



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

FOR IMMEDIATE RELEASE

AMP Submits Written Comments to FDA on Next Generation Sequencing Regulation, Emphasizing Need for Consistent and Proper Performance of Tests

Bethesda, MD, March 23, 2015:

The Association for Molecular Pathology (AMP), the premier global, non-profit organization serving molecular diagnostic professionals, submitted written comments on March 20 to the U.S. Food and Drug Administration (FDA) in response to the agency's request for feedback in association with its February 20, 2015 public workshop entitled, "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests." In its comments, AMP urged FDA to focus its attention on helping to ensure the performance characteristics of next generation sequencing (NGS) instruments, reagents, and related software. AMP further recommended that FDA partner with private sector organizations and experts to set standards for FDA-cleared or approved instruments, test kits, and software.

During the FDA public workshop, dozens of stakeholders, including a number of AMP members, presented important perspectives on FDA's role in regulating NGS diagnostic tests. Panel discussions and public comments advised FDA on how to develop databases that support the regulatory structure necessary to continue the advancement of innovation in precision medicine while protecting public health – a recommendation that is echoed in AMP's written comments. "While we see the value for FDA to help ensure performance consistency of NGS diagnostic tests, we stand firm that the assay design, validation, and interpretation of NGS procedures are essential medical services performed by highly qualified professionals, and that these central practices of medicine must remain outside the purview of FDA," said Andrea Ferreira-Gonzalez, PhD, Chair of AMP's NGS Working Group.

In a preliminary discussion paper released by FDA, several points of discussion were identified as needing greater evaluation before the Agency could implement proposed regulation in the area. In response, AMP's NGS Working Group has emphasized that new regulatory initiatives must utilize an approach that is sufficiently flexible to readily accommodate the continual technological developments and exponentially increasing body of medical and scientific knowledge that characterizes NGS-based diagnostic tests in a timely manner.

"As health care professionals, we find ourselves at the beginning of a revolution in medical practice, where advances in genetic and genomic technologies promise to yield enormous benefits for patients and public health," said Roger D. Klein, MD, JD, Chair, AMP Professional Relations Committee. "It is critical that FDA recognize the promise these new technologies hold for patients and health care providers, and refrain from taking actions that could impair this progress. As such, we believe that FDA can best contribute to patient care, medical advancement, and public health by ensuring that the performance characteristics of FDA-cleared or approved instruments, test kits, software, and reagents that are sold to customer laboratories are consistent with vendors' claims in their labeling, promotional materials, and sales activities."

Written comments submitted by AMP on behalf of its members can be found online at http://www.amp.org/documents/AMPNGSWrittenComments_final_March2015.pdf.

About the Association for Molecular Pathology

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.

MEDIA CONTACT:

Maurissa Messier on behalf of AMP

Maurissa@bioscribe.com

760-659-6700