



ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
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FOR IMMEDIATE RELEASE

AMP Submits Written Testimony for Hearing on “Examining the Regulation of Diagnostic Tests and Laboratory Operations”

AMP opposes proposed House Energy and Commerce draft legislation and urges Committee to use AMP’s proposal as the basis for any legislation

Bethesda, MD, November 18, 2015

The Association for Molecular Pathology (AMP), the premier global, professional society serving molecular diagnostics professionals, yesterday submitted written testimony to the House Energy and Commerce Subcommittee on Health for their hearing on “Examining the Regulation of Diagnostic Tests and Laboratory Operations.” AMP urged the Committee to use AMP’s proposal to modernize the Clinical Laboratory Improvement Amendments (CLIA) at the Centers for Medicare & Medicaid Services (CMS) as the basis for legislation that would preserve innovative patient care by building upon the current CMS-based system for oversight of laboratory developed procedures (LDPs).

“Molecular pathologists are highly trained professionals and our professional judgment is used throughout the design, validation, performance, ongoing monitoring, and interpretation of test results. It is our mission to ensure that patients have access to innovative, accurate, reliable, and medically useful laboratory testing procedures,” said Roger D. Klein, MD, JD, AMP Professional Relations Chair. “The AMP CLIA Modernization proposal preserves patient access to essential laboratory services that would no longer be offered if a costly FDA-based regulatory system were imposed upon academic medical centers, cancer centers, hospitals and small independent laboratories,” he added.

AMP’s proposal enhances the current CLIA regulations, raises standards, and addresses stakeholder concerns by:

- Utilizing realistic standards for adverse event reporting in a manner consistent with clinical laboratory operations
- Requiring that test information be publicly displayed in a searchable, standardized format for review by physicians, laboratories and patients
- Maintaining clinical laboratory oversight under a single agency, CMS, and does not place unreasonable and unmanageable burdens on laboratories.

AMP cited various concerns with the Committee’s draft legislation including its interference with the practice of medicine and the potential of the legislation to concentrate testing to only a few laboratories that are far removed from patients and ordering physicians, potentially disrupting traditional healthcare teams. The written testimony also stated that AMP does not believe that the FDA is the appropriate agency to regulate LDPs because molecular professionals provide medical services and do not manufacture products for sale. Finally, submitting LDPs for premarket approval by the FDA is financially and administratively unfeasible for most hospital laboratories. These regulatory and legal costs would force laboratories to stop offering a large extent of their services.

The testimony is available online at: <http://bit.ly/1luKb3m>

ABOUT AMP

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 2,300+ members include individuals from academic and community medical centers, government, and industry; including pathologist and doctoral scientist laboratory directors; basic and translational scientists; technologists; and trainees. Through the efforts of its Board of Directors, Committees, Working Groups, and members, AMP is the primary resource for expertise, education, and collaboration in one of the fastest growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high quality, appropriate testing. For more information, visit www.amp.org.

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