ASSOCIATION FOR MOLECULAR PATHOLOGY
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June 1, 2014

The Honorable Fred Upton
Chairman
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
Member
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Sent via e-mail: Cures@house.mail.gov

Re: Request for Information (RFI) Regarding the 21st Century Cures Initiative

Dear Chairman Upton and Representative DeGette:

Thank you for engaging the community on the 21st Century Cures initiative. This letter is in response to your request for comments, as requested in the white paper entitled "21st Century Cures: A Call to Action." The Association for Molecular Pathology (AMP) shares your goals of accelerating the discovery, development, and delivery of promising new treatments to patients. AMP is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who 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 and the in vitro diagnostics industry. To help maintain the United States' position as a leader in innovation in precision medicine and to continue to reap the benefits of the investment in the Human Genome Project, Congress should work to remove regulatory and reimbursement hurdles harming the diagnostic industry.

Regulatory:
Since 2006, the US Food and Drug Administration (FDA) has chosen enforcement discretion over the regulation of laboratory developed tests. In December 2013, AMP published a new position statement called, "Revisiting Oversight and Regulation of Molecular-Based Laboratory-Developed Tests."[1] AMP proposes defining these diagnostics as laboratory developed procedures and have them regulated by the CLIA program within the Centers for Medicare and Medicaid Services. As much of the testing shifts from single gene or marker analysis to whole genome sequencing that reports on hundreds of health associations, the current FDA process is neither scalable nor practical. Considering the significant role of the molecular pathologist in developing, designing, and validating these procedures, CLIA is capable of providing sufficient oversight. **Congress can provide clarity that LDPs should not be under the jurisdiction of the FDA.**

With advances in genomic medicine, providers can use targeted therapy to tailor dosing, improve drug response and avoid adverse events. Many drugs, especially in the field of oncology, now include information about molecular diagnostics in their labeling. Pharmaceutical manufacturers control the label's content and can choose to describe a laboratory test by its molecular description or by its brand name.

[1]http://jmd.amjpathol.org/article/S1525-1578(13)00221-3/abstract

When the FDA approves drug labeling that includes the brand name of a diagnostic test, the medical community often views this as a tacit endorsement of that one company's test; indeed, diagnostic companies' marketing strategies may exploit this view. This limits pathologists from choosing the test that best suits the needs of their patients, physicians and laboratory environment. Rather than consulting with the molecular pathologist to consider all relevant information from the patient's medical history, together with the most effective laboratory testing strategy at the least cost, treating physicians such as oncologists may reflexively order the test listed in the labeling. Therefore, referencing diagnostic tests by their brand names in drug labeling may create a situation where patients are not receiving optimal care. Further, AMP believes this will restrict patient access to subsequently approved/cleared and increasingly innovative tests.

To promote patient safety and high quality care, **AMP recommends that FDA specify that diagnostics be described by the biological description of the gene or mutation in drug labeling and that identification of recommended diagnostic testing not be by brand name. Essential performance characteristics (e.g. limit of detection) can be specified. Standardized HUGO nomenclature should be used.**[2] [3]

Coverage and Reimbursement:

The flawed and delayed implementation of coverage and pricing for the new molecular diagnostics CPT codes has resulted in a significant decline in patient access to medically necessary tests. Particularly concerning is the fact that pediatric indigent patients now have little access to these diagnostic tests through Medicaid. Because CMS did not pay for any molecular tests for at least the first six months of 2013, and coverage is now being denied for many tests that were covered prior to January 1, 2013, molecular laboratories have and continue to suffer drastic revenue loss due to coverage denial or nonpayment, including those in the country's leading academic medical centers. Many molecular laboratories have closed or been subsumed into other laboratories, or removed certain tests from their menu of services. In many of the laboratories that remain, workforce has been significantly reduced or employees' pay decreased by as much as 50%. All of this results in reduced patient access to molecular diagnostics and also hinders innovation. In late 2013, a coalition of medical professional organizations led by AMP met with CMS to attempt to resolve many of the problems created with the adoption of the new codes and submitted more than 100 pages of comments and data describing the challenges with the new program.[4] The lack of transparency and rationale for coverage determinations combined with the inability of the public to formally comment is of great concern to AMP. **We ask that you review the executive summary of this document and we hope to work with your Committee to address these concerns as well as the recommendations the coalition provided to the CMS coverage group in April of this year.**

Federal employee travel:

AMP is very concerned that changes in federal employee travel policy could hamper government scientists and health professionals' participation in medical and scientific meetings, delay or halt private public partnerships and collaborations, and restrict interactions with agency officials implementing and overseeing programs with direct implications for the field of molecular pathology. In fact, AMP has already experienced harm stemming from the agencies' reactions to the increasing Congressional interest in federal employee travel. AMP invited a CMS official to speak at its annual meeting in October 2012 in Long Beach, CA. This request was denied stating that not only could the official not attend, but anyone who worked within his division would not be permitted to attend. Not only could no one from CMS attend in person, but they also denied our request to participate by videoconference because HHS does not allow video conferencing from government computers with outside institutions due to security concerns. In January 2013, CMS implemented more than 100 new CPT codes for molecular pathology tests that had significant implications for AMP members. Yet, no one from CMS was able to educate AMP members at their annual meeting on how to appropriately use these new codes for billing Medicare. For AMP's 2013 annual meeting, Mr. Marc Hartstein from CMS' payment group agreed to speak to attendees by videoconference, but we had to incur significant expense, beyond what would have been

[2] http://www.amp.org/publications_resources/position_statements_letters/documents/PositionStatement_DrugLabelingCompanionDx_Final051611.pdf
[3] http://amp.org/publications_resources/position_statements_letters/documents/FDALetter_RxDrugLabeling_March2013.pdf
[4] http://amp.org/publications_resources/position_statements_letters/documents/2013/MolDx%20Coverage%20Letter%20and%20Attachments%20100302013%20FINAL.pdf

necessary for sponsored travel, to contract with a private videoconferencing service local to Mr. Hartstein so he could address attendees. **This draconian barrier between government officials and the primary group of medical practitioners providing services should not be tolerated as it hinders transparency, the essential public input process, and public accountability.**

First, an important aspect of scientific medical meetings is the informal contacts and networking that lead to scientific exchanges early on in the research process. At times, this flow of information and spontaneous collaboration is more important than what one may read in a scientific journal. Restricting federally employed scientists from engaging in this aspect of the scientific process could potentially slow research and stifle innovation. Similarly, scientific and medical meetings provide opportunities for "cross pollination" across industry and basic science researchers. At meetings, the commercial sector often learns the latest discoveries in the research lab and this creates opportunities for academia, industry and the government to collaborate. These interactions help spur the translation of basic research into clinical applications and can only occur in person. And, restrictions on travel have the potential to slow innovation.

Government scientists working in regulatory and research agencies are advising on and making critical decisions that impact funding, approval of treatments, coverage and payment determinations, as well as other important scientific and healthcare activities. **Attending scientific and medical meetings keeps these federally employed scientists informed of the latest advances in scientific understanding and clinical research.** Considering the impact that their decisions have on defining the focus of grants, patients' access to new treatments, promoting public health, and more, it is imperative that they are able to attend these meetings to continue their education.

Furthermore, these restrictions would severely restrict the training, certification and licensure for government physicians and health professionals throughout the government, including those serving the military and veteran populations. For instance, the Veteran's Administration has more than 200,000 employees, about 20,000 physicians across more than 150 medical centers. Those physicians need to earn CME credits to maintain certifications and licensure, and to also ensure that veterans are receiving the most up to date clinical care. If they are restricted from attending CME accredited conferences, then they will not be able to maintain legally required credentialing and licensure and be unable to provide patient care. Additionally, these skills cannot be learned by webinar and one employee cannot learn them and then be responsible for teaching the thousands of other physicians. They need to attend medical meetings for hands on training and demonstrations.

These meetings are not frivolous and attendees, including federal employees, receive great value in attending in person for the reasons outlined above. The organizations providing CME complete a rigorous accreditation process to ensure that the content is valid and free from commercial interest. **As the Committee considers policy restricting federal employee travel, AMP respectfully requests that nonprofit scientific and medical associations' meetings whose primary goal is continuing education be exempted from a cap or restriction on federal employee travel.**

AMP appreciates the opportunity to provide these comments in response to your request for information on "21st Century Cures: A Call to Action." We hope this information helps inform your efforts and that this is the beginning of a beneficial relationship between the Committee and AMP. Please do not hesitate to contact Mary Williams, AMP's Executive Director, at mwilliams@amp.org if we may be of assistance or provide additional information.

Sincerely,

Elaine Lyon, PhD
AMP President