THE ChAMPion

AMP update on U.S. policy issues affecting molecular diagnostics.

Vol. 1, No. 1, March 2016

Welcome to the ChAMPion

Dear AMP members,

We are excited to announce the first edition of the AMP policy newsletter, The ChAMPion, where our aim is to provide members with valuable and informative updates on public policy issues affecting molecular pathology. The AMP advocacy program includes both the Professional Relations and Economic Affairs Committees. We strive to inform and influence public policy by representing our membership to federal agencies and Congress regarding issues affecting our patients and our labs. In 2016, we aim to better educate the membership on these rapidly evolving issues and this newsletter, devoted solely to advocacy issues, is one first step. Over the last several years, AMP has increasingly become more involved in advocacy as regulatory and reimbursement forces adversely affecting molecular diagnostic testing have increased. Both committees work diligently for AMP but truly effective advocacy efforts are most successful when the entire membership gets involved. So thank you in advance, and we look forward to working with and for you in 2016!

Sincerely,

Samuel Caughron, MD, Chair, Economics Affairs Committee
Roger Klein, MD, JD, Chair, Professional Relations Committee

Advocacy News

AMP responds to FDA's report on Oversight of Laboratory Developed Testing Procedures

On December 16, 2015, AMP responded to FDA's recently released report titled "The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies" with a detailed analysis of the laboratory developed procedures (LDPs) mentioned in the FDA report. After reviewing the case studies, AMP concluded that only a few of the 20 tests identified by the FDA could cause patient harms that FDA oversight might have prevented. Further, the Centers for Medicare & Medicaid Services (CMS) has the statutory authority to evaluate these tests through the CLIA program utilizing a robust network of third party network of medical and scientific experts, and had that authority been fully exercised, would arguably have been more successful than FDA at addressing problems with the LDPs. The remaining examples summarized in the report were either highly speculative; reflected a problem with treating physicians using treatments outside accepted medical practice; analytical errors, which both FDA and CMS acknowledge are best addressed by CLIA; or failure of treating physicians to follow up a screening test with a diagnostic confirmation test.

AMP maintains its position that the most reasonable and effective path forward is for Congress to insist that the CLIA program modernize, expand its current network of third party medical experts, and utilize scientific expertise from FDA and the Centers for Disease Control and Prevention (CDC) rather than relinquishing its duties regarding the accuracy and reliability of LDPs. Read AMP's analysis of the FDA report here: http://www.amp.org/emailads/documents/AMPResponseFDACaseReportFinal.pdf

AMP submits comments to Health and Human Services on the Common Rule NPRM

AMP submitted comments on January 6, 2016 to the Common Rule Notice of Proposed Rulemaking (NPRM), which updates the Federal Policy for the Protection of Human Subjects promulgated as the Common Rule. While AMP is pleased with some of the efforts to streamline regulations governing human research protections such as changes that allow the use of a single IRB for multi-center research protocols and the exemption of low risk clinical trials, AMP is very concerned with the NPRM's expansion of the definition of human subject to include biospecimens. In our comment letter, we endorse ASIP's position and rationale as they relate to expanding the definition of human subject to include biospecimens. AMP's comments are available here:
http://www.amp.org/publications_resources/position_statements_letters/documents/AMPCommentsonCommonRuleNPRMDocketIDHHS-OPHS-2015-0008-FINAL.pdf

AMP submits comments on the EEOC GINA Proposed Rule

The Equal Employment Opportunity Commission (EEOC) released a proposed rule in the fall of 2015 regarding the Genetic Information Nondiscrimination Act (GINA) and wellness programs. This rule, if finalized in its current form, would severely undermine the protections ensured by GINA. The proposed rule redefines "voluntary" participation in a wellness program, and would allow wellness programs to penalize employees and their spouses up to 30% of their entire health insurance cost if they refuse to answer questions related to their health status. This proposed rule is contradictory to current GINA regulations, which state that workplace wellness programs cannot attach financial incentives or penalties to requests of genetic information from employees. AMP worked with the Genetic Alliance to draft a sign-on letter that voices our strong opposition to the EEOC GINA proposed rule. The sign-on letter included over 600 signatures from organizations and private citizens and was submitted the federal docket on January 28, 2016. The sign-on letter is available here:
http://www.amp.org/publications_resources/position_statements_letters/documents/Genetic_Alliance_GINA_NPRM_Comments.pdf

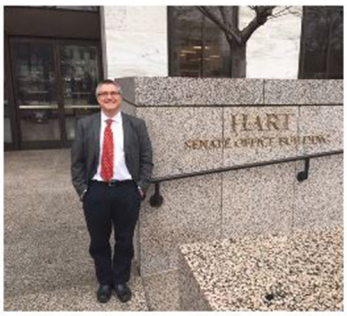
FDA announces two workshops of interest to the AMP membership

Next Generation Sequencing-Based Oncology Panels Public Workshop: This workshop will be held on February 25, 2016 at the FDA Campus in Silver Spring, Maryland and will also be webcast. The purpose of this workshop is to obtain feedback on analytical and clinical validation approaches for next generation sequencing (NGS)-based oncology panels. Comments and suggestions generated through this workshop will help guide the development of appropriate regulatory standards for evaluation of NGS-based oncology panels in cancer patient management. Written comments on the public workshop must be submitted by March 28, 2016. For more information visit:
http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm480046.htm

Patient and Medical Professional Perspectives on the Return of Genetic Test Results and Interpretations Public Workshop: The workshop will be held on March 2, 2016 at the FDA Campus in Silver Spring, Maryland and will also be webcast. The purpose of this workshop is to understand patient and provider perspectives on receiving potentially medically relevant genetic test results. The topic(s) to be discussed will focus on better defining the specific information patients and providers prefer to receive, with an emphasis on the type(s) and amount of evidence available to interpret the results for medical purposes, how those results should be returned, and what information is needed to understand the results in the event that they could effectively aid in medical decision making. Written comments must be submitted by March 31, 2016. For more information visit: http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm478841.htm

AMP will provide both oral and written comments on these workshops.

Join AMP on the Hill!



On January 8th of this year I visited Capitol Hill, where AMP staff and governmental affair consultants arranged visits to both House and Senate offices from my home state of Texas. I had the opportunity to introduce congressional staffers to AMP, describe our vital role in patient care, and explain regulatory and reimbursement issues facing the industry. Although I we did not meet with legislators, their staffers were eager to learn about the issues facing clinical laboratories and open to discussion of oversight of laboratory developed procedures. We got strong feedback that they truly value hearing from their constituents about their role in personalized patient care. Advocating on Capitol Hill is a crucial activity for AMP, so elected officials gain understanding of the molecular pathology profession. Not only did I learn a lot but I had fun advocating for molecular professionals. If you are visiting the DC area and would like AMP to arrange a day on Capitol Hill for you, please do not hesitate to contact Tara Burke at tburke@amp.org. AMP staff will help to prepare you by providing you with preparatory materials and will join you in your meetings.

-Federico Monzon, MD, President-Elect

Upcoming Events

March Webinar: Have you even wondered how a molecular test gets valued and paid for but were too afraid to ask? The EAC will be hosting a FREE webinar on March 8, 2016 at 1pm EST titled Molecular Coding, Coverage, and Reimbursement 101. Register now!

Seeking Volunteers for Medicare Carrier Advisory Committees: The Economic Affairs Committee is currently looking for candidates willing to serve on their state Carrier Advisory Committee (CAC). CACs are established by Medicare Administrative Contractors (MACs) and the CACs discuss draft Local Coverage Determinations (LCDs), provide input, and comment on draft policies. They also serve as a key link between Medicare and the provider community. If you live in Connecticut, Hawaii, Louisiana, Maine, Nevada, New York, South Dakota, Tennessee, Texas, or Washington state and are interested in becoming more involved in the process for determining appropriate coverage policies, please contact Tara Burke at tburke@amp.org for more information.

Association for Molecular Pathology, 9650 Rockville Pike, Bethesda, MD 20814 (USA)
Tel: 301-634-7939 | Fax: 301-634-7995 | Email: policy@amp.org