about the how useful the test is in obtaining the correct results and improving clinical care.
- Oversight of clinical laboratory quality, currently tasked to the Centers for Medicare and Medicaid Services (CMS), should be strengthened to make sure that the information provided by genetic and other advanced diagnostic tests is accurate, reliable, and timely. FDA and CMS need to review their respective oversight roles to avoid unnecessary duplication, the letter advises.

The letter is remarkable for the breadth of its 108 signatories, according to Kathy Hudson, director of the Genetics and Public Policy Center at Johns Hopkins University, which has signed the document. “Many of us are more accustomed to being on opposite sides of the table when it comes to regulating genetic testing,” she says. “The level of consensus here truly represents a watershed moment in laying this critical foundation for personalized medicine.”

“The importance of this issue to patients is clear from the large number of patient advocacy groups who signed onto this letter,” said Sharon Terry. Terry is the chief executive officer of the Genetic Alliance and a board member of the Coalition for 21st Century Medicine, both of which signed the document.

Full text of the letter is available here:

<http://www.dnapolicy.org/resources/LtrtoSecSebeliusrePersonalizedMedicine.pdf>

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About the Genetics and Public Policy Center

The Genetics and Public Policy Center at Johns Hopkins University is a trusted source of information about, and analysis of, public policy related to human genetics. The Center is supported by The Pew Charitable Trusts, with research funding from the National Human Genome Research Institute and Eli Lilly and Company.

About the Coalition for 21st Century Medicine

The Coalition for 21st Century Medicine represents some of the world’s most innovative diagnostic technology companies, clinical laboratories, researchers, physicians, venture capitalists and patient advocacy groups – all linked by a common mission to develop advanced diagnostics that improve the quality of healthcare for patients. For more information about the Coalition for 21st Century Medicine please visit <http://www.twentyfirstcenturymedicine.org>.