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United States House of Representatives
Committee on Energy and Commerce, Subcommittee on Health

Hearing on

"21st Century Cures: Examining the Regulation of Laboratory Developed Tests"

Written testimony submitted by
Association for Molecular Pathology

September 9, 2014

Dear Chairman Pitts and Ranking Member Pallone,

Thank you for the opportunity to submit written testimony for the hearing titled, "21st Century Cures: Examining the Regulation of Laboratory Developed Tests." The Association for Molecular Pathology (AMP) is an international medical professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from the government, academic and commercial clinical laboratories, community hospitals, and the *in vitro* diagnostics industry.

AMP has been an active participant in the ongoing discussion among policymakers and other stakeholders on the oversight and regulation of laboratory developed tests (LDTs). The Association has provided public comments to the Food and Drug Administration (FDA) many times over the past ten years and in January 2014, AMP published a revised position statement on the oversight and regulation of molecular-based LDTs.[1] We encourage the Committee to review this new position statement as it considers policy on the issue. We are very pleased that you are holding a hearing on this important topic today.

The FDA's Notification to Congress to establish a framework to regulate LDTs is a very dramatic shift from the Agency's current position of enforcement discretion. It is an historic break from the traditional regulation of clinical laboratories, the basis for which has been the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and state level requirements. We believe the FDA's proposal to regulate clinical laboratories is unjustified and will be detrimental to both patients and providers. As such, the FDA should engage in a very transparent and open process of formal rulemaking, with multiple opportunities to provide public comment prior to embarking on this course. Additionally, we believe FDA's proposed framework would impose a substantial economic burden on clinical laboratories that would potentially threaten patient access to important medical services. Therefore, we strongly encourage Congress to require the agency to complete an economic impact study of the framework prior to FDA's finalizing and implementing its requirements. Upon initial review of the details in the Notification, AMP has numerous specific concerns with the proposed framework as well as many clarifying questions. The Association will continue to analyze the framework and intends to submit comments during the public comment period once the guidance document is officially noticed in the Federal Register.

In the interim, AMP appreciates the opportunity to provide this written testimony on the regulation of LDTs and offers its assistance and expertise to you, your colleagues, and your staff as you consider this issue and continue your work on the Path to 21st Century Cures.

[1] http://jmd.amjpathol.org/article/S1525-1578(13)00221-3/pdf

Laboratory Developed Procedures:

AMP members are not manufacturers, but rather health care providers who provide laboratory services to our patients. We are physicians and board-certified doctoral level scientists, who have extensive education and training in our fields. Molecular pathology professionals design tests after assessing that they will be medically useful and they do so often at the request of oncologists, pediatricians and other physicians who need the information to help guide their patient management decisions. The stringent validation process includes establishing both analytic and clinical validity. In addition, molecular pathology professionals consult with ordering physicians in determining the appropriate tests to perform, given an individual patient's clinical presentation. We then interpret the results of the testing in the context of other medical information. These factors distinguish LDTs from medical devices, such as artificial joints or *in vitro* diagnostic test kits that are sold and distributed to laboratories around the world. AMP believes that any changes in the oversight of clinical laboratories should acknowledge these differences.

To clearly distinguish LDTs from traditional medical devices, AMP proposes referring to these tests as laboratory-developed procedures (LDPs). AMP defines an LDP as a professional service that encompasses and integrates the design, development, validation, verification, and quality systems used in laboratory testing and interpretative reporting in the context of clinical care. The term LDP better represents the nature of complex laboratory testing, which is very much a medical service provided by appropriately trained and qualified professionals.

Regulation of LDPs:

For the vast majority of LDPs, AMP believes that the CLIA program at the CMS is the appropriate vehicle through which to conduct oversight. CLIA requires laboratories to establish for each test system the performance specifications for accuracy, precision, analytical sensitivity, analytical specificity, reportable range of test results, reference intervals, and other performance requirements. We believe the requirements the CLIA regulations impose on laboratory directors and mandated clinical consultants, as well as the expertise of ordering physicians, address the need to ensure the clinical validity of tests that laboratories provide. However, any perceived gaps in such regulations could be straightforwardly addressed by simply modifying these regulations. Further CMS can increase transparency in its regulatory process for the public, by updating its information technology infrastructure to make CLIA's registry of laboratories and their test offerings easily and readily available online.

Thank you again for the opportunity to provide testimony to your hearing on the regulation of LDPs. As health care professionals, patient care is our highest priority. The current regulatory framework has worked well for the vast majority of laboratory tests and has provided laboratories with the flexibility to develop new assays, adapt FDA cleared assays to specific circumstances, rapidly and continually improve and upgrade the quality of tests in response to increased medical knowledge. LDPs have made important contributions to patient care, and have played a key role in advancing diagnostics generally. The imposition of an extensive new regulatory scheme such as that proposed by FDA poses an enormous threat to future diagnostic development, and to the health and well-being of our patients.

We hope that the information provided helps inform your work and please do not hesitate to contact AMP's Executive Director, Mary Williams, at mwilliams@amp.org if we may be of assistance.