ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
9650 Rockville Pike. Bethesda, Maryland 20814
Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

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

Hearing on

"Examining the Regulation of Diagnostic Tests and Laboratory Operations"

Written testimony submitted by
Association for Molecular Pathology

November 17, 2015

Chairman Upton and Ranking Member Pallone:

Thank you for the opportunity to submit written testimony to the hearing on "Examining the Regulation of Diagnostic Tests and Laboratory Operations." We appreciate the time and effort that you, the rest of the Energy and Commerce Committee, and your staff have devoted to this important issue, and we strongly encourage the Committee to continue working with molecular pathology professionals as you consider legislation.

The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who develop, perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, clinical testing laboratories, and the in vitro diagnostics industry. It is our goal as an organization to ensure that patients have access to innovative and accurate laboratory testing procedures.

Molecular pathology professionals dedicate their careers to ensuring that patients receive the most appropriate services for their clinical conditions, and that all laboratory developed procedures (LDPs) are accurate, precise, clinically relevant, and continually monitored for quality performance. In order to answer stakeholder concerns, and in support of AMP's dedication to patient care and innovation in the field of molecular pathology, AMP's experts have prepared and shared with Congress a proposal to modernize the Clinical Laboratory Improvement Amendments (CLIA) program at the Centers for Medicare & Medicaid Services (CMS). The AMP proposal to enhance oversight over laboratory services does not slow innovation or constrain the flexibility and adaptability of LDPs. Most important, it preserves patient access to essential laboratory services provided by academic medical centers, cancer centers, hospitals and health systems, and small independent laboratories that will no longer be offered if a costly FDA-based regulatory system is imposed upon these key health care organizations and the professionals employed by them. FDA has long presented anecdotal information comprised of a short list of LDPs, insisting that the only path forward is FDA oversight. The AMP proposal enhances the current CLIA and raises standards. AMP believes that under its proposal these LDPs can be adequately assessed. Therefore, we urge the Committee to use AMP's proposal as the basis for legislation that would preserve innovative patient care by building upon the current CMS-based system for oversight of LDPs.

AMP does not believe that the Food and Drug Administration (FDA) is the appropriate agency to regulate LDPs. Our professional members provide medical services. They do not manufacture products. Manufacturing

products for sale and providing a medical service are fundamentally different activities. For this reason and others outlined below, AMP must oppose the proposed Energy and Commerce draft legislation despite the improvements that have been made to the previous draft that the Committee circulated earlier this year.

Although we appreciate the addition of clarifications related to review of modified LDPs and support the requirement that the senior management of any regulatory agency overseeing LDPs include individuals with management experience in clinical laboratory operations, the proposed legislation would not make patients safer. Rather, it would deny seriously ill patients access to necessary, innovative, and potentially lifesaving care at our nation's top academic medical centers and major cancer hospitals.

Moreover, the Committee's draft legislation would interfere with the practice of medicine, and if enacted, threatens to concentrate testing in a few large laboratories that are far removed from patients and ordering physicians, disrupting traditional healthcare teams comprised of pathologists, geneticists, oncologists, and other health care providers. Submitting LDPs for premarket approval by the FDA is financially and administratively unfeasible for most hospital laboratories. The draft legislation also shifts much of product liability from manufacturers to clinical laboratories and medical professionals. These regulatory and legal costs would force laboratories to stop offering a large extent of their services, or close down entirely, resulting in a constriction in patient access to these vital medical services.

AMP's proposal does not address in vitro diagnostic (IVD) test kits; however, we support reform of the regulation of manufactured and distributed IVDs. Current FDA regulations prevent manufacturers from readily modifying, enhancing, or otherwise improving upon commercial kits. This flawed regulatory paradigm limits the choices and options molecular pathologists and other laboratory professionals have as they strive to optimally care for their patients. Still, the provision of LDP services and the design, development, manufacture, packaging, and distribution of IVD kits remain separate and distinct activities with very different underlying medical and economic models, and must continue to be independently regulated.

Unlike manufactured, packaged, and distributed IVD test kits, LDPs are medical services throughout the design, validation, performance, ongoing monitoring, and interpretation of test results. Professional judgment is used during each of these activities, providing continual opportunities to promote test accuracy, reliability and patient safety throughout provision of the services. For an LDP, the defining measure of quality is the direct involvement of an appropriately qualified professional in every aspect of the testing service. This distinguishing feature of all LDPs is not at all incorporated into the Energy and Commerce draft legislation.

The AMP proposal contains a number of salutary features that meet stakeholder concerns. First, AMP addresses adverse event reporting in a manner consistent with the operation of a clinical laboratory rather than a manufactured IVD, utilizing realistic standards based on effects of laboratory test results on patients. Second, AMP's proposal requires that the information be publicly displayed in a searchable, standardized format to enable easy review and comparison among LDPs by treating physicians, laboratories, and patients. The draft legislation does not include a provision of this kind. Finally, in contrast to the Energy and Commerce Committee's proposed legislation, the AMP proposal maintains clinical laboratory oversight under a single agency. The Energy and Commerce legislation would create an overly complex, duplicative regulatory system for LDPs that would place an unreasonable and unmanageable burden on laboratories within academic medical centers, cancer centers, hospitals and health systems, and smaller independent laboratories. For example, the Energy and Commerce draft assigns regulation of "processing" of an LDP to FDA, while placing oversight of performance of and LDP within CLIA. However, it is not clear how processing can be consistently distinguished from performance, or which Agency's rules would govern under specific circumstances. Therefore, we again ask the Committee to use the AMP plan as the basis for any proposed legislation addressing regulation of LDPs to provide the best overall system for patient care.

As an Agency, FDA should continue in the role it knows best, ensuring that the performance characteristics of vendor supplied instruments, test kits, software, and reagents are what manufacturers claim them to be in their labeling, promotional materials, and activities. But the Agency should do so using an approach that is sufficiently flexible to accommodate continual technological developments and exponentially increasing medical and scientific knowledge in a timely manner. In this way, FDA can best contribute to patient welfare and public health, by helping molecular pathologists and other laboratory professionals provide the best care possible to our patients.

AMP has considered the desires of treating physicians and patients and AMP believes that all stakeholders have the same ultimate desired outcome: that laboratory testing procedures be high quality, accurate, and precise. AMP's proposal to enhance CLIA regulations does this while also preserving patient access to testing procedures and ensuring that patients and their treating physicians can work together to determine the best testing and treatment options for each individual. This lies at the heart of precision medicine. AMP's proposal presents a path forward for LDPs used in many contexts including responding to public health emergencies, diagnosing or determining risks of inherited diseases, monitoring disease progression, and informing treatment decisions for patients. The section focused on CLIA within the Committee's draft legislation falls short of what AMP recommends and we urge the committee to use AMP's proposal as the basis for legislation on CLIA modernization.

Thank you again for the opportunity to submit this testimony on this draft legislation. AMP looks forward to working with the Committee and federal agencies to design modernized regulations for LDPs that ensure both analytical and clinical validity as well as provide the nimbleness necessary to foster innovation and enable patient access to appropriate testing. If you have any questions or if AMP can be of further assistance, please contact Mary Williams at mwilliams@amp.org.