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

Association for Molecular Pathology Public Comments

Presented by Charles E. Hill, MD, PhD, AMP President

Clinical Laboratory Improvement Advisory Committee Meeting

Thursday, November 19, 2015

Atlanta, Georgia

Thank you for the opportunity to provide public comments today. My name is Dr. Charles Hill and I am an Associate Professor at the Emory University School of Medicine and the President of the Association for Molecular Pathology (AMP). This committee is very familiar with AMP therefore, for the sake of time, I will skip the organization's description.

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.

AMP believes that the best agency for providing oversight of laboratory developed procedures (LDPs) is CMS in the CLIA program. CLIA utilizes third party accreditors that have an extensive network of specialty subject matter experts to conduct inspections, provide proficiency testing and other activities to help CLIA achieve its mission. In order to adequately address increasingly complex testing, we believe that the CLIA regulations should be modernized. With this necessary updating, mechanisms to include an assessment of clinical validity, using third party subject matter experts, are imminently possible. In fact, AMP believes this is the best regulatory path forward, both for patient care and for the taxpayer. Earlier this year, AMP's experts prepared and shared with Congress a proposal to modernize the CLIA program at CMS. While we maintain that there is no evidence of systemic problems with laboratory testing or LDPs that would necessitate a significant increase in what is already rigorous oversight, the CLIA statute and regulations are over 20 years old. They should be updated to better fit with contemporary practice. CLIAC would be critical to this process. The AMP proposal is a streamlined, cost-effective approach that enhances transparency, ensures quality and preserves innovation.

The AMP proposal contains a number of salutary features that meet stakeholder concerns. The proposal provides assurance of quality without jeopardizing innovation or patient access to necessary care, directs CMS to stipulate a minimum level of standards for LDP analytical and clinical validity, and provides for rapid response during public health emergencies. Duplication of activities within and between agencies is avoided and states' exempt status remains unchanged. Further, 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. Lastly, 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.

AMP does not believe that the 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. Implementation of either the FDA draft guidance or the proposed split with regulation of assay development at FDA prior to introduction and regulation of post-introduction activities at CLIA will drastically disrupt patient care and the provision of professional services nationwide. Not even the largest medical centers can take on the activities and expenses of the FDA demands. Commercial reference laboratories are likely to reduce their test menus to those that promise a reasonable return on their regulatory costs. Devastating consequences will include tests that are frozen in time and patients unable to benefit from new non-invasive procedures for specimen collection.

In addition, insurance coverage and reimbursement for most molecular tests is inadequate or not available at all. For many patients, their only option for advanced care defaults to university medical centers, where mission trumps all. However, even they cannot continue to provide care in a financially unsustainable model. We foresee a reduction in services and an emergence of regulatory monopolies where testing will be available only to those with the resources to pay for it themselves. Concomitant to this will be a reduction in centers where the next generation of molecular pathology professionals can be trained.

Further, AMP is concerned about misleading recent public statements by FDA, including their testimony earlier this week at a House Energy and Commerce Subcommittee Hearing as well as their report released this week titled “The Public Health Evidence for FDA Oversight of LDTs: 20 Case Studies.” Knowledge derived from forty years of regulating boxed and shipped products under the medical device regulations cannot be directly applied to LDP professional services. We believe FDA either is intentionally downplaying or does not recognize the massive expansion that will be required to conduct pre-introduction review of many thousands of moderate and high-risk tests. Additionally, FDA’s report failed to acknowledge that some of the problems used as examples were with how test results were applied by treating physicians or with lab staff training, neither of which could have been avoided with FDA premarket review of clinical validity. We must not apply decades-old regulations to today. We must not apply regulations designed for boxed and shipped products to medical services. The best path forward is a modernized CLIA program.

We would like to thank the CDC and members of the CLIAC for providing essential scientific collaboration and guidance to the Department of Health and Human Services and I look forward to the Committee’s discussion on regulatory oversight of LDPs.