AMP releases 'A Molecular Diagnostic Perfect Storm' white paper

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The Association for Molecular Pathology (AMP), the premier global, non-profit organization serving molecular testing professionals, announced the release of an important white paper addressing the consequences of regulatory and reimbursement forces directed against molecular diagnostic testing that threaten patient care. The paper, titled, A Molecular Diagnostic Perfect Storm: The Convergence of Regulatory & Reimbursement Forces that Threaten Patient Access to Innovations in Genomic Medicine is now available online.

"The breakthroughs made possible by mapping the human genome - a multi-billion dollar project that took more than a decade to complete - are being threatened by government regulations, which in turn are threatening patient access to truly revolutionary treatments," said Victoria M. Pratt, PhD, Indiana University School of Medicine, active AMP Member, and lead author of the paper. "We hope that this manuscript further enlightens regulatory and reimbursement stakeholders about the storm brewing in Washington that could dismantle the development and coverage of important molecular diagnostic tests."

Medical professionals in universities, cancer centers, clinical laboratories, and pharmaceutical/manufacturing companies across the country have honored the public trust in the Human Genome Project by developing hundreds of innovative diagnostic tests and therapies that are advancing modern medicine in ways that would have been impossible without this breakthrough. By eliminating the barriers outlined in "The

Perfect Storm" paper, genome-based research will continue to play a critical role in the development of more powerful tools to treat complex diseases such as cancer, diabetes, and cardiovascular disease.

Threats stemming from efforts by the U.S. Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS), the two federal agencies that oversee molecular diagnostic testing, are the cause of this "Perfect Storm."

The FDA's new policies will effectively reformulate existing medical device regulations and consider medical professionals as manufacturers which will impose substantially new and duplicative requirements on clinical laboratories and hospitals. Meanwhile, CMS, who runs Medicare, the nation's largest insurer and whose actions are frequently mimicked in the private sector, has taken a heavy handed approach in denying coverage or reducing payment for several medically necessary molecular pathology tests. Unfortunately, health care providers - those developing and delivering innovative diagnostic tests -along with patients, who are the ultimate intended beneficiaries, are caught in the middle.

"AMP is addressing the consequences of this gathering perfect storm of regulatory and reimbursement challenges directed against molecular diagnostic testing with recommendations designed to preserve patient access to these essential medical services" said AMP President, Janina Longtine, MD. "We are greatly concerned that these forces are coalescing to bring about consolidation of laboratory testing, to the detriment of local testing. This would have far-reaching negative effects on the healthcare system. As such, AMP is committed to working with the regulatory and reimbursement bodies to find a resolution that optimizes patient safety and offers access to important medical tests."